Indiana Pharmacy Laws and Regulations

A Compilation of Indiana Code and Indiana Administrative Code

2006 Edition

Distributed by the Indiana Board of Pharmacy
and the Indiana Professional Licensing Agency
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For questions about federal law and regulations pertaining to drugs and the practice of pharmacy, contact the nearest office of the U.S. Food and Drug Administration (FDA) or the U.S. Drug Enforcement Administration (DEA).

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IC 25-26-13
Chapter 13. Regulation of Pharmacists and Pharmacies.

Creation of Board
IC 25-26-13-1
Sec. 1. The practice of pharmacy is declared to be a professional occupation in the state of Indiana, affecting the public health, safety, and welfare and must be subject to regulation and control in the public interest by the board of pharmacy. It is further declared to be a matter of public interest and concern that the practice of pharmacy merit and receive the confidence of the public and that only qualified persons be permitted to practice pharmacy in the state of Indiana.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-1.5
Sec. 1.5. A right or benefit accrued under IC 25-26-1 through IC 25-26-12 before July 1, 1977, is continued under this chapter.
As added by P.L.1-1989, SEC.52.

IC 25-26-13-2
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 intern" means a person who is:

(1) permitted by the board to engage in the practice of pharmacy while under the personal supervision of a pharmacist and who is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(2) a graduate of an approved college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee Certificate and who is permitted by the board to obtain practical experience as a requirement for licensure as a pharmacist;

(3) a qualified applicant awaiting examination for licensure; or

(4) an individual participating in a residency or fellowship program.

"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 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:

(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) 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.

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987, SEC.72; P.L.2-1993, SEC.144; P.L.187-1999, SEC.1; P.L.270-2001, SEC.2; P.L.288-2001, SEC.1; P.L.1-2002, SEC.97; P.L.204-2005, SEC.14.

IC 25-26-13-3

Sec. 3. (a) The Indiana board of pharmacy is created. It shall consist of seven (7) members not more than four (4) of whom may be from the same political party, appointed by the governor for terms of four (4) years. One (1) member of the board, to represent the general public, must be a resident of this state who has never been associated with pharmacy in any way other than as a consumer. Except for the member representing the general public, the members must be pharmacists in good standing of recognized experience and ability from varied practice settings who hold a current license to practice pharmacy in Indiana. One (1) member of the board must be a practicing hospital pharmacist. A person employed as a full-time staff member or as a professor at a school of pharmacy may not serve on the board. If a member leaves the board for any reason before the end of the member's term, the member's successor shall serve for the unexpired portion of the term.

(b) Not later than ten (10) days after a member's appointment, the member must subscribe by oath or affirmation to faithfully uphold the duties of the member's office. If a member fails to qualify as provided, a new member shall be appointed in the member's place.

(c) At the first meeting of each year the board shall elect from among its members a president and vice president who shall perform duties and have powers as the board prescribes.

(d) The board shall meet at least eight (8) times per year at such times and places as the board selects. At each meeting the board shall continue in session from day to day, for not more than five (5) days, until the business of the meeting is complete. Four (4) members of the board shall constitute a quorum.

(e) Each member of the board is entitled to compensation as determined by the rules of the budget agency for each day the member is actually engaged in business of the board, together with necessary travel and other expenses incurred in the performance of the member's duties.

(f) Approval by a majority of the quorum is required for any action to be taken by the board.

As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.185; P.L.157-1986, SEC.1; P.L.48-1991, SEC.45; P.L.187-1999, SEC.2.

IC 25-26-13-4

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.

(3) Establishing standards and procedures before January 1, 2006, to ensure that a pharmacist:

(A) has entered into a contract that accepts the return of expired drugs with; or

(B) is subject to a policy that accepts the return of expired drugs of;

a wholesaler, manufacturer, or agent of a wholesaler or manufacturer concerning the return by the pharmacist to the wholesaler, the manufacturer, or the agent of expired legend drugs or controlled drugs. In determining the standards and procedures, the board may not interfere with negotiated terms related to cost, expenses, or reimbursement charges contained in contracts between parties, but may consider what is a reasonable quantity of a drug to be purchased by a pharmacy. The standards and procedures do not apply to vaccines that prevent influenza, medicine used for the treatment of malignant hyperthermia, and other drugs determined by the board to not be subject to a return policy. An agent of a wholesaler or manufacturer must be appointed in writing and have policies, personnel, and facilities to handle properly returns of expired legend drugs and controlled substances.

(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.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.186; P.L.75-1992, SEC.20; P.L.2-1993, SEC.145; P.L.177-1997, SEC.5; P.L. 204-2005; SEC.15; P.L. 212-2005, SEC.22.

IC 25-26-13-4.5
Sec. 4.5. (a) As used in this section, "impaired pharmacist" means a licensed pharmacist who has been affected by the use or abuse of alcohol or other drugs.
(b) The board shall assist in the rehabilitation of an impaired or a licensed pharmacist. The board may:
(1) enter into agreements, provide grants, and make other arrangements with statewide nonprofit professional associations or foundations, or entities specifically devoted to the rehabilitation of impaired health care professionals to identify and assist impaired pharmacists or licensed pharmacists; and
(2) accept and designate grants, public and private financial assistance, and licensure fees to fund programs under subdivision (1).
(c) Except as provided in subsection (e), all:
(1) information furnished to a nonprofit professional organization or foundation, including interviews, reports, statements, and memoranda; and
(2) findings, conclusions, or recommendations that result from a proceeding of a professional organization or foundation;
are privileged and confidential.
(d) The records of a proceeding under subsection (c) may be used only in the exercise of the proper functions of the board and may not become public records or be subject to a subpoena or discovery proceeding.
(e) Information received by the board from the board designated rehabilitation program for noncompliance by the licensed pharmacist may be used by the board in any disciplinary or criminal proceedings instituted against the impaired licensed pharmacist.
(f) The board designated rehabilitation program shall:
(1) immediately report to the board the name and results of any contact or investigation concerning an impaired licensed pharmacist that the program believes constitutes an imminent danger to either the public or the impaired licensed pharmacist; and
(2) in a timely fashion report to the board an impaired licensed pharmacist:
(A) who refuses to cooperate with the program;
(B) who refuses to submit to treatment; or
(C) whose impairment is not substantially alleviated through treatment.
As added by P.L.188-1995, SEC.4.

IC 25-26-13-5
Sec. 5. (a) The executive director shall keep a record of the proceedings of the board. The record shall contain the names and addresses of all persons who apply to the board for a license or permit and the action taken on each.
(b) The board shall hire and supervise a sufficient number of inspector-investigators to enforce the controlled substances law (IC 35-48). Inspector-investigators hired by the board are employees of the health professions bureau.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.187; Acts 1982, P.L.113, SEC.64; P.L.169-1985, SEC.87.

IC 25-26-13-6
Sec. 6. The board may accept and expend funds from sources other than the state of Indiana, provided that:
(1) such funds are awarded for the pursuit of a specific objective which the board is authorized to accomplish by this chapter, or which the board is qualified to accomplish by reason of its jurisdiction or professional expertise;
(2) such funds are expended for the pursuit of the objective for which they are awarded;
(3) activities connected with or occasioned by the expenditures of such funds do not interfere with or impair the performance of the board's duties and responsibilities and do not conflict with the exercise of the board's powers as specified by this chapter;
(4) such funds are kept in a separate, special account in the state treasury; and
(5) periodic reports are made to the governor concerning the board's receipt and expenditure of such funds.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-7
Sec. 7. With respect to pharmacists, pharmacies, drugs, controlled drugs, legend drugs, and devices and the enforcement of this chapter, the board shall have the same powers, duties, and functions as specified in IC 16-42-20-2. *As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.2-1993, SEC.146.*

IC 25-26-13-8
Sec. 8. (a) Not later than October 31 of each odd-numbered year, a form for application for renewal of a pharmacy permit shall be sent to each permit holder, together with a bill for fees due.
(b) Not later than April 30 of each even-numbered year, a form for application for renewal of a pharmacist's license shall be sent to each license holder, together with a bill for fees due.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.188.

IC 25-26-13-9
Sec. 9. (a) The board shall establish standards for pharmacist intern programs. Such standards shall include, but not be limited to, the number of hours

students must spend in a program, the number of hours a student must spend in a pharmacy each week, and the types of duties the student may perform.
(b) The board shall, by regulation, establish standards and requirements for continuing education and shall endorse those continuing education programs which meet the standards and requirements.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-10
Sec. 10. (a) An applicant for registration as a pharmacist intern must furnish proof satisfactory to the board that the applicant:
(1) is actively enrolled in a school of pharmacy accredited by the American Council of Pharmaceutical Education;
(2) has obtained the Foreign Pharmacy Graduate Examination Committee Certificate; or
(3) is a qualified applicant awaiting the examination for licensure as a pharmacist.
(b) A registration under this section is valid for one (1) year and may be renewed by the board for an additional year until the expiration date established by the Indiana professional licensing agency under IC 25-1-5-4.
(c) An application for registration or renewal must be accompanied by the appropriate fee and one (1) of the following:
(1) Proof of having obtained the Foreign Pharmacy Graduate Examination Committee Certificate.
(2) Proof of active enrollment in a school of pharmacy accredited by the American Council of Pharmaceutical Education.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.187-1999, SEC.3.

IC 25-26-13-10.5
Sec. 10.5. (a) A pharmacy intern may engage in the practice of pharmacy if the activities are under the direct supervision of a pharmacist. The pharmacist in charge is responsible for the activities relating to the practice of pharmacy performed by the pharmacy intern.
(b) A pharmacist shall review in person the prescription drug order and the dispensed product prepared by a pharmacy intern before the product is dispensed to the patient or the patient's agent.

IC 25-26-13-11
Sec. 11. (a) To be eligible for licensure as a pharmacist, an individual must file such evidence as is required by the board that:
(1) the individual is at least eighteen (18) years of age;
(2) the individual does not have a conviction for a crime that has a direct bearing on the individual's ability to practice competently;
(3) the individual:
(A) has graduated with a professional degree from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on Pharmacy Accreditation and approved by the board; or
(B) has:
(i) graduated with a professional degree from a school of pharmacy located outside the United States and Canada; and
(ii) met the requirements under subsection (c); and
(4) the individual has satisfactorily completed a pharmacist intern program approved by the board.
(b) An applicant who has graduated with a professional degree from a school of pharmacy accredited by the Canadian Council on Pharmacy Accreditation and approved by the board must obtain the Foreign Pharmacy Graduate Examination Committee Certificate administered by the National Association of Boards of Pharmacy before taking the examination required under subsection (d).
(c) An applicant who has graduated with a professional degree from a school of pharmacy located outside the United States and Canada must do the following:
(1) Provide the board with verification of the applicant's academic record and graduation.
(2) Obtain the Foreign Pharmacy Graduate Examination Committee Certificate administered by the National Association of Boards of Pharmacy.
(d) After filing an application on a form provided by the board, submitting the information required in subsection (a), and successfully completing the examination administered by the board, the applicant may be licensed as a pharmacist.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.189; Acts 1982, P.L.113, SEC.65; P.L.169-1985, SEC.88; P.L.149-1987, SEC.73; P.L.152-1988, SEC.21; P.L.48-1991, SEC.46; P.L.33-1993, SEC.44; P.L.242-1995, SEC.2.

IC 25-26-13-12
Sec. 12. (a) An individual who is licensed as a pharmacist in another state where the requirements for licensure were not less than those required in this state at the time of original licensure may be issued a license in this state if:
(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;
(2) the individual has graduated with a professional degree in pharmacy from a school of pharmacy accredited by the American Council of Pharmaceutical Education or the Canadian Council on Pharmacy Accreditation and approved by the board; and
(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy.
(b) An individual who has a professional pharmacy degree from a school of pharmacy located outside the United States and Canada and who is licensed in another state where the requirements for licensure are substantially the same as those in this state may be issued a license under this chapter if:
(1) the individual has registered with and been approved by the National Association of Boards of Pharmacy;
(2) the individual has provided the board with proof of the applicant's:
(A) academic record and graduation with a professional degree from a school of pharmacy; and
(B) completion of the Foreign Pharmacy Graduate Examination Committee Certificate administered by the National Association of Boards of Pharmacy; and

(3) the individual has successfully completed an examination administered by the board concerning the federal statutes and regulations and the Indiana statutes and rules governing the practice of pharmacy.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.169-1985, SEC.89; P.L.156-1986, SEC.2; P.L.149-1987, SEC.74; P.L.33-1993, SEC.45; P.L.242-1995, SEC.3; P.L.288-2001, SEC.2.

IC 25-26-13-12.5
Repealed.

IC 25-26-13-13
Sec. 13. (a) A person holding a pharmacist license shall be considered an active pharmacist if his fees are current and he has complied with all continuing education requirements.
(b) Any active pharmacist either by his own choice or by action of the board after hearing, may be classified as an inactive pharmacist. An inactive pharmacist may maintain his license by paying his license fees. An inactive pharmacist is exempt from the continuing education requirements. A person may not actively engage in the practice of pharmacy while classified as an inactive pharmacist.
(c) A person classified as an inactive pharmacist may reactivate his license by meeting current continuing education requirements and successfully demonstrating to the board's satisfaction his ability to actively practice as a pharmacist.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-14
Sec. 14. (a) A pharmacist's license expires July 1 of each even-numbered year, unless renewed before that date.
(b) If an application for renewal is not filed and the required fee paid before July 1 of each even-numbered year, the license expires and becomes invalid, and may be reinstated only by meeting the requirements under IC 25-1-8-6.
(c) Subject to IC 25-1-4-3, a statement attesting that the pharmacist has met the continuing education requirements shall be submitted with the application for license renewal.
(d) If a pharmacist surrenders the pharmacist's license to practice pharmacy in Indiana, the board may subsequently consider reinstatement of the pharmacist's license upon written request of the pharmacist. The board may impose any conditions it considers appropriate to the surrender or to the reinstatement of a surrendered license. The practitioner may not voluntarily surrender the practitioner's license to the board without the written consent of the board if any disciplinary proceedings are pending against the practitioner under this chapter or IC 25-1-9.
(e) If a person fails to renew a license that expires under subsection (a) within three (3) years after the date the license expires, the board may reinstate the license only if the person:
(1) meets the requirements under IC 25-1-8-6; and
(2) passes an examination concerning state and federal laws that the board considers relevant to the practice of pharmacy.
(f) The board may require a person who applies for a license under subsection (e) to appear before the board and explain the reason the person failed to renew the person's license.
(g) If a person fails to renew a license that expires under subsection (a) within seven (7) years after the date the license expires, the person must apply for a new license.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.190; P.L.169-1985, SEC.90; P.L.149-1987, SEC.75; P.L.48-1991, SEC.47; P.L.269-2001, SEC.25.

IC 25-26-13-15
Sec. 15. (a) A pharmacist shall hold in strictest confidence all prescriptions, drug orders, records, and patient information. He may divulge such information only when it is in the best interest of the patient or when requested by the board or its representatives or by a law enforcement officer charged with the enforcement of laws pertaining to drugs or devices or the practice of pharmacy.
(b) A person who has knowledge by virtue of his office of any prescription drug order, record, or patient information may not divulge such information except in connection with a criminal prosecution or proceeding or a proceeding before the board, to which the person to whom the information relates is a party.
(c) A pharmacist or pharmacy is immune from civil liability for any action based on its good faith release of information under this section.
As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-16
Sec. 16. (a) A pharmacist shall exercise his professional judgment in the best interest of the patient's health when engaging in the practice of pharmacy.
(b) A pharmacist has a duty to honor all prescriptions from a practitioner or from a physician, podiatrist, dentist, or veterinarian licensed under the laws of another state. Before honoring a prescription, the pharmacist shall take reasonable steps to determine whether the prescription has been issued in compliance with the laws of the state where it originated. The pharmacist is immune from criminal prosecution or civil liability if he, in good faith, refuses to honor a prescription because, in his professional judgment, the honoring of the prescription would:
(1) be contrary to law;
(2) be against the best interest of the patient;
(3) aid or abet an addiction or habit; or
(4) be contrary to the health and safety of the patient.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.156-1986, SEC.3.

IC 25-26-13-16.5

Sec. 16.5. Pharmacists licensed by Indiana may fill prescriptions of optometrists who are:

(1) licensed by Indiana; and

(2) certified under IC 25-24-3;

for a drug that is included in the formulary adopted under IC 25-24-3-10.

As added by P.L.147-1991, SEC.3.

IC 25-26-13-17

Sec. 17. (a) The board shall establish classes of pharmacy permits as follows:

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

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

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

(A) open to the general public; or

(B) located in an institution listed under a Type II permit;

and provides pharmaceutical care to a patient who is located in an institution or in the patient's home.

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

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

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

(A) a home health care patient;

(B) a long term care facility; or

(C) a member of the general public.

(b) Hospitals holding a Type II permit may offer drugs or devices to an employee, student, or medical staff member or their dependents for their own use.

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

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

(1) filing an application on a form prepared by the board;

(2) having each location inspected by the board; and

(3) obtaining approval from the board.

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

As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.149-1987, SEC.76; P.L.147-1991, SEC.4.

IC 25-26-13-18

Sec. 18. (a) To be eligible for issuance of a pharmacy permit, an applicant must show to the satisfaction of the board that:

(1) Persons at the location will engage in the bona fide practice of pharmacy. The application must show the number of hours each week, if any, that the pharmacy will be open to the general public.

(2) The pharmacy will maintain a sufficient stock of emergency and frequently prescribed drugs and devices as to adequately serve and protect the public health.

(3) Except as provided in section 19 of this chapter, a registered pharmacist will be in personal attendance and on duty in the licensed premises at all times when the practice of pharmacy is being conducted and that the pharmacist will be responsible for the lawful conduct of the pharmacy.

(4) One (1) pharmacist will have not more than four (4) certified pharmacy technicians or pharmacy technicians in training certified under IC 25-26-19 under the pharmacist's immediate and personal supervision at any time. As used in this clause, "immediate and personal supervision" means within reasonable visual and vocal distance of the licensed person.

(5) The pharmacy will be located separate and apart from any area containing merchandise not offered for sale under the pharmacy permit. The pharmacy will:

(A) be stationary;

(B) be sufficiently secure, either through electronic or physical means, or a combination of both, to protect the products contained in the pharmacy and to detect and deter entry during those times when the pharmacy is closed;

(C) be well lighted and ventilated with clean and sanitary surroundings;

(D) be equipped with a sink with hot and cold running water or some means for heating water, a proper sewage outlet, and refrigeration;

(E) have a prescription filling area of sufficient size to permit the practice of pharmacy as practiced at that particular pharmacy; and

(F) have such additional fixtures, facilities, and equipment as the board requires to enable it to operate properly as a pharmacy in compliance with federal and state laws and regulations governing pharmacies.

A pharmacy licensed under IC 25-26-10 (before its repeal on July 1, 1977) on June 30, 1977, must comply with the provisions of this clause before December 31, 1982, unless for good cause shown the board grants a waiver or otherwise exempts it.

(b) Prior to opening a pharmacy after receipt of a pharmacy permit, the permit holder shall submit the premises to a qualifying inspection by a representative of the board and shall present a physical inventory of the drug and all other items in the inventory on the premises.

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

the licensed area.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.3-1990, SEC.90; P.L.27-1998, SEC.1; P.L.187-1999, SEC.4.

IC 25-26-13-19

Sec. 19. (a) A pharmacy holding a Type I or Type VI permit may be open to the general public without a pharmacist on duty if the following conditions are met:

(1) Approval is obtained from the board.

(2) All legend drugs and other merchandise that can only be dispensed by a pharmacist are securely locked or secured by an alternative system approved by the board when the pharmacist is absent.

(3) During the pharmacist's absence, a sign at least twenty (20) inches by thirty (30) inches is prominently displayed in the prescription department stating: "Prescription Department Closed, No Pharmacist on Duty".

(4) Only a pharmacist has access to the secured area.

(b) The board may revoke or limit a pharmacy's privilege under this section after a hearing under IC 4-21.5-3.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.7-1987, SEC.125; P.L.147-1991, SEC.5; P.L.288-2001, SEC.3.

IC 25-26-13-20

Sec. 20. (a) A person desiring to open, establish, operate, or maintain a pharmacy shall apply to the board for a pharmacy permit on a form provided by the board. The applicant shall set forth:

(1) the name and occupation of the persons desiring the permit;

(2) the location, including street address and city, of the pharmacy;

(3) the name of the pharmacist who will qualify the pharmacy by being responsible to the board for the legal operation of the pharmacy under the permit; and

(4) such other information as the board may require.

(b) If the applicant desires to open, establish, operate, or maintain more than one (1) pharmacy, he must file a separate application for each. Each pharmacy must be qualified by a different pharmacist.

(c) The board shall permit a pharmacist to serve as a qualifying pharmacist for more than one (1) pharmacy holding a type II pharmacy permit upon the holder of the type II permit showing circumstances establishing that:

(1) the permit holder has made a reasonable effort, without success, to obtain a qualifying pharmacist who is not serving as a qualifying pharmacist at another type II pharmacy; and

(2) the single pharmacist could effectively fulfill all duties and responsibilities of the qualifying pharmacist at both locations.

(d) The board shall grant or deny an application for a permit not later than one hundred twenty (120) days after the application and any additional information required by the board are submitted.

(e) The board may not issue a pharmacy permit to a person who desires to operate the pharmacy out of a residence.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.169-1985, SEC.91; P.L.270-2001, SEC.3.

IC 25-26-13-21

Sec. 21. (a) A pharmacy permit is not transferable as to location or ownership.

(b) Not later than ten (10) days after the change of ownership of a pharmacy, an application shall be submitted for transfer of ownership accompanied by a signed and dated certificate of sale. The original permit remains valid until a new permit is issued or the application is rejected by the board. Not later than ten (10) days after notice of the board's action, the old permit is void and must be returned immediately by the new owner.

(c) If the holder of a pharmacy permit desires to change the location of the pharmacy, he shall file an application on a form provided by the board for a permit for the new location.

(d) All applications for transfers of ownership or location of a pharmacy must be accompanied by the appropriate fee.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.191.

IC 25-26-13-22

Sec. 22. (a) A pharmacy permit shall expire on December 31 of the odd-numbered year next succeeding the date of issuance.

(b) If an application for renewal has not been filed and the required fee paid by January 1 following the date of expiration, the pharmacy permit shall lapse and may be reinstated only by paying the lapsed permit fee and the appropriate permit fee.

(c) No pharmacy may be open for business, after December 31 of the renewal year, until the renewal is perfected.
As added by Acts 1977, P.L.276, SEC.1. Amended by Acts 1981, P.L.222, SEC.192; P.L.169-1985, SEC.92.

IC 25-26-13-23

Sec. 23. (a) The board shall establish appropriate fees to carry out this chapter.

(b) All fees are nonrefundable. A receipt shall be issued for all fees and fines submitted.

(c) All fees collected under this section shall be transferred to the treasurer of state and deposited in the general fund of the state.

(d) The board shall adopt rules to establish fines for violation of an article listed in IC 25-26 or a rule adopted under IC 25-26-13-4, IC 25-26-14-13 or IC 35-48-3-1.

(e) A fine collected by the board shall be transferred to the treasurer of state and deposited in the state general fund.

(f) No fine established under subsection (d) shall be less than twenty-five dollars ($25).

(g) At the time of license renewal, each licensed pharmacist shall pay a renewal fee, a part of which shall be used for the rehabilitation of impaired

pharmacists. Notwithstanding subsection (c), the lesser of the following amounts from fees collected under this subsection shall be deposited in the impaired pharmacists account of the state general fund established by section 30 of this chapter:

(1) Sixteen percent (16%) of the license renewal fee for each license renewed under this section.

(2) The amount per license needed to operate the impaired pharmacists program, as determined by the health professions bureau.

IC 25-26-13-24

Sec. 24. The pharmacy permit and the licenses of the pharmacists primarily employed in the pharmacy shall be prominently displayed in an area where customers at the prescription counter can readily see them.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-25

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.

(c) Except as provided in subsection (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.

(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 (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 (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".

(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.
(f) The original prescription form or the other board approved record described in subsection (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.
(g) A prescription is valid for not more than one (1) year after the original date of issue.
(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.
(i) A pharmacist may not knowingly dispense a prescription after the demise of the patient.
(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).
(k) A pharmacist may use the pharmacist's professional judgment as to whether to accept medication for return under this section.
(l) A pharmacist who violates subsection (d) commits a Class A infraction.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.239-1989, SEC.1; P.L.33-1993, SEC.46; P.L.188-1995, SEC.6; P.L.187-1999, SEC.5; P.L.270-2001, SEC.4; P.L.288-2001, SEC.4; P.L.1-2002, SEC.98; P.L.182-2003, SEC.4; P.L.97-2004, SEC.95; P.L.75-2004, SEC.2; P.L.204-2005, SEC.16.

IC 25-26-13-25.5
Sec. 25.5. A prescription may be transmitted electronically from a practitioner to a pharmacy only through the use of an electronic data intermediary approved by the board.
As added by P.L. 204-2005, SEC.17.

IC 25-26-13-26
(*Repealed by Acts 1981, P.L.222, SEC.296.)*

IC 25-26-13-26.1
(*Repealed by P.L.152-1988, SEC.30.)*

IC 25-26-13-27
Sec. 27. (a) If a pharmacy will be closed for five (5) consecutive days or more, the permit holder shall notify the board and take such steps to secure the drugs in the pharmacy as the board may direct.
(b) If a pharmacy is to be permanently closed for any reason, the owner or qualifying pharmacist shall:
(1) notify the board not less than twenty (20) days before the transfer of any controlled substances and submit a copy of the inventory form required by the federal drug enforcement administration together with the name, address, and registration number of the person to whom the drugs will be transferred;
(2) remove all legend drugs from stock by:
(A) returning them to the wholesaler or manufacturer if he consents;
(B) transferring them to another pharmacy; or
(C) destroying them in the presence of a representative appointed by the board;
(3) before disposing of any other merchandise in the pharmacy, dispose of all controlled drugs and legend drugs as provided in clauses (1) and (2) and submit the licensed premises to an inspection by a representative of the board to certify that all legend and controlled drugs have been removed;
(4) remove from inside and outside the licensed area all symbols and signs using the words "drugs", "drugstore", "prescriptions", "pharmacy", "pharmacy department", "apothecary", or "apothecary shop", or any combination of such titles; and
(5) return the pharmacy permit for cancellation by the board within ten (10) days after all legend drugs, controlled drugs, drugs and devices are removed from the premises.
As added by Acts 1977, P.L.276, SEC.1. Amended by P.L.147-1991, SEC.6.

IC 25-26-13-28

Sec. 28. At the request of the board, the attorney general in the name of the state shall apply for an injunction in the circuit court of the county wherein a violation of this chapter is occurring.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-29

Sec. 29. (a) It is unlawful:

(1) For any person to display or permit to be displayed, a pharmacy permit in any facility or place of business other than that for which it was issued.

(2) For any person to accept a prescription for filling or compounding at any place or facility for which there is not a valid pharmacy permit.

(3) For any person to operate a pharmacy or to take, assume, exhibit, display, or advertise by any medium, the title "drugs", "prescriptions", "medicine", "drug store", "pharmacy", or "apothecary shop", or any combination of such titles or any other title, symbol, term, or description of like import intended to cause the public to believe that it is a pharmacy unless he holds a valid pharmacy permit.

(4) For any person to engage or offer to engage in the practice of pharmacy or to hold himself out as a pharmacist without a valid pharmacist's license that is classified as active by the board.

(b) A person who violates a provision of subsection (a) of this section commits a Class D felony.

(c) Nothing in this chapter shall apply to, nor in any manner interfere with the business of a general merchant in selling and distributing nonnarcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts.

As added by Acts 1977, P.L.276, SEC.1.

IC 25-26-13-30

Sec. 30. (a) The impaired pharmacists account is established within the state general fund to provide money for the rehabilitation of impaired pharmacists under this article. The account shall be administered by the health professions bureau.

(b) Expenses of administering the account shall be paid from money in the account. The account consists of money collected under section 4.5(b) of this chapter.

(c) The treasurer of state shall invest the money in the account not currently needed to meet the obligations of the account in the same manner as other public money may be invested. Money remaining in the account at the end of a state fiscal year does not revert to the state general fund.

(d) There is appropriated to the board from the account an amount sufficient to carry out the purpose described in subsection (a).

As added by P.L.188-1995, SEC.7.

IC 25-26-13-31

Sec. 31. (a) A pharmacist may do the following:

(1) Obtain and maintain patient drug histories and other pharmacy records that are related to drug or device therapies.

(2) Perform drug evaluation, drug utilization review, and drug regimen review.

(3) Participate in the selection, storage, and distribution of drugs, dietary supplements, and devices. However, drug selection must comply with IC 16-42-19 and IC 16-42-22.

(4) Participate in drug or drug related research.

(b) A pharmacist who participates in an activity allowed under subsection (a) is required to follow the standards for the competent practice of pharmacy adopted by the board.

As added by P.L.187-1999, SEC.6.

IC 25-26-13-32

Sec. 32. If a state of emergency is declared by:

(1) the governor under IC 10-14-3-12; or

(2) the President of the United States;

the board may, for the duration of the state of emergency, suspend the provisions of a statute or rule under this article that would prevent, hinder, or delay the appropriate delivery of pharmaceutical care.

TITLE 856 INDIANA BOARD OF PHARMACY

ARTICLE 1. PHARMACIES AND PHARMACISTS

Rule 1. Application Requirements *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 1.1. Definitions

856 IAC 1-1.1-1 Adoption of definitions
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2; IC 35-48-1-1

Sec. 1. All terms which are defined in IC 25-26-13-2 shall have the same meanings as they are so defined when used in the rules and regulations of the Indiana board of pharmacy found in Article 1 of Title 856 of the Indiana Administrative Code. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-1; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

856 IAC 1-1.1-2 "Pharmacy Practice Act" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. The term "Pharmacy Practice Act" when used in these regulations is in reference to Acts 1977, Public Law codified at IC 25-26-13 as amended from time to time. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-2; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

856 IAC 1-1.1-3 "In personal attendance" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. The term "in personal attendance" as the same is in IC 25-26-13-18(a) of the Pharmacy Practice Act means being physically present in the area specified as the dimensions of the pharmacy in the relevant pharmacy permit application. *(Indiana Board of Pharmacy; 856 IAC 1-1.1-3; filed Dec 3, 1985, 3:02 pm: 9 IR 767; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; errata filed Jan 9, 2002, 4:20 p.m.: 25 IR 1645)*

Rule 2. Pharmacists' Certificate

856 IAC 1-2-1 Display of certificate
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. Certificates of licensure shall be conspicuously displayed in the drugstore, pharmacy, hospital, dispensary or other place where drugs are sold or dispensed and where the owner or holder thereof is in employment. Failure to comply with this rule shall be deemed sufficient cause for suspension or revocation of the license. *(Indiana Board of Pharmacy; Reg 2,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-2 Illegal display of certificate; prohibition
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. The display of a certificate of licensure as a pharmacist in a drugstore, pharmacy, hospital, dispensary, or other place where drugs are sold or dispensed, and in which place the owner and holder of such license is not in bona fide employment, shall be deemed an illegal use of such license, and upon satisfactory proof of such illegal use, such license may be revoked. *(Indiana Board of Pharmacy; Reg 2,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-3 Notification of address change
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 3. All holders of a license as a pharmacist shall notify the Indiana board of pharmacy of any change of address. *(Indiana Board of Pharmacy; Reg 2,Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-2-4 Service by mail sufficient notice

Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. The Board has no way of knowing whether or not a notice reaches its destination and, therefore, when a notice has been mailed to the person concerned, the duty of the Board has been performed. *(Indiana Board of Pharmacy; Reg 2,Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 119; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-2-5 Duplicate certificate or drugstore permit; fees *(Repealed)*

Sec. 5. *(Repealed by Indiana Board of Pharmacy; filed Aug 12, 1987, 9:45 am: 11 IR 94)*

Rule 3. Experience *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 3.1. Examination and Experience Requirements

856 IAC 1-3.1-1 Licensure by examination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All pharmacist applicants for licensure by examination qualified by law and as provided in rules of the board shall take the complete examination consisting of North American Pharmacist Licensure Examination (NAPLEX™) and the Multistate Pharmacy Jurisprudence Examination (MPJE™). All exams shall be given in the English language only. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-1; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-2 Information for licensure
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. (a) Persons seeking licensure by examination shall file an application on a form supplied by the board.

(b) Persons seeking licensure by examination shall provide the following information on, or submit such information with, the application for licensure:

(1) Complete name, address, and telephone number.

(2) Date and place of birth.

(3) Certification of complete history and structure of hours of pharmacy experience prior to and after graduation.

(4) Intern/extern certificate number, including date and state from which certificate was issued.

(5) Two (2) recent passport-type (2″× 2″) photographs of the applicant, taken within eight (8) weeks prior to filing the application.

(6) The fee as required by 856 IAC 1-27-1.

(7) Either:

(A) certification of graduation from a program approved by the board pursuant to 856 IAC 1-5-1; or

(B) in the case of an applicant applying in the last half-year of the curriculum, certification from the dean of an approved pharmacy program that the applicant is expected to successfully complete the curriculum; however, the applicant shall not be allowed to sit for the examination until the board has received certification of graduation.

(Indiana Board of Pharmacy; 856 IAC 1-3.1-2; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; filed Aug 12, 1987, 9:45 a.m.: 11 IR 94; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-3.1-3 Passing scores
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. To successfully pass an examination, the applicant must attain a general average of not less than seventy-five (75) on the examination taken after the effective date of this rule. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-3; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-4 Reexamination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. If an applicant fails an examination or any portion of an examination and wishes to retake the failed portions, the applicant shall file a new complete application, except that the applicant may include affidavits or data concerning his or her experience in a pharmacy and attendance at a college or school of pharmacy by referring to the original application. An applicant who fails to pass a portion of the examination after two (2) sittings shall be permitted

to take subsequent examinations, providing the candidate first both appears before the board for consultation, and receives the express written permission of the board. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-4; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-5 Pharmacist intern/extern; experience requirement
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. The period of practical experience required by law for an applicant for a pharmacist license shall be computed and credited from the date of registration as a pharmacist intern/extern, with no credit given for any experience in pharmacy prior to registration or during a period when the registration has lapsed or is suspended or revoked by the board. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-5; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-6 Board approval required for practical experience programs for pharmacist intern/extern registration; pharmacy permit required, exceptions; prior approval of nonpharmacy experience site; minimum-maximum hours of practical experience
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. (a) The Indiana board of pharmacy (board) shall approve all practical experience programs wherever served. Persons responsible for the integrity and content of practical experience programs shall furnish information regarding material changes to the board, prior to implementation, for approval of the program. Approval may be withheld for cause, which may include, but is not limited to, unapproved material change in the program or change in program administration.

(b) All persons wishing to satisfy their practical experience requirements in Indiana shall possess a valid registration as a pharmacist intern or extern in Indiana while the practical experience hours are being served.

(c) If the experience is in a pharmacy that is required by law to have a pharmacy permit, that pharmacy must have a valid pharmacy permit. A pharmacy permit is not required if:

(1) the practical experience is being obtained at a site other than a pharmacy, for example, sites primarily engaged in:
(A) manufacturing;
(B) research;
(C) consulting;
(D) drug information;
(E) drug utilization review; or
(F) other pharmacy-related activity; or

(2) the experience is in a pharmacy that is not required to have a permit, for example, federally owned facilities.

(d) Prior approval is required for experience in a site other than a pharmacy. A written request must be submitted to the board prior to beginning the experience period if:

(1) an individual intern or preceptor is seeking board approval, the request for approval shall include:
(A) a detailed description of the proposed practical experience program with respect to time, place, duties, responsibilities, and supervision; and
(B) the name of the person responsible for supervising the experience; or

(2) an approved college or school of pharmacy is seeking board approval for experiential courses, the request for approval shall include:
(A) a detailed description of the proposed practical experience course with respect to duties, responsibilities, and supervision; and
(B) the name of the course coordinator responsible for site selection and maintenance of the integrity of the program.

(e) Acceptable practical experience time per week shall consist of not less than four (4) and not more than sixty (60) hours of time per week served under the supervision of a pharmacist or another board approved practical experience supervisor. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-6; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2876; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1331)*

856 IAC 1-3.1-7 Pharmacist intern/extern; program requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 7. (a) Practical experience requirements for pharmacist interns/externs in Indiana may be satisfied by complying with either of the following:

(1) Completion of the practical experience requirements of the college or school of pharmacy from which the intern/extern has graduated, if the curriculum of the college or school has been accredited by:
(A) the American Council on Pharmaceutical Education (ACPE);
(B) the Canadian Council on Pharmacy Accreditation (CCPA); or
(C) another board-approved practical experience program.

(2) In the event the intern/extern has graduated from a nonaccredited program as outlined in subdivision (1) or has no practical experience as a part of that individual's educational curriculum, the intern/extern must complete a minimum of one thousand five hundred (1,500) hours of practical experience under the supervision of a pharmacist and provide the board, prior to or concurrent with application for licensure, a written description of the objectives and duties of that experience.

(b) If a candidate for licensure as a pharmacist in Indiana has been licensed as a pharmacist in another state or jurisdiction and has been engaged in the practice of pharmacy as defined in IC 25-26-13-2 for a period of not less than one (1) year, the practical experience requirement is waived.

(Indiana Board of Pharmacy; 856 IAC 1-3.1-7; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Jan 3, 2000, 10:03 a.m.: 23 IR 1107; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)

856 IAC 1-3.1-8 Pharmacist intern/extern; minimum/maximum hours of supervision *(Repealed)*

Sec. 8. *(Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)*

856 IAC 1-3.1-9 Pharmacist intern/extern; practical experience affidavits
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 9. The acceptable pharmacist intern or pharmacist extern practical experience time must be verified by practical experience affidavits signed at the termination of each period of practical experience. All such affidavits must list all practical experience time on a calendar week basis showing actual time served each week. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-9; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-10 Pharmacist intern/extern; unacceptable experience time *(Repealed)*

Sec. 10. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-3.1-11 Out-of-state externship and other practical experience programs; postgraduate requirements; taking the licensure examination before completion of practical experience
Authority: IC 25-26-13-4
Affected: IC 25-26-13-11

Sec. 11. (a) Time accepted for experience gained in approved school supervised practical experience programs in other states successfully completed while enrolled in a professional degree program recognized under IC 25-26-13-11(a)(3) will be credited toward fulfillment of experience hours required under section 7 of this rule. Time accepted for practical experience obtained while not enrolled in a professional degree program and approved under section 6 of this rule may be credited to experience requirements at the board's discretion, whether or not served in Indiana.

(b) A description of the out-of-state practical experience program with the number of hours it contains shall be submitted with the certification for evaluation by the board subject to the following:

(1) Students supplying detailed information on their program at least eight (8) weeks in advance of the board examination date will have their hours evaluated to determine the number that will be accepted toward the prelicensure five hundred twenty (520) hour requirement.

(2) Students not supplying sufficient detailed information on their program or failing to submit the same within eight (8) weeks before the board examination to allow evaluation may take the exam prior to the evaluation of their program. After evaluation, they will be notified of the hours that may be accepted. If sufficient hours are not accepted, licensure will not be granted.

(c) A candidate for licensure who has graduated from an approved school of pharmacy may take the examination before completing the required practical experience hours. However, the candidate will not be licensed as a pharmacist until affidavits are received for the entire practical experience requirement. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-11; filed Dec 3, 1985, 3:02 p.m.: 9 IR 768; errata, 9 IR 1101; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2877; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-3.1-12 Out-of-state practical experience; reciprocity
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 12. Practical experience time served in another state will be accepted and will permit the applicant to take the NAPLEX examination subject to section 11 of this rule if the following requirements are met:

(1) The practical experience time served in such other state meets all requirements of Indiana law and is experience time of the type that is acceptable to the Indiana board of pharmacy (board).

(2) The applicant has a valid intern or apprentice license from the state where the experience is served. Or, if that other state does not require an intern or apprentice license, the applicant must submit certification or an affidavit from the secretary of the board that state showing that no intern or apprentice license is required.

(Indiana Board of Pharmacy; 856 IAC 1-3.1-12; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1332)

856 IAC 1-3.1-13 Fraud or misrepresentation in applying for or taking examination
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 13. Any misrepresentation made or any fraud perpetrated in an application for examination, or in the examination, shall be deemed sufficient cause for the refusal of such application, or to complete such examination, and if such misrepresentation or fraud is not discovered until later than at the time

of the submission of such application, or until the completion of such examination, it shall be deemed sufficient cause for the dismissal from the examination, or the refusal to grant a certificate, or the revocation of the certificate if already issued, and the fee paid with such application for such examination shall be forfeited; provided, however, that the action of the board shall be subject to the law in force with respect to the denial of a license or permit on application. *(Indiana Board of Pharmacy; 856 IAC 1-3.1-13; filed Dec 3, 1985, 3:02 pm: 9 IR 769; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 4. Reciprocity

856 IAC 1-4-1 License transfer
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. All applicants for license transfer registration must submit their application, with a certified photograph of the applicant and if necessary a copy of their birth certificate attached thereto, and may be requested to appear in person before the Indiana board of pharmacy (board) for a personal interview during a board meeting. An Indiana law examination must be passed before any certificate of licensure will be issued. A practical examination will be administered to the applicant if the board determines that the applicant has not been actively practicing pharmacy in the twelve (12) months preceding the application. Applications for license transfer must be reviewed and approved at a board meeting prior to examination and prior to the applicant's board requested personal appearance. *(Indiana Board of Pharmacy; Reg 4, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; filed Dec 3, 1985, 3:02 p.m.: 9 IR 769; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

856 IAC 1-4-2 Application forms
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applicants applying for license transfer in Indiana are required to make application on the official application blanks issued by the National Association of Boards of Pharmacy. *(Indiana Board of Pharmacy; Reg 4,Sec 2; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

856 IAC 1-4-3 Restoration of Indiana certification by reciprocity *(Repealed)*

Sec. 3. *(Repealed by Indiana Board of Pharmacy; filed Apr 23, 1999, 2:06 p.m.: 22 IR 2878)*

856 IAC 1-4-4 Qualifications of applicants for license transfer
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Applicants for license transfer will be admitted to Indiana only if their qualifications for licensure, possessed at the time of their original registration in the state from which they came, were equal to the requirements of Indiana at that time. *(Indiana Board of Pharmacy; Reg 4,Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 120; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

Rule 5. Recognition of Accredited Schools

856 IAC 1-5-1 Recognition of accredited schools or colleges *(Repealed)*

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

Rule 6. Drugstores, Pharmacies, Apothecary Shops *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)

Rule 6.1. Drugstores, Pharmacies, Apothecary Shops

856 IAC 1-6.1-1 Pharmacy equipment; lack of access between adjacent pharmacies
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. (a) In addition to the requirements of IC 25-26-13-18, the qualifying pharmacist for each pharmacy issued a permit by the board shall be responsible for all decisions concerning the additional fixtures, facilities, and equipment needed by the pharmacy to operate properly in compliance with the law regulating pharmacies. In making those decisions, the qualifying pharmacist shall consider minimum health, safety, and security measures as well as the type and scope of practice, the patient's needs, and the laws and rules that apply.

(b) If requested by a representative of the Indiana board of pharmacy (board), the qualifying pharmacist shall justify, in writing, all decisions made under this rule.

(c) The board shall determine whether minimum health, safety, and security measures have been satisfactorily met by an applicant for a pharmacy permit before the permit is issued or at any time the permit is in effect.

(d) If the board determines that a pharmacy does not meet the requirements of IC 25-26-13-18 and this rule, it will identify and notify the qualifying pharmacist of the deficiencies. The qualifying pharmacist shall correct or cause to be corrected the deficiencies identified within thirty (30) days of notification by the board of the noncompliance.

(e) Failure to timely correct the deficiencies identified is grounds for denial or revocation of a permit.

(f) To assure that no pharmacy is left unattended by a pharmacist while that pharmacy is in operation, no means of access may be constructed or maintained between adjacent pharmacies. *(Indiana Board of Pharmacy; 856 IAC 1-6.1-1; filed Jun 20, 2001, 3:59 p.m.: 24 IR 3651)*

Rule 7. Pharmacy Permits

856 IAC 1-7-1 Change of pharmacy ownership
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In case of change of ownership of a pharmacy the original permit becomes void and must be returned, by the new owner, with application to the Board of Pharmacy for a new permit. *(Indiana Board of Pharmacy; Reg 7,Sec 1; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-2 Application for permit to conduct pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 2. All applications for a permit to conduct a pharmacy will require the action of at least a quorum of the Board. *(Indiana Board of Pharmacy; Reg 7,Sec 2; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-3 Relocation of pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11; IC 25-26-13-18

Sec. 3. To be eligible for relocation of a pharmacy an applicant must show to the satisfaction of the board that the requirements for the eligibility for a pharmacy permit as set out in IC 25-26-13-18 will be met. Prior to relocating a pharmacy the proprietor shall file an application, on a form prescribed and furnished by the board, setting out all information so requested on such form. Prior to moving a pharmacy, after receipt of board approval, the permit holder shall submit the premises to a qualifying inspection by a representative of the board. *(Indiana Board of Pharmacy; Reg 7, Sec 3; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 121; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-4 Licensed pharmacist required for each pharmacy
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-11

Sec. 4. Every application for a permit to operate a pharmacy must set forth the name of the pharmacist, licensed by the Indiana board of pharmacy, who will be in full responsible charge for the legal operation of the pharmacy under said permit. Any person, firm, corporation, co-partnership or association owning or operating more than one pharmacy must secure a permit for each such pharmacy and no single registered pharmacist shall be permitted to qualify for more than one store. Provided, however, nothing in this regulation shall be construed to apply to the ownership of such pharmacy but shall apply only to the issuance of permits for the operation of such pharmacy. *(Indiana Board of Pharmacy; Reg 7, Sec 4; filed Jun 18, 1962, 10:00 am: Rules and Regs. 1963, p. 122; filed Dec 3, 1985, 3:02 pm: 9 IR 770; readopted filed Sep 14, 2001, 3:04 p.m.: 25 IR 532; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-7-5 Pharmaceutical consultation service for extended care facilities; notice to board *(Expired)*

Sec. 5. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

856 IAC 1-7-6 Consulting pharmacist and dispensing pharmacist; definitions *(Expired)*

Sec. 6. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

856 IAC 1-7-7 Duties of consulting pharmacist *(Expired)*

Sec. 7. *(Expired under IC 4-22-2.5, effective January 1, 2003.)*

Rule 8. Known Pharmaceutical Manufacturer and Manufacturer—Definition

856 IAC 1-8-1 Known pharmaceutical manufacturer; definition *(Repealed)*

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-8-2 "Manufacturer" defined *(Repealed)*

Sec. 2. *(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)*

Rule 9. Application for Prohibited Drugs *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 10. Non-Drug Products *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 11. Toxic Preparations *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 12. Poisons *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)

Rule 13. General Definitions

856 IAC 1-13-1 Calendar week *(Repealed)*

Sec. 1. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-13-2 "Be in personal attendance" defined *(Repealed)*

Sec. 2. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

856 IAC 1-13-3 "Prescription department closed" closing hours; electronic monitoring; applicability
Authority: IC 25-26-13-4
Affected: IC 25-26-13-10; IC 25-26-13-19

Sec. 3. (a) This section and section 4 of this rule implement IC 25-26-13-19 concerning board approval for Type I and Type VI pharmacies to be opened to the general public without a pharmacist on duty. This section and section 4 of this rule apply only in situations where the entire area of the business is licensed as a pharmacy. This section, section 4 of this rule, and IC 25-26-13-19 do not apply where the only area of a business licensed as a pharmacy is the prescription department.

(b) The following definitions apply throughout this section:

(1) "Absence of pharmacist" means those periods when the prescription department is closed and secured and the pharmacist is not present in the pharmacy.

(2) "Electronic monitoring system" means a system having the ability by light beam, heat, motion, or other electronically activated method to detect the presence of unauthorized persons or instrumentalities in a given area, and relay or report that detection as described in this section.

(3) "Prescription department" means that area of the pharmacy where the legend drugs, devices, and other merchandise or items which can only be dispensed or delivered by a pharmacist are located and which must be secured in the absence of the pharmacist.

(4) "Reasonable barrier" means an obstruction or barricade that blocks or impedes the entry into the area by an ordinary person, and includes, but is not limited to, a latched or locked gate of sufficient height and construction that an ordinary person cannot breach the barrier and/or violate the space being monitored without detection.

(5) "Secured" means either of the following:

(A) An area is completely enclosed as to its perimeter, from floor to ceiling, and locked.

(B) Through installation of reasonable barriers, an area not readily accessible which is monitored by a board approved electronic monitoring system covering all portions of the secured areas.

(c) Before a pharmacy may be open to the general public without a pharmacist on duty, the pharmacy must file an application with the board and have it approved by the board under IC 25-26-13-19. The pharmacy must abide by the closing hours designated in the application. Any change from the hours as stated in the application must be submitted in writing to the board.

(d) Under IC 25-26-13-19, a prescription department may be locked or secured while the remainder of the pharmacy remains open to the public if the following criteria are met:

(1) The prescription department is constructed in such a manner or located in such an area that reasonable barriers are in place which prevent the easy and/or quick access to legend drugs and other articles which are in the prescription department. These barriers may be doors or other obstacles as the occasion requires.
(2) The prescription department, if not secured and locked as described in subsection (b)(5)(A), must be secured and monitored by a board approved electronic monitoring device that provides the following:
(A) On-site audible alarm that is clearly and continuously audible at all points within the pharmacy.
(B) Off-site audible or visual alarm that is continuously monitored at all times that the pharmacy remains open while the prescription department is closed and secured.
(3) Any violation or breach of the secured area shall be duly recorded by the qualifying pharmacist of the pharmacy and by the off-site security monitoring agency and reported to the board within seventy-two (72) hours of the violation or breach. This report shall include the nature of the violation or breach.
(4) Facilities monitored electronically must provide for backup power for the eventuality that there is an electronic power failure for any reason. Such backup power shall be capable of continuing the monitoring for a period of no less than thirty-six (36) hours.
(5) The electronic monitoring system shall be activated and inactivated only by key or combination. Alarms which have been triggered shall only be reset and/or reactivated by a pharmacist. The key or combination shall only be in the possession or knowledge of a pharmacist. Reasonable exceptions shall be made to this for security system operators. However, in no case shall a security system operator have access to the secured area without the presence of a pharmacist. Such exceptions shall be listed in the application under this section and shall be subject to approval by the board.
(e) Under IC 25-26-13-10(b), the board may revoke or limit the privilege to be open to the general public without a pharmacist on duty if the pharmacy violates this section or section 4 of this rule. *(Indiana Board of Pharmacy; Reg 13, Sec 3; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 124; filed May 15, 1992, 5:00 p.m.: 15 IR 2246; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-13-4 Record of hours open without a pharmacist on duty
Authority: IC 25-26-13-4; IC 25-26-13-19
Affected: IC 25-26-13-4; IC 25-26-13-19

Sec. 4. The pharmacist shall maintain a record stating any hours that the pharmacy has been open for business without having a pharmacist on duty if those hours vary from the hours listed in the application under section 3(c) of this rule. Entries in this written record shall be made in ink of the time the pharmacist is absent. The written record shall be maintained in the pharmacy and shall be available for examination by members of the board or their inspectors for a period of not less than two (2) years from the date of the last entry in the record. *(Indiana Board of Pharmacy; Reg 13, Sec 4; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed May 15, 1992, 5:00 p.m.: 15 IR 2247; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-13-5 Legend drugs *(Repealed)*

Sec. 5. *(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)*

Rule 14. Physical Inventory of Merchandise *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 15. Pharmacists' Notification of Termination

856 IAC 1-15-1 Pharmacist leaving employ of pharmacy; notice to board; application to qualify permit
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4; IC 25-26-13-18

Sec. 1. If a qualified pharmacist, who, having upon the basis of his or her qualifications caused a pharmacy permit to be granted to any person, firm, corporation or copartnership desiring to operate, maintain, open or establish a pharmacy should leave the employ of such pharmacy, he or she shall immediately notify the Indiana board of pharmacy (board) and the owner shall file an application with the board to qualify the permit with another pharmacist. *(Indiana Board of Pharmacy; Reg 15, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 125; filed Dec 3, 1985, 3:02 p.m.: 9 IR 771; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)*

Rule 16. New Pharmacist *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 17. Practice of Pharmacy *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 18. Narcotic License *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 19. Adoption by Reference of U.S. Federal Rules Pertaining to Narcotics *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Feb 11, 1981, 9:05 am: 4 IR 379)

Rule 20. Violations and Penalties

856 IAC 1-20-1 Prohibitions
Authority: IC 25-26-13-4
Affected: IC 25-26; IC 35-48

Sec. 1. A pharmacist licensed to practice pharmacy under IC 25-26-13-1 through 25-26-13-29, or a pharmacist extern or a pharmacist intern licensed under IC 25-26-13-10, as a part of the responsibility, to not knowingly violate the Indiana board of pharmacy's (board's) standards for the competent practice of pharmacy shall not do the following:
(1) Violate the Uniform Indiana Controlled Substances Act found at IC 35-48-1-1 through 35-48-4-14, as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the Uniform Indiana Controlled Substances Act, which were effective by January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.
(2) Violate the Indiana Legend Drug Act found at IC 16-6-8-1 through 16-6-8-9 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as amended up to and including January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.
(3) Violate IC 16-1-30-1 through IC 16-1-30-19 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, as amended to and including January 1, 1983, which deal with adulterated and misbranded drugs or devices, or any rules promulgated by the board under the authority of IC 16-1-30-1 through IC 16-1-30-19 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]*, which were effective as of January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.
(4) Violate 21 U.S.C. 801 through 21 U.S.C. 1191, as amended, up to January 1, 1983, which deal with drug abuse and any of the rules and regulations promulgated under the authority of said Title and Sections as of January 1, 1983, insofar as such violations would pertain to the sale of drugs and devices in Indiana as defined by IC 25-26-13-2.
(5) Violate the Federal Food, Drug, and Cosmetic Act, which is found at 21 U.S.C. 301 through 21 U.S.C. 392, as amended, up to January 1, 1983, or any rules or regulations promulgated under the authority of the said act as of January 1, 1983, insofar as such violation would pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.
(6) Violate Executive Proclamations of the President of the United States, which were effective by January 1, 1983, which pertain to the sale of drugs or devices in Indiana as defined by IC 25-26-13-2.
(7) Sell, as defined in IC 25-26-13-2, controlled substances or legend drugs with or without prescription, where such sale or distribution is not in good faith and enables the person to whom the sale is made to supply or divert the controlled substances or legend drugs in an unlawful manner. The sale or distribution of controlled substances or legend drugs in unusually large amounts and within an unusually short period of time to the same individual is considered to be against the public welfare, health and safety and may be determined to be a sale or distribution not in good faith.
(8) Sell, as defined in IC 25-26-13-2, to the public any drugs, biologicals, medicinal substances, or devices when such pharmacist knows such drugs, biologicals, medicinal substances, or devices to be forgeries or a counterfeit product or beyond the manufacturer's expiration date.
(9) Aid or abet in the practice of a pharmacy a person not having a license to practice as a pharmacist in Indiana.
(10) Practice pharmacy in such a manner as to amount to incompetency or negligence in the sale or dispensation of legend drugs as defined in the Indiana Legend Drug Act under IC 16-6-8-2 *[IC 16-6 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* or controlled substance as defined in the Uniform Controlled Substances Act of 1973, under IC 35-48-1-1.
(11) Violate the act regulating the practice of pharmacy in Indiana, which is codified at IC 25-26-13-1 through IC 25-26-13-29 as amended up to and including January 1, 1983, or any of the rules promulgated by the board under the authority of the said act, which were effective by January 1, 1983.
(Indiana Board of Pharmacy; Reg 20; filed Nov 17, 1978, 2:06 p.m.: 2 IR 63; filed Jul 28, 1983, 9:01 a.m.: 6 IR 1745; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1333)

Rule 21. Resale of Returned Substances

856 IAC 1-21-1 Resale of returned substances
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) This section implements and interprets IC 25-26-13-25(h) concerning the resale or redistribution of medications.
(b) For a medication to have been properly stored and securely maintained according to sound pharmacy practices, the storage and administration of medications in the institutional facility must be under the immediate control of licensed nursing personnel.
(c) If the medication was originally packaged by the dispensing pharmacy, it cannot be resold or redistributed unless:
(1) the medication has been repackaged into unit-dose packaging using packaging materials that meets Class A or Class B standards, found in the United States Pharmacopeia (U.S.P.), page 1574, published by the United States Pharmacopeia, 22nd Revision, January 1, 1990, United States Pharmacopeia Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852, which standards are incorporated herein by reference; and
(2) the repackaging process complies with the standards as found in the "Proper Treatment of Products Subjected to Additional Manipulations, Section 1191" of the United States Pharmacopeia, page 1705, 22nd Revision, 1990, which section is incorporated herein by reference.
(d) A medication repackaged under the provisions of subsection (c) shall be labeled with an expiration date of not greater than one (1) year until the manufacturer's expiration date, whichever is earlier. *(Indiana Board of Pharmacy; Reg 21, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 128; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1334)*

Rule 22. Narcotics—Defined *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 23. Dispensing of Dangerous Drugs

856 IAC 1-23-1 Dispensing of dangerous drugs
Authority: IC 25-26-13-4
Affected: IC 16-42-22; IC 25-26-13-4; IC 25-26-13-11

Sec. 1. In the sale or dispensing of any prescription drug or narcotic, the pharmacist shall be required to affix to the immediate container in which such prescription drug or narcotic is delivered a label bearing the following information:
(1) The name, address, and telephone number of the establishment from which such drug was sold.
(2) The date on which the prescription for such drug was filled.
(3) The number of such prescription as filed in the prescription files of the pharmacy where the prescription was filled.
(4) The name of the practitioner who prescribed such drug.
(5) The name of the patient, and if such drug was prescribed for an animal, a statement of the species of the animal and the owner's name.
(6) The directions for use of the drug as contained in the prescription.
(7) The name of the drug (trade or generic, or both) in compliance with the Generic Drug Law found in IC 16-42-22.
(Indiana Board of Pharmacy; Reg 23,Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 129; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)

Rule 24. Hospital Pharmacies *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1982, 10:04 am: 5 IR 1420)

Rule 25. Internship for Apprentice Pharmacists *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)

Rule 26. Continuing Professional Education

856 IAC 1-26-1 Continuing professional education; general requirements; definitions
Authority: IC 25-26-13-4
Affected: IC 25-1-9-3; IC 25-26-13-14

Sec. 1. (a) The following definitions apply throughout this rule:
(1) "Continuing professional education" or "continuing education" means accredited postlicensure professional educational experience derived from participation in postgraduate studies, institutes, seminars, lectures, conferences, workshops, and such other forms of educational experiences so as to maintain the professional competency of the practice of pharmacy, improve pharmacy professional skills, and preserve pharmaceutical standards for the purpose of the protection of the health and welfare of the citizens of Indiana.
(2) "Hours" means measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the Indiana board of pharmacy (board) relative to maintaining the competency of a pharmacist.
(3) "Contact hour" means not less than fifty (50) nor more than sixty (60) minutes of clock time participating in a continuing education program.
(4) "Continuing education unit" or "CEU" means ten (10) contact hours of continuing education credit.
(5) "Approved by ACPE" means pharmacy continuing education providers that meet the requirements of "The ACPE Continuing Education Provider Approval Program Criteria for Quality and Interpretive Guidelines" as published by the American Council on Pharmaceutical Education, Inc., Chicago, Illinois on July 1991.
(b) In order to qualify for licensure renewal, a pharmacist must meet the continuing professional education requirements as follows:
(1) Thirty (30) hours (three (3) CEUs) of continuing education as required by this rule shall be required each biennium.
(2) No hours may be carried forward from one (1) biennium to another. However, if a pharmacist fails to meet the requirements of this rule during the biennial period, the pharmacist may earn and report sufficient hours during a succeeding biennium and apply the continuing education hours retroactively to the previous biennium as if they had been earned in that previous biennium in order to qualify for renewal of the pharmacist's license. In the event a pharmacist applies credits to a previous biennium for the reasons stated in this section, those credits may not be used for any other biennium.
(3) All continuing education program hours from sponsors not approved by ACPE must be evaluated and accepted by the board.
(4) Continuing education biennium shall be that time period consisting of January 1 of all even-numbered years through December 31 of the following odd-numbered year.
(c) Accredited continuing education hours may be compiled in the following ways if the sponsor grants the participant a certificate of completion:
(1) Cassette and audio-visual presentation.
(2) In-company professional seminars.
(3) Accredited school of pharmacy continuing education programs.
(4) Postgraduate courses in pharmaceutical sciences.
(5) Correspondence courses.
(6) Programs granted continuing education credit by other states.

(7) Continuing education television series.
(8) Programs sponsored by professional groups in public health provider services.
(9) Professional society and association sponsored program.
(10) Approved business, management, and computer courses.
(11) Programs of sponsors approved by ACPE.

(d) Accredited continuing education hours may be compiled from other programs and experiences if they are evaluated and accepted by the board as meeting the definition of continuing professional education as found in subsection (a)(1).

(e) As provided in subsection (b)(3), continuing education sponsors (hereinafter referred to as sponsors) are responsible for submitting continuing education programs to the board for approval in addition to the following:

(1) A sponsor shall be any person, school, association, or corporation who develops a continuing education program.

(2) The continuing education program must receive approval of the board for final acceptance.

(3) If a sponsor wishes to notify prospective participants in advance of the value (in hours or in CEUs) of a program, the content of the program shall be submitted to the board for evaluation. If the sponsor does not submit the content for evaluation, the sponsor shall note in all material relevant to the program that it has not been evaluated and the hours of credit listed are subject to review by the board.

(4) Sponsors shall receive written notice from the board for approval or disapproval from the board. Approved programs shall be given an identification number stating the year and hourly value.

(5) Program changes must be made to and accepted by the board or the evaluation and acceptance of the program becomes null and void.

(6) Continuing education credit may be granted only once for each program to any individual participant.

(7) Any member of the board shall have the right to attend and participate in any continuing education program.

(8) Programs may be evaluated after presentation or participation if a written request is made to the board within ninety (90) days of the date of presentation.

(9) Sponsors shall retain a file of participants' program completion for four (4) years.

(10) When applying to the board for credit, sponsors shall supply the following information on the application for continuing education course approval, supplied by the board:

(A) Name and address of applicant.
(B) Program title.
(C) Location, date, and time of program.
(D) Sponsoring organization.
(E) Type of program.
(F) Name and qualification of each speaker.
(G) Three (3) learning objectives for the program.
(H) Contact hours of the course.
(I) Method for evaluating the program.

(f) Pharmacists licensed with the board (hereinafter called participants) have the following responsibilities:

(1) Obtain a minimum of thirty (30) hours of continuing education per biennium unless first licensed during the biennium which would make those newly licensed individuals subject to subdivision (5):

(A) a maximum of one-fifth ($^1/_5$) of the total hours may be business, management, or computer courses;
(B) at least four-fifths ($^4/_5$) of the total hours must be pharmacy practice related; and
(C) at least one-half (½) of the total hours must be provided by sponsors approved by ACPE.

(2) Report program name, identification number, and approved hours of continuing education to the board at the time of license renewal.

(3) Retain a file of certificates of completion for four (4) years from the end of the biennium for which the continuing education applied in order to provide copies of certificates upon request for the board's periodic audit of continuing education compliance.

(4) Earn one and one-fourth (1.25) hours of continuing education credit for each month or part of a month from date of licensure until the end of the biennium in which licensure originates if the pharmacist becomes licensed during the biennium. However, a pharmacist who becomes newly licensed for the first time in any state in the last six (6) months of the biennium shall not be required to complete any continuing education for the biennium.

(5) Continuing education hours may be transferred from another state to Indiana if the transfer state recognizes Indiana continuing education hours.

(g) Failure to comply with any one (1) or all of the provisions of this rule while continuing to hold a license as a pharmacist in Indiana shall constitute professional incompetence by failing to keep abreast of current professional theory or practice under IC 25-1-9-3(a)(4)(B) and the pharmacist is subject to discipline under IC 25-1-9. *(Indiana Board of Pharmacy; Reg 29; filed Mar 1, 1974, 3:05 p.m.: Rules and Regs. 1975, p. 516; filed Oct 26, 1984, 3:26 p.m.: 8 IR 212; filed Jan 21, 1994, 3:00 p.m.: 17 IR 1096, eff Jan 1, 1994 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #93-152 was filed Jan 21, 1994.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1335)*

Rule 27. Fee Structure

856 IAC 1-27-1 Fees

Authority: IC 25-1-8-2; IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The following fees apply to an applicant for licensure to practice as a pharmacist:

(1) Application for examination for a pharmacist's license	$100
(2) Reexamination of the jurisprudence examination	$25
(3) Reexamination of the practical examination	$25

(4) Licensure by reciprocity (license transfer)	$100
(5) Application for the renewal of a biennial license	$160
(6) Certification of qualifications, grades, or registration to another state	$10
(7) Wall certificate	$10
(8) Duplicate pharmacist pocket license	No Fee
(9) Compilation of pharmacy laws	$10

(b) The following fees apply to an applicant for permission to operate, maintain, open, or establish a pharmacy:

(1) Initial application	$100
(2) Application for renewal of biennial license	$200
(3) Application for change of ownership	$50
(4) Application for change of location	$50
(5) Application for remodel	$50
(6) Duplicate pharmacy permit	No Fee
(7) Nonresident pharmacy initial application	$100
(8) Application for renewal of nonresident pharmacy biennial license	$200

(c) The following fees apply to applicants for permits or certifications authorized by the board:

(1) Intern/extern initial application	$10
(2) Intern/extern annual renewal	$10
(3) Pharmacy technician initial application	$25
(4) Pharmacy technician biennial renewal	$25

(Indiana Board of Pharmacy; Reg 29; filed Aug 30, 1977, 8:25 a.m.: Rules and Regs. 1978, p. 660; filed Mar 5, 1985, 2:42 p.m.: 8 IR 802; filed Nov 13, 1985, 3:08 p.m.: 9 IR 772; filed Apr 30, 1986, 9:43 a.m.: 9 IR 2204; filed Sep 8, 1987, 2:30 p.m.: 11 IR 95; filed Jul 24, 1991, 2:45 p.m.: 14 IR 2238; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; filed May 29, 1998, 11:56 a.m.: 21 IR 3931; filed Aug 5, 1998, 3:48 p.m.: 21 IR 4535; filed Apr 16, 2002, 9:03 a.m.: 25 IR 2739; filed Dec 12, 2003, 10:45 a.m.: 27 IR 1574) NOTE: Renumbered Reg 30 by 1978 Amendment.

Rule 28. Institutional Pharmacies *(Repealed)*
(Repealed by Indiana Board of Pharmacy; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1643)

Rule 28.1. Institutional Pharmacies and Pharmacy Services

856 IAC 1-28.1-1 Definitions
Authority: IC 25-26-13-4
Affected: IC 16-42-19-5; IC 25-6-3-7; IC 25-26-13

Sec. 1. In addition to the definitions in IC 25-26-13-2 and for purposes of this rule, the following definitions apply throughout this rule:
(1) "Cabinet" includes a mechanical storage device for dispensing drugs. The term means a locked or secured enclosure located outside the pharmacy licensed area:
(A) to which only specifically authorized personnel may obtain access by key or combination available only to those authorized persons by:
(i) security code;
(ii) password; or
(iii) other method of positively identifying an individual; and
(B) that is sufficiently secure to deny access to unauthorized persons.
(2) "Cognitive services" means those acts and operations related to a patient's drug therapy that are judgmental in nature, based on knowledge, and derived from empirical factual information.
(3) "Consultant pharmacist" means a pharmacist licensed pursuant to IC 25-26-13-11 and who engages in the practice of pharmacy in or for long term care facility or other residential patients, other than as a supplying pharmacist.
(4) "Consulting" means the provision of nonsupply related cognitive services that include, but are not necessarily limited to, the following:
(A) Drug regimen review as defined in IC 25-26-13-2.
(B) Provision of advice and counsel on drugs, the selection and use thereof to the facility, the patients therein, the health care providers of the facility regarding the appropriateness, use, storage, handling, administration, and disposal of drugs within the facility.
(C) Participation in the development of policies and procedures for drug therapy within the institution, including storage, handling, administration, and disposing of drugs and devices.
(D) Assuring the compliance with all applicable laws, rules, and regulations.
(E) Provision of educational and drug information sources for the education and training of the facility health care professionals.
(F) Accepting responsibility for the implementation and performance of review of quality-related or sentinel events as defined in this rule.
(5) "Emergency drugs" means those drugs that:
(A) may be required to meet the immediate therapeutic needs of patients; and
(B) are not available from any other authorized source in sufficient time to prevent risk of harm to patients by delay resulting from obtaining such drugs from other sources.

(6) “Institutional facility” means any health care facility whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where practitioners, as defined by IC 16-42-19-5, who are duly licensed, engage in private practice and pharmacies licensed under IC 25-26-13-17.

(7) “Institutional pharmacy” means that portion of an institutional facility where pharmacy is practiced and is:

(A) the location of the selection, compounding, production, sale, storage, and distribution of drugs, devices, and investigational or new drugs used in the diagnosis and treatment of injury, illness, and disease pursuant to drug orders and prescriptions by practitioners; and

(B) licensed with the board under IC 25-6-3-7.

(8) “Performance improvement program” means a continuous, systematic review of key medication use processes to identify, evaluate, and improve medication use and patient care.

(9) “Pharmacist in charge” (by whatever title, for example, “pharmacy manager”, “pharmacy director”, or “director of pharmacy”) means the pharmacist who directs the activities of the institutional pharmacy and who is, as such, responsible for:

(A) all activities of the institutional pharmacy; and

(B) meeting the requirements of:

(i) IC 25-26-13;

(ii) the rules of the board; and

(iii) any federal requirements pertaining to institutional pharmacies.

The qualifying pharmacist may, depending on the circumstances, also be the pharmacist in charge, though the pharmacist in charge is not required to be the qualifying pharmacist.

(10) “Policy and procedure manual” means a written document containing the agreed-to institutional rules of operation and methodology for the effective delivery of pharmacy services.

(11) “Qualifying pharmacist” means the pharmacist who accepts responsibility for the operation of a pharmacy as defined in IC 25-26-13-2 and whose name is listed on the pharmacy permit granted under IC 25-26-13-17.

(12) “Quality-related event” means the inappropriate provision of pharmaceutical services whether or not resulting in an adverse health incident, including the following:

(A) A variation from the practitioner’s order, including, but not limited to, the following:

(i) Dispensing an incorrect drug.

(ii) Dispensing an incorrect drug strength.

(iii) Dispensing an incorrect dosage form.

(iv) Dispensing a drug to a wrong patient.

(v) Providing inadequate or incorrect packaging, labeling, or directions.

(vi) Failing to provide an ordered drug.

(B) A failure to identify and manage:

(i) overutilization or underutilization;

(ii) therapeutic duplication;

(iii) drug-disease contraindications;

(iv) drug-drug interactions;

(v) incorrect drug dosage or duration of therapy;

(vi) drug-allergy interactions; or

(vii) clinical abuse and/or misuse.

(13) “Reversible condition” means a condition that requires intervention to resolve in a reasonable time.

(14) “Sentinel event” means an unexpected occurrence involving serious adverse effect, such as disability, life threatening condition, prolonged hospitalization, or death in a patient resulting from medication use.

(15) “Supplying pharmacist” means that pharmacist licensed in the state where the pharmacist is practicing and who is practicing in a supplying pharmacy (as defined in this rule) and who accepts responsibility for all aspects the drugs and devices sold (as defined in IC 25-26-13-2) or dispensed to a facility.

(16) “Supplying pharmacy” means a pharmacy licensed in the state where the pharmacy is located and which provides drugs and devices to patients in long term care or other facilities where patients reside.

(17) “Temporary condition” means a condition that resolves in a reasonable time without intervention.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-1; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1636)

856 IAC 1-28.1-2 Purpose

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 2. The purpose of this rule is to set forth the responsibilities of pharmacists and pharmacies serving institutional and home health care patients. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-2; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)*

856 IAC 1-28.1-3 Applicability

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 3. This rule is applicable to pharmacies located:

(1) within institutional facilities as defined in section 1 of this rule and classified as Type II pharmacies in IC 25-26-13-17; and
(2) outside institutional facilities that serve institutionalized patients who are classified as Type III and Type VI pharmacies as in IC 25-26-13-17.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-3; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-4 Pharmacist in charge; responsibilities
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 4. The pharmacist in charge or an appropriate designee shall:
(1) be responsible for establishing and carrying out a performance improvement program as defined in section 1 of this rule; and
(2) develop or be responsible for development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-4; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-5 Policies and procedures manual
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 5. (a) The pharmacist in charge shall develop or be responsible for the development of a policies and procedures manual that shall be of sufficient scope and detail that pharmacists practicing in the institutional pharmacy will be able to practice effectively and safely.
(b) The manual required in this section shall be available for inspection by a member of the board or its representative.
(c) The policies and procedures manual shall contain, at a minimum, the following:
(1) Provisions for a continuous quality improvement committee that shall be comprised of staff members of the pharmacy, including, but not necessarily limited to, the following:
(A) Pharmacists.
(B) Pharmacist interns or externs.
(C) Pharmacy technicians.
(D) Clerical or support staff.
(E) Other persons deemed necessary by the qualifying pharmacist.
(2) Provisions for the pharmacist in charge or designee to ensure that the committee conducts a review of quality related events at least every three (3) months.
(3) A process to record, measure, assess, and improve quality of patient care.
(4) The procedure for reviewing quality related or sentinel events.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-5; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1637)

856 IAC 1-28.1-6 Personnel
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 6. The qualifying pharmacist and/or the pharmacist in charge shall develop and implement, or cause to be developed and implemented, policies and procedures that specify duties to be performed by pharmacy technicians and other ancillary personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-6; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)*

856 IAC 1-28.1-7 Pharmacist's duties
Authority: IC 25-26-13-4
Affected: IC 16-42-19-3; IC 25-26-13-2; IC 25-26-13-31; IC 25-26-16

Sec. 7. (a) Pursuant to authority granted in IC 25-26-13-2 and IC 25-26-13-31, the duties of the pharmacists practicing in the institutional pharmacy include, but are not limited to, the requirements in this section.
(b) The pharmacist practicing in an institutional pharmacy shall, at a minimum, do the following:
(1) Obtain and maintain patient drug histories and drug profiles.
(2) Perform drug evaluations, drug utilization review, drug regimen review, and drug therapy management under protocol approved by the medical staff of the institution and authorized by IC 25-26-16.
(3) Interpret the drug order written by a practitioner in or transmitted to an institutional facility and either received in or subsequently transmitted to the pharmacy.
(4) Be responsible for checking all drug orders within a maximum of twenty-four (24) hours, including those written during periods when the pharmacy is closed and orders are filled from sources, including emergency kits, drug cabinets, or the pharmacy as authorized under section 8(c) of this rule.
(5) Be responsible for drug product selection of the item that will be used to fill the drug order that may be established either by policy or formulary pursuant to the institution's pharmacy and therapeutics committee or related committee.
(6) Be responsible for determining the legality, completeness, and appropriateness of the drug order and product pursuant to IC 16-42-19-3.
(7) Participate in drug or drug-related research.

(8) Provide counseling, advising, and education of patients, patients' care givers, and health care providers and professionals on issues regarding drugs or drug therapy.

(9) Compound, label, administer, and dispense drugs or devices.

(10) Assess, record, and report quality related events as defined in this rule.

(11) Be responsible for storage and distribution of drugs and devices.

(12) Provide documentation in the medical record of the recommendations made related to the patient's therapeutic response to medication.

(13) Any other duties that shall from time to time be necessary for the proper operation of the institutional pharmacy.

(c) The consultant pharmacist shall, in addition to the duties in subsection (b), provide cognitive services as defined in this rule, including, at a minimum, the following:

(1) Drug regimen reviews as defined in IC 25-26-13-2.

(2) Offer advice and counsel to other health care providers as deemed appropriate regarding the pharmaceutical care of the patient.

(3) Develop or assist in the development of policies and procedures for the legal, safe, and effective means of handling, storing, and disposing of drugs and devices.

(4) Be responsible for assuring the safe and appropriate receipt, labeling, storage, and disposal of all drugs placed outside the pharmacy licensed area in emergency drug kits or other storage devices as authorized by law or rule.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-7; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)

856 IAC 1-28.1-8 Absence of pharmacist

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 8. (a) During such times as an institutional pharmacy is closed and unattended by a pharmacist, the drugs may be obtained for patient use as outlined in this section.

(b) Cabinets, including mechanical storage devices for dispensing drugs, are locked or secured enclosures located outside the pharmacy licensed area, to which only specifically authorized personnel may obtain access by key, combination, or security code, password, or other method of positively identifying an individual, and are sufficiently secure to deny access to unauthorized persons. The qualifying pharmacist and/or pharmacist in charge shall, in conjunction with the appropriate committee of the institutional facility, develop inventory listings of the drugs to be included in such cabinets and shall ensure the following:

(1) Such listed drugs, properly labeled, are available therein.

(2) Only prepackaged drugs (meaning that no repackaging is required at the time of removal for an individual patient's use) are available therein, in amounts sufficient for immediate therapeutic requirements for a period not to exceed twenty-four (24) hours.

(3) When drugs are used, a record is made to include a written physician's order or accountability record.

(4) All drugs therein are reviewed by a pharmacist upon return to duty, not to exceed twenty-four (24) hours.

(5) There are written policies, procedures, and forms established to implement the requirements of this subsection.

(c) Whenever any drug is not available from floor supplies or cabinets, as defined in this section, and such drug is required to treat the immediate needs of a patient, such drug may be obtained from the pharmacy in accordance with the requirements of this subsection. One (1) supervisory licensed nurse in any given shift may have access to the pharmacy and may remove drugs there from. The qualifying pharmacist shall require that the removal of any drug from the pharmacy by an authorized nurse be recorded on a suitable form, which includes the name of the drug, strength, amount, date, time, and signature of nurse, and that a copy of the order shall be left with the form.

(d) Requirements for hospital emergency drug boxes, drug carts, emergency kits, emergency drug kits, crash carts, drug kits, or other storage method for emergency drugs are as follows:

(1) Pharmacy policy and procedures shall assure the:

(A) availability;

(B) control; and

(C) security;

of emergency drug carts, drug kits, or drug boxes in the pharmacy and patient care areas.

(2) Procedures shall include the following:

(A) Determination of drugs and quantities of drugs to be included.

(B) Labeling for expiration date.

(C) Process for restocking the cart, kit, or box.

(D) Security measures to prevent unauthorized access.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-8; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1638)

856 IAC 1-28.1-9 Emergency drug kits from Type III and Type VI pharmacies

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17; IC 35-38

Sec. 9. (a) Emergency drug kits supplied by pharmacies with a Type III or Type VI permit shall be in compliance with this section.

(b) All drugs in the emergency kit shall be provided and owned by a single supplying pharmacy.

(c) All drugs in the emergency drug kit shall be selected and approved by a committee whose membership includes, at a minimum, the following:

(1) The facility's consultant pharmacist.

(2) A licensed nurse.
(3) A physician (medical doctor or doctor of osteopathy).
(4) The facility administrator.
(d) The selection process must identify drugs and quantities thereof in the emergency drug kit.
(e) The lists of drugs and quantities included in the emergency drug kit shall be reviewed as required periodically, but no less often than yearly.
(f) Labeling as follows:
(1) The exterior labeling of the emergency drug kit as described in this subsection shall contain, at a minimum, the following:
(A) Drug name (trade name, generic name, or active ingredients).
(B) Drug strength or size, if any.
(C) Quantity included therein.
(D) Expiration date of the kit as defined in this section.
(2) All drugs contained in the emergency drug kit as described in this section shall be labeled, at a minimum, with the following:
(A) Drug name (trade name, generic name, or active ingredients).
(B) Drug strength or size, if applicable.
(C) Name of the manufacturer, packer, or distributor.
(D) Lot number.
(E) Expiration date.
(g) The expiration date of the emergency drug kit, as required in subsection (f)(1)(D) shall be the earliest date of expiration of any of the drugs included in the kit at any time.
(h) All emergency kits subject to this subsection:
(1) shall be stored in a secure area, suitable for the prevention of unauthorized access to or diversion of the drugs therein;
(2) if controlled substances, as defined in IC 35-38, are stored in such a manner as to facilitate periodic reconciliation by the facility nursing staff, that reconciliation shall be recorded in an appropriate manner as determined by the committee described under this section; and
(3) all controlled substances contained in emergency drug kits shall remain the property of the supplying pharmacy and as such shall be included in the pharmacy's biennial inventory as required by 21 CFR 1303.04 and 21 CFR 1301.11.
(i) The nurse responsible for removing drugs from an emergency drug kit shall record or cause to be recorded, in a manner designated under subsection (h)(2), the following minimum information:
(1) Name of the patient.
(2) Name of the drug.
(3) Strength of the drug.
(4) Quantity removed.
(5) Date of removal.
(6) Time of removal.
(j) Removal of a controlled substance in Schedule II pursuant to an oral authorization from a practitioner shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-7 regarding prescription requirements for controlled substances in Schedule II.
(k) Removal of a controlled substance in Schedule III, IV, or V, pursuant to an oral authorization from a practitioner, shall be documented, and the nurse accepting such authorization is responsible for compliance with 856 IAC 2-6-12.
(l) Whenever an emergency kit is opened, for any reason, the supplying pharmacy shall be notified in a timely manner, and the pharmacy shall restock, if necessary, and reseal the kit promptly so as to prevent risk of harm to patients of the facility. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-9; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1639)*

856 IAC 1-28.1-10 Security
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 10. The pharmacy shall be capable of being secured against entry by key, combination, code, password, or other method developed that can positively identify an individual so as to prevent access by unauthorized personnel. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-10; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640)*

856 IAC 1-28.1-11 Performance improvement events, sentinel events, corrective and avoidance measures, review, records, and documentation
Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 11. (a) The pharmacist in charge shall, as a part of the pharmacy's performance improvement program, assure or be responsible for assuring that data are collected to:
(1) monitor the stability of existing medication use processes;
(2) identify opportunities for improvement; and
(3) identify changes that will lead to and sustain improvement.
(b) Identification of quality related or sentinel event as defined in section 1 of this rule shall be cause for:
(1) an intensive analysis of causal factors involved in the event; and
(2) plans for corrective actions.

(c) Records of all processes, analysis, and corrective measures instituted involving such pharmacy quality related or sentinel event shall be maintained for a period of not less than two (2) years.

(d) The committee created under section 5(c)(1) of this rule shall, at a minimum, consider the effects on quality of the pharmacy system due to the following:

(1) Staffing levels of both professional and technical personnel.

(2) Workflow.

(3) Use of technology.

(e) Requirements for documentation of performance improvement monitoring of medication use processes, confidentiality of records, summarization, and examination by the board shall be as follows:

(1) Each quality related or sentinel event that occurs, or is alleged to have occurred, as the result of activities involving pharmacy operations, shall be documented in a written or electronic storage record created solely for that purpose.

(2) The quality related or sentinel event shall be:

(A) initially documented by the pharmacist to whom it is first described; and

(B) recorded on the same day of its having been so described to the pharmacist.

(3) Documentation shall include a description of the event that is of sufficient detail to permit analysis of the event.

(4) The pharmacist in charge shall summarize, or cause to be summarized, efforts to improve the medication use process on a semiannual basis.

(5) No patient names or employee names shall be included in this summary report.

(6) This report shall be maintained for a period of not less than two (2) years.

(7) The records created and maintained as a component of a pharmacy performance improvement program are confidential to the extent law permits. However, to assure compliance, the board or its representative may review the policies and procedures manual and a summarization of events described in subsection (b).

(Indiana Board of Pharmacy; 856 IAC 1-28.1-11; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1640)

856 IAC 1-28.1-12 Drug distribution, storage, and accountability

Authority: IC 25-26-13-4

Affected: IC 25-26-13-17

Sec. 12. (a) All drugs and devices in pharmacies located within institutions shall be obtained and used in accordance with written policies and procedures that have been prepared or approved by the qualifying pharmacist or pharmacist in charge and the medical staff who explain the:

(1) selection;

(2) distribution;

(3) storage; and

(4) safe and effective use of:

(A) drugs;

(B) new drugs;

(C) investigational new drugs; and

(D) devices;

in the facility.

(b) The pharmacist in charge of the pharmacy located within an institution shall be responsible for the following:

(1) The safe and efficient:

(A) distribution;

(B) control;

(C) storage; and

(D) accountability;

for all drugs and devices.

(2) The compliance with all applicable Indiana and federal laws and rules.

(c) Labeling requirements are as follows:

(1) All drugs, other than unit-of-use packages, dispensed by an institutional pharmacy, intended for use within the facility, shall be distributed in appropriate containers and adequately labeled so as to identify, at a minimum, the following:

(A) Patient identification.

(B) Brand name or generic name, or both.

(C) Strength, if applicable.

(D) Route of administration.

(E) Quantity.

(F) Pharmacist's initials.

(G) Location of the patient within the institution.

(2) Unit-of-use packages shall contain information to adequately label them, at a minimum, as follows:

(A) Drug name (brand or generic, or both).

(B) Strength, if applicable.

(C) Control number and/or expiration date.

(3) All drugs dispensed by an institutional pharmacy to patients about to be discharged, or temporarily discharged, from institutions with Type III or Type IV permits, shall be labeled with the following minimum information:

(A) Name, address, and telephone number of the institutional pharmacy.
(B) Date and identifying serial number.
(C) Name of patient.
(D) Name of drug and strength, if applicable.
(E) Directions for use by the patient and route of administration.
(F) Name of prescribing practitioner.
(G) Precautionary information if any contained in the prescription.

(d) Requirements for the disposition of discontinued or recalled drugs are as follows:

(1) The qualifying pharmacist or pharmacist in charge shall be responsible for the development and implementation of policies and procedures for the return to the pharmacy of drugs and containers that are:

(A) discontinued, outdated, or recalled; or
(B) in containers with worn, illegible, or missing labels;

for proper disposition.

(2) The qualifying pharmacist or pharmacist in charge or his or her designee shall make proper disposition of such drugs at the storage site.

(e) The qualifying pharmacist or pharmacist in charge shall ensure that drugs are dispensed from the institutional pharmacy only upon authorized practitioner's:

(1) written orders;
(2) direct copies;
(3) facsimiles thereof; or
(4) electronically transmitted by other means and printed or displayed appropriately.

(f) Accountability requirements are as follows:

(1) The qualifying pharmacist or pharmacist in charge of an institutional pharmacy shall ensure that policies and procedures documenting the trail of:

(A) controlled substances; and

(B) such other drugs as may be specified by the appropriate committee of the institutional facility, from ordering and receiving by the pharmacy through administration or wastage of drug at the patient level.

(2) The qualifying pharmacist or pharmacist in charge shall be responsible for review of this process on a continual basis by review of:

(A) proofs-of-use documentation; or
(B) other electronic documentation methodology.

(3) At a minimum, the documentation process shall be able to identify the following:

(A) The name of the drug.
(B) The dose.
(C) The patient's name.
(D) The date and time of administration to the patient.
(E) The identification of the individual administering.
(F) The record of aliquot portion destroyed, if any, and identification of witness.

(g) All records and reports that are required for pharmacy functions shall be maintained according to policies and procedures developed within the institution with the approval of the pharmacist in charge for a period of not less than two (2) years. *(Indiana Board of Pharmacy; 856 IAC 1-28.1-12; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1641)*

856 IAC 1-28.1-13 Drug self-administration

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 13. Self-administration of drugs by patients of an institutional facility shall be permitted only if such use is specifically authorized by the treating or ordering physician and:

(1) the patient's knowledge of self-administration has been evaluated; or
(2) the patient has received training in the proper manner of self-administration:
(A) by a pharmacist; or
(B) according to hospital policy; and

there is no risk of harm to the patient.

(Indiana Board of Pharmacy; 856 IAC 1-28.1-13; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)

856 IAC 1-28.1-14 Patient's own medication

Authority: IC 25-26-13-4
Affected: IC 25-26-13-17

Sec. 14. (a) An institutional pharmacy is prohibited from accepting and dispensing drugs that are brought into the institution by the patient, even if intended for use by that same patient. However, use of the patient's own medication may be permitted if:

(1) the patient or the patient's representative may maintain the patient's own medication:

(A) at the bedside; or
(B) for drugs with special storage requirements, including, but not limited to, refrigeration in an appropriate storage area in the patient care area under control of nursing personnel for appropriate administration to that patient only; and
(2) the nurses in charge of that patient's care shall witness the administration and maintain records of such use.

(b) If the patient or the patient's representative brings in medication part or all of which is still present at such time a patient expires, those drugs shall be delivered to the institutional pharmacy for appropriate destruction. Such drugs may not be turned over to the patient's representatives. This rule shall be made clear to the parties involved prior to the permission to use such medication. Patients who are discharged shall take with them their own medications brought to the institution under the terms of this section.

(c) In the event the patient is discharged and leaves drugs brought in under this section, either deliberately or inadvertently, such drugs shall be documented and stored at the appropriate nursing location for a maximum of seven (7) calendar days. If not claimed by the patient or the patient's agent within those seven (7) calendar days, the drugs so stored shall be destroyed as described in subsection (b). *(Indiana Board of Pharmacy; 856 IAC 1-28.1-14; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)*

856 IAC 1-28.1-15 Inspections
Authority: IC 25-26-13-4
Affected: IC 16-42-3-3; IC 25-26-13-17

Sec. 15. The qualifying pharmacist or pharmacist in charge shall be responsible for the timely inspection of all areas where drugs are stored, used, or administered. The inspection can be carried out by qualified designee and appropriate records kept. The inspection shall verify, at a minimum, the following:
(1) Disinfectants and drugs solely for nontherapeutic external use are stored separately and apart from drugs for internal use or injection.
(2) Drugs requiring special storage conditions are appropriately stored to assure the drugs are not adulterated as described in IC 16-42-3-3.
(3) Drugs subject to deterioration are removed from any accessible location prior to the expiration date (manufacturer's or other such as required under 856 IAC 1-21) and disposed of appropriately.
(4) Emergency drugs designated by the institution are in adequate supply and are properly stored in the institution.
(5) All necessary and required security and storage standards are met.
(6) All pharmacy-related policies and procedures of the institution are complied with.
(Indiana Board of Pharmacy; 856 IAC 1-28.1-15; filed Dec 26, 2001, 2:44 p.m.: 25 IR 1642)

Rule 29. Electronic Data Processing of Prescriptions

856 IAC 1-29-1 Approval of electronic data processing system
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. (a) No electronic data processing system may be used by a pharmacist pursuant to a Type I, Type III, and Type VI pharmacy permit as an alternative to his or her recordation of prescription information unless that system has been approved by the Indiana board of pharmacy (board).

(b) No electronic data processing system may be used by a pharmacist as an alternative to his recordation of information directly on the original prescription pursuant to IC 25-26-13-25(c), without the approval of the board, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in this rule. Any such system must be approved by the board before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. Approval is subject to withdrawal for cause so that the pharmacist must in such a case discontinue use of the system as an alternative. *(Indiana Board of Pharmacy; 856 IAC 1-29-1; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2543; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)*

856 IAC 1-29-2 On-line retrieval and printout capabilities; data requirements; discontinuance of system
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Any such proposed computerized system must provide on-line retrieval (via visual display device or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include:
(1) prescription number;
(2) date of issuance of the original prescription order by the prescriber;
(3) full name and address of the patient;
(4) name and address of prescriber;
(5) DEA number of prescriber when drug prescribed is controlled substance;
(6) the name, strength (if applicable), dosage form, and quantity of medication originally dispensed;
(7) total number of refills authorized by prescriber.
(b) In addition to the information contained in subsection (a) above, the following information shall be maintained for each filling:
(1) date dispensed;
(2) quantity dispensed, if different from the quantity prescribed;
(3) identification of dispensing pharmacist;

(4) adequate information to determine the number of authorized refills remaining.

(c) The system shall be able to produce a complete printout of current prescription status that would provide all necessary refill information for use in the event that the pharmacy wishes to discontinue use of the computer system. The report shall list all currently refillable prescriptions in sequence by prescription number. The following information shall be included:

(1) prescription number;

(2) date dispensed, quantity, and pharmacist's identification;

(3) the number of refills presently remaining and the amount owed, if any, from any partial refills.

(Indiana Board of Pharmacy; 856 IAC 1-29-2; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-29-3 Hard-copy of daily dispensing; verification and retention; back-up capability

Authority: IC 25-26-13-4

Affected: IC 25-26-13-25

Sec. 3. (a) A pharmacy using an electronic data processing system must provide a separate hard-copy printout of prescription order and refill data for each day's dispensing or other board approved uniformly maintained readily retrievable system. This hard-copy printout or other board approved system shall include the following:

(1) prescription number;

(2) date of dispensing;

(3) patient name;

(4) drug and strength (if applicable);

(5) quantity dispensed;

(6) prescriber identification;

(7) pharmacist identification;

(8) refill status;

(9) controlled drug schedule identification.

(b) The dispensing pharmacist must verify that the data is correct to the best of his knowledge and date and sign the document or log book in the same manner as he would sign a check or legal document.

(c) This documentation shall be maintained for a period of five (5) years from the dispensing date. The daily hard-copy printout may be replaced with a monthly printout or other permanent documentation containing the same information.

(d) Each system must have the capability of informational back-up and such documentation must be stored in a secure location. *(Indiana Board of Pharmacy; 856 IAC 1-29-3; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-4 Auxiliary system

Authority: IC 25-26-13-4

Affected: IC 25-26-13-25

Sec. 4. In the event that a pharmacy which employs such an electronic data processing system experiences system down time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line service. However, nothing in this section shall preclude a pharmacist from using his professional judgment to benefit the health of the patient. *(Indiana Board of Pharmacy; 856 IAC 1-29-4; filed Aug 16, 1984, 3:55 pm: 7 IR 2544; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-5 Safeguards

Authority: IC 25-26-13-4

Affected: IC 25-26-13-15; IC 25-26-13-25

Sec. 5. When utilizing electronic data processing systems, pharmacists shall comply with IC 25-26-13-15. *(Indiana Board of Pharmacy; 856 IAC 1-29-5; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-6 Data entry; supervision

Authority: IC 25-26-13-4

Affected: IC 25-26-13-25

Sec. 6. When electronic data processing equipment is utilized in any pharmacy, input of drug information shall be performed by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information entered and verify the prescription order. *(Indiana Board of Pharmacy; 856 IAC 1-29-6; filed Aug 16, 1984, 3:55 pm: 7 IR 2545; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-29-7 Existing systems; compliance date *(Repealed)*

Sec. 7. *(Repealed by Indiana Board of Pharmacy; filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-29-8 Transfer of prescriptions between pharmacies *(Repealed)*

Sec. 8. *(Repealed by Indiana Board of Pharmacy; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2249)*

856 IAC 1-29-9 Applicability of rule
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 9. This rule applies to pharmacies with Type I, Type III, Type IV, and Type VI permits. *(Indiana Board of Pharmacy; 856 IAC 1-29-9; filed Aug 16, 1984, 3:55 p.m.: 7 IR 2545; filed Mar 8, 1989, 10:00 a.m.: 12 IR 1634; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed Sep 21, 1992, 9:00 a.m.: 16 IR 724; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 30. Sterile Pharmaceuticals; Preparation and Dispensing

856 IAC 1-30-1 Purpose
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 1. The purpose of this rule is to provide standards for the preparation, labeling, and distribution of sterile pharmaceutical products by licensed pharmacists, pursuant to a drug order or prescription. *(Indiana Board of Pharmacy; 856 IAC 1-30-1; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-2 "Biological safety cabinet" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. As used in this rule, "biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel, and environment, according to National Sanitation Foundation (NSF) Standard 49. *(Indiana Board of Pharmacy; 856 IAC 1-30-2; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-3 "Class 100 environment" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 3. As used in this rule, "Class 100 environment" means an ISO class 5 atmospheric environment, which contains less than one hundred (100) particles five-tenths (0.5) microns in diameter per cubic foot of air, according to the ISO for clean rooms and associated controlled environments. *(Indiana Board of Pharmacy; 856 IAC 1-30-3; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-4.1 "Hazardous" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.1. As used in this rule, "hazardous" means any drug or waste that may:
(1) be:
(A) cytotoxic;
(B) genotoxic;
(C) oncogenic;
(D) mutagenic;
(E) teratogenic; or
(2) otherwise pose a potential health hazard.
(Indiana Board of Pharmacy; 856 IAC 1-30-4.1)

856 IAC 1-30-4.2 "ISO" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.2. (a) "ISO" means the International Organization for Standardization.

(b) That certain document being titled International Organization for Standardization, as published by the International Organization for Standardization 1, rue de Varembé, Case postale 56 CH-1211 Geneva 20, Switzerland is hereby incorporated by reference as if fully set out in this rule. *(Indiana Board of Pharmacy; 856 IAC 1-30-4.2)*

856 IAC 1-30-4.3 "NSF" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.3. (a) "NSF" means the National Sanitation Foundation.

(b) That certain document being titled The Standard for Performance (copyright 2004), as published by the National Sanitation Foundation, P.O. Box 130140, 789 North Dixboro Road, Ann Arbor, Michigan 48113-0140 is hereby incorporated by reference as if fully set out in this rule. *(Indiana Board of Pharmacy; 856 IAC 1-30-4.3)*

856 IAC 1-30-4.4 "Parenteral" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.4. As used in this rule, "parenteral" means a sterile preparation of drugs for injection through one (1) or more layers of the skin. *(Indiana Board of Pharmacy; 856 IAC 1-30-4.4)*

856 IAC 1-30-4.5 "Positive patient outcome" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.5. As used in this rule, "positive patient outcome" means the:
(1) cure or prevention of disease;
(2) elimination or reduction of symptoms; or
(3) arresting or slowing of disease process;
so as to improve the patient's quality of life.
(Indiana Board of Pharmacy; 856 IAC 1-30-4.5)

856 IAC 1-30-4.6 "Product quality and characteristics" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4.6. As used in this rule "product quality and characteristics" means the following:
(1) Sterility.
(2) Potency associated with environmental quality.
(3) Preparation activities.
(4) Checks and tests.
(Indiana Board of Pharmacy; 856 IAC 1-30-4.6)

856 IAC 1-30-5 "Qualified pharmacist" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 5. As used in this rule, "qualifying pharmacist" means a licensed pharmacist, identified in the policy and procedure manual, required by section 7 of this rule, as responsible for the preparation of the sterile pharmaceuticals, in compliance with the policy and procedure manual and the applicable laws governing the practice of pharmacy in Indiana. *(Indiana Board of Pharmacy; 856 IAC 1-30-5; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)*

856 IAC 1-30-6 "Sterile pharmaceutical" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 6. As used in this rule, "sterile pharmaceutical" means ~~a~~ any dosage form of a drug, including, but not limited to, parenteral, injectable, and ophthalmic dosage forms, which dose form is free from living microbes, and free from chemical or physical contamination. *(Indiana Board of Pharmacy; 856 IAC 1-30-6; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1017, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-7 Policy and procedure manual
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. Each pharmacy preparing and dispensing, or holding itself out to prepare or dispense, sterile pharmaceuticals shall maintain a policy and procedure manual relating to the compounding, dispensing, delivery, administration, storage, and use of sterile pharmaceutical products, pursuant to prescriptions or drug orders, or both, as part of the pharmacy policy and procedure manual or as a separate policy and procedure manual. This manual shall be available at the pharmacy for inspection by the board or its designated inspector. The manual shall be reviewed annually by the pharmacist-in-charge or the qualifying pharmacist and revised if needed. The manual shall include the name of the pharmacist-in-charge of the preparation of sterile pharmaceuticals and policies and procedures for the following:
(1) Clinical services provided.
(2) The handling, storage, disposal, and cleanup of accidental spills of hazardous drugs, if they are prepared.
(3) Disposal of unused supplies and drugs.
(4) Drug destruction and returns.
(5) Drug dispensing.
(6) Drug labeling and relabeling.
(7) Drug storage.
(8) Duties and qualifications for professional and nonprofessional staff.
(9) Equipment.
(10) Handling of infectious wastes, if drug products or administration devices are returned to the pharmacy after administration in the case of home administration.
(11) Infusion devices and drug delivery systems, if utilized.
(12) Investigational drugs, if dispensed.
(13) Quality assurance procedures to include the following:
(A) Recall procedures.
(B) Storage and expiration dating.
(C) Educational procedures for professional staff, nonprofessional staff, and the patient, if needed, in the case of home administration.
(D) Sterile procedures to include monitoring the temperature of the refrigerator, routine maintenance, and report of hood certification.
(E) Sterility testing or monitoring, if employed, in the case of routine bulk compounding from nonsterile chemicals.
(14) Reference manuals.
(15) Sterile product preparation procedures.
(Indiana Board of Pharmacy; 856 IAC 1-30-7; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-8 Physical requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 8. (a) A licensed pharmacy preparing sterile pharmaceuticals shall have a designated area for preparing compounded, sterile pharmaceuticals. The designated area shall be restricted to only those personnel authorized for the preparation of sterile pharmaceuticals. This area may be in a separate room or in a portion of a larger room. The area cannot be a warehouse or stockroom setting and must be free of dust and dirt.
(b) The designated preparation area shall be used only for the preparation of sterile pharmaceutical products and related functions.
(c) The licensed pharmacy preparing sterile pharmaceutical products shall have the following equipment:
(1) An environmental control device capable of maintaining at least an ISO Class 5 (Class 100) environment in the work space where critical objects are exposed and critical activities are performed. This device must be capable of maintaining ISO Class 5 (Class 100) conditions during normal activity. Examples of appropriate devices include the following
(A) Laminar airflow hood.
(B) Zonal laminar flow of high efficiency particulate air (HEPA) filtered air.
(C) Barrier isolators.
(2) A sink with hot and cold running water that is convenient to the compounding area but outside the buffer area for the purpose of hand scrubs before compounding.
(3) Disposal containers for used needles, syringes, gowns, gloves, etc., and, if applicable, for hazardous waste from the preparation of chemotherapy agents and infectious wastes from patients.
(4) Environmental controls including biohazard cabinetry when hazardous drug products are prepared.
(5) A refrigerator with a thermometer.

(6) Infusion devices, if appropriate.
(7) Documentation to demonstrate adequate cleaning and sanitizing of the environment along with records of all necessary air sampling for particulates and microorganisms.
(8) Environmental control to maintain an ISO Class 8 (Class 100,000) conditions in the buffer area.

(d) The pharmacy shall maintain supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products. All expired, recalled, or adulterated and misbranded drug substances must be removed from the restricted area. The licensed pharmacy preparing sterile pharmaceuticals shall include the following supplies:
(1) Disposable needles, syringes, and other supplies needed for aseptic admixture.
(2) Disinfectant cleaning tools and solutions.
(3) A hand washing agent with antibacterial action.
(4) Disposable towels or wipes.
(5) Filters and filtration equipment, if utilized.
(6) A hazardous drug spill kit shall be available in the facility if hazardous drugs are prepared.
(7) Disposable gowns and gloves.

(e) No one may have access to the pharmacy in the absence of the pharmacist, except as stated in 856 IAC 1-28.1-8.

(f) The pharmacy shall have sufficient current reference materials related to sterile products to meet the needs of pharmacy. A pharmacy preparing or proposing to prepare sterile pharmaceuticals shall have in its reference library:
(1) the Handbook on Injectable Drugs, published by the American Society of Hospital Pharmacists (ASHP), 4630 Montgomery Avenue, Bethesda, Maryland 20814;
(2) the King's Guide to Parenteral Admixtures, published by Pacemarq Inc., 11701 Borman Drive, St. Louis, Missouri 63146; or
(3) another board-approved, printed or electronic database sufficient for determining mixing and administration guidelines and drug incompatibilities such as would be contained in the references listed in subdivision (1) or (2).

(g) If the pharmacy is handling or preparing hazardous drugs, the pharmacy shall have a current copy of Occupational Safety and Health Administration requirements for handling hazardous drugs as published ~~in~~ by the Occupational Safety and Health Administration, Office of Occupational Medicine, Directorate of Technical Support, Occupational Safety and Health Administration, U.S. Department of Labor. *(Indiana Board of Pharmacy; 856 IAC 1-30-8; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1018, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Nov13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-9 Personnel
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 9. (a) Each pharmacist, pharmacist intern, pharmacist extern, and pharmacy technician engaged in preparing sterile pharmaceuticals must be trained in the specialized functions of preparing and dispensing compounded, sterile pharmaceuticals, including the principles of aseptic technique and quality assurance. Documentation of such training or experience shall be made available for inspection by the board or its representatives.

(b) The qualifying pharmacist shall be responsible for the following:
(1) Purchasing, storage, compounding, repackaging, dispensing, and distribution of all sterile pharmaceuticals.
(2) Development and continuing review of all:
(A) policies and procedures;
(B) training manuals; and
(C) quality assurance programs.

(c) The qualifying pharmacist shall:
(1) assure the environmental control of all products shipped, as controllable by the pharmacist to the extent such aspect of shipping is controllable by the pharmacist; and
(2) be responsible for adherence to all current USP Standards related to sterile compounding, personnel cleansing and gowning; or
(3) reject or cause to be rejected any such shipment or drugs as prepared in violation of applicable USP Standards.
(Indiana Board of Pharmacy; 856 IAC 1-30-9; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-10 Support personnel
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 10. (a) The pharmacist may be assisted by support personnel in compliance with IC 25-26-13-18(a)(4). Such personnel shall have specialized training in the preparation of sterile pharmaceuticals and shall work under the supervision of a licensed pharmacist. The training provided to these personnel shall be described in writing. The duties and responsibilities of supportive personnel must be consistent with their training and experience.

(b) This section is not to preclude other licensed health care professionals, as allowed by law, may also prepare sterile pharmaceuticals when there is an immediate need, or when the preparation in a pharmacy is not practical. *(Indiana Board of Pharmacy; 856 IAC 1-30-10; filed Jan 28, 1992, 5:00*

p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-11 Staffing
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 11. A pharmacist shall be accessible at all times to respond to patients' and other health professionals' questions and needs. *(Indiana Board of Pharmacy; 856 IAC 1-30-11; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-12 Profile or medication record system
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 12. A pharmacy-generated profile or medication record system for sterile pharmaceuticals administered to patients, except for those inpatients in an institutional facility, as defined in 856 IAC 1-28-1(a), holding a Type II pharmacy permit, shall be maintained separately from the prescription file. The patient profile or medication record system shall contain at a minimum the following:
(1) Patient's name, date of birth or age, weight, and sex.
(2) Sterile pharmaceutical products dispensed.
(3) Drug content and quantity.
(4) Directions for the patient, if administered outside the facility.
(5) Identification of the dispensing pharmacist and other authorized personnel responsible for preparing the sterile pharmaceutical.
(6) Other drug therapy information, if applicable.
(7) Known or suspected drug sensitivities and allergies of the patient to drugs and foods, if applicable.
(8) Primary diagnosis and chronic conditions if the sterile pharmaceutical is administered outside the facility.
(Indiana Board of Pharmacy; 856 IAC 1-30-12; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1019, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-13 Labeling
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 13. (a) Each sterile pharmaceutical product dispensed to a patient shall be labeled with the following:
(1) Date of preparation by the pharmacy.
(2) Patient name and bed number, if an institutionalized patient.
(3) Name of each drug in the preparation, strength, and amount.
(4) Expiration date of the preparation, including time, if applicable.
(5) Identity of the pharmacist compounding and dispensing the sterile pharmaceutical, and identity of other authorized personnel preparing the product, if applicable.
(6) Other information required by the dispensing pharmacy regarding storage requirements or special warnings.
(b) In addition, if the patient residing at home or outside the facility where the sterile pharmaceutical is prepared, the following labeling requirements apply:
(1) Identifying prescription number.
(2) Prescriber's full name.
(3) Name, address, and telephone number of the licensed pharmacy.
(4) Directions for use shall be provided, either on the label or by other written instructions, including infusion rate and date and time of administration.
(Indiana Board of Pharmacy; 856 IAC 1-30-13; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; errata filed Mar 17, 1992, 10:20 a.m.: 15 IR 1394; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1337)

856 IAC 1-30-14 Records and reports
Authority: IC 25-26-13-4
Affected: IC 25-26-13-15; IC 25-26-13-18

Sec. 14. (a) The qualifying pharmacist shall be responsible for such records and reports as required to ensure the patient's health, safety, and welfare. Such records shall be readily available and maintained for two (2) years from the date of issuance of the prescription or drug order and be subject to inspection by the Indiana board of pharmacy or its designated inspector. These records shall include the following:
(1) Patient profile or medication record system.
(2) Policy and procedure manual.

(3) Training manuals.
(4) Policies and procedures for disposal of hazardous waste, when applicable.

(b) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's record. Release of this information shall be in accordance with IC 25-26-13-15.

(c) If appropriate, the qualifying pharmacist must document the patient's training and competency in managing this type of therapy provided by the pharmacist to the patient in the home environment. A pharmacist must be involved in the patient training process in any area that related to drug:
(1) compounding;
(2) labeling;
(3) administration;
(4) storage;
(5) stability;
(6) compatibility; or
(7) disposal.

The pharmacist shall be responsible for seeing that the patient's competency in the areas in subdivisions (1) through (7) is reassessed at appropriate intervals. *(Indiana Board of Pharmacy; 856 IAC 1-30-14; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)*

856 IAC 1-30-15 Disposal of infectious waste
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 15. The qualifying pharmacist is responsible for assuring that there is a system for the disposal of infectious waste returned from outside the facility in a manner consistent with the protection of the public's health and safety and in compliance with applicable state and federal law. *(Indiana Board of Pharmacy; 856 IAC 1-30-15; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)*

856 IAC 1-30-16 Emergency kit
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 16. When sterile pharmaceuticals are provided to home care patients, the dispensing pharmacy may supply the nurse with emergency drugs, if the treating physician has authorized the use of such drugs by a protocol, for use in an emergency situation, e.g., anaphylactic shock. *(Indiana Board of Pharmacy; 856 IAC 1-30-16; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-30-17 Hazardous drugs
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 17. In addition to the minimum requirements for a pharmacy established by rules of the board, the following requirements are necessary to ensure the protection of the personnel involved in those licensed pharmacies that prepare hazardous drugs:
(1) All hazardous drugs shall be compounded in a Class II, biological safety cabinet. If this cabinet is not dedicated solely to the compounding of hazardous drugs, policies and procedures must be in place for the cleaning and decontaminating this biological safety cabinet.
(2) Protective apparel shall be worn by personnel compounding hazardous drugs. This shall include disposable gloves and gowns with tight cuffs.
(3) Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.
(4) Procedures for disposal of hazardous waste shall be specified within the policy and procedure manual as required by section 7 of this rule and comply with all applicable local, state, and federal requirements.
(5) Written procedures for handling both major and minor spills of hazardous agents must be developed and included in the policy and procedure manual.
(6) Prepared doses of hazardous drugs shall be dispensed and labeled with proper precautions inside and outside and shipped in a manner designed to minimize the risk of accidental rupture of the primary container.
(Indiana Board of Pharmacy; 856 IAC 1-30-17; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1020, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-30-18 Quality assurance
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 18. (a) The designated qualifying pharmacist shall conduct a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. Samples of finished products shall be examined, or other continuous monitoring methods shall be used to assure that the pharmacy is capable of consistently preparing sterile pharmaceuticals meeting specifications in accordance with good compounding practices and the current USP/NF Chapter on sterile preparation. Quality assurance procedures shall include the following:
(1) Recall procedures for compounded sterile pharmaceuticals.
(2) Storage and dating for compounded sterile pharmaceuticals.
(3) Sterile procedures, including the following:
(A) Monitoring the temperature of the refrigerator.
(B) Routine maintenance.
(C) Report of laminar flow hood certification.
(4) Written documentation of periodic hood cleaning.

(b) All biological safety cabinets and Class 100 environments shall be certified by an independent contractor or facility specialist as meeting Federal Standard 209B or National Sanitation Foundation Standard 49, as referenced in section 2 of this rule, for operational efficiency. Such certification shall be performed every six (6) months. Records documenting certification, which at a minimum includes laminar air flow velocity and particle count, shall be maintained for a period of not less than two (2) years.

(c) Prefilters for the clean air source shall be replaced or cleaned as applicable on a regular basis and the replacement or cleaning date documented.

(d) A vertical flow Class II biological safety cabinet may be used to compound any sterile pharmaceutical product; however, ~~it~~ the cabinet must be thoroughly cleaned between each use for hazardous and nonhazardous drug compounding.

(e) If manufacturing of parenteral solutions is performed utilizing nonsterile chemicals, extensive end product testing, as referenced in Remington's Pharmaceutical Sciences, published by Mack Publishing Company, Easton, Pennsylvania 18042, or other
Federal Drug Administration approved testing methods, must be documented prior to the release of the product from quarantine. This process must include appropriate tests for particulate matter, microbial contamination, and testing for pyrogens. This does not preclude the extemporaneous compounding of certain sterile pharmaceuticals.

(f) There shall be
(1) written justification of the chosen expiration dates for compounded parenteral products documented in the policy and procedure manual; and
(2) documentation of quality assurance audits at planned intervals, including infection control and sterile technique audits.
(Indiana Board of Pharmacy; 856 IAC 1-30-18; filed Jan 28, 1992, 5:00 p.m.: 15 IR 1021, eff Jan 1, 1992 [IC 4-22-2-36 suspends the effectiveness of a rule document for thirty (30) days after filing with the secretary of state. LSA Document #91-6 was filed Jan 28, 1992.]; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1338)

Rule 31. Facsimile Machines

856 IAC 1-31-1 "Facsimile machine" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 1. As used in this rule, "facsimile machine" means a machine that electronically transmits exact images through connection with a telephone network. *(Indiana Board of Pharmacy; 856 IAC 1-31-1; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-31-2 Use of a facsimile machine to electronically transmit a prescription or drug order
Authority: IC 25-26-13-4
Affected: IC 25-1-9; IC 25-26-13

Sec. 2. Prescription or drug orders for legend drugs may be transmitted by facsimile machine from an authorized prescribing practitioner to a pharmacy under the following restrictions:
(1) The original prescription or order transmitted by facsimile machine contains:
(A) all information required under IC 25-26-13-2;
(B) the name and address of the pharmacy to which the prescription or drug order is being transmitted; and
(C) the name of the person transmitting the prescription or drug order.
(2) A statement that the prescription is valid only if transmitted by facsimile machine is included on the face of the original prescription or drug order.
(3) Actual transmission is done by or under the direct supervision of the authorized prescribing practitioner or by an authorized agent.
(4) A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's authorized agent to a pharmacy via facsimile equipment, provided the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subdivision (5) or (6).
(5) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance to be compounded for the direct administration to a patient in a private residence, long term care facility, or hospice setting by means of parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent by facsimile. The facsimile serves as the original written prescription, and it shall be maintained in accordance with IC 25-26-13-25.

(6) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II substance for a resident of a long term care facility licensed under 410 IAC 16.2-3.1 may be transmitted by the practitioner or the practitioner's authorized agent to the dispensing pharmacy by facsimile. The facsimile serves as the original written prescription for the purpose of this subdivision, and it shall be maintained in accordance with IC 25-26-13-25.
(7) A prescription prepared in accordance with 856 IAC 2-6-4 written for a Schedule II narcotic substance for a patient enrolled in a hospice program, inpatient or outpatient, certified by Medicare under Title XVIII or licensed by Indiana may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this subdivision and maintained in accordance with IC 25-26-13-25.
(8) A controlled substance prescription or drug order for a Schedule III, IV, or V controlled substance may be sent by facsimile machine and must be sent by the prescribing practitioner or an authorized agent.
(9) A facsimile machine transmitted copy of a prescription or drug order must produce a nonfading copy or be reduced to writing, either manually or via other processes, for example, photocopying, that produces a nonfading document. Proper notation on the file copy shall indicate that the prescription order was initially received via facsimile machine transmission.
(10) The receiving facsimile machine must be located in the prescription department of the pharmacy or in another nonpublic area of the pharmacy to protect patient/pharmacist/authorizing prescribing practitioner confidentiality and security as required by IC 25-26-13-15.
(11) Using facsimile equipment to circumvent documentation, authenticity, verification, or other standards of the profession of pharmacy will be considered professional incompetence under IC 25-1-9.
(Indiana Board of Pharmacy; 856 IAC 1-31-2; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1390; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; filed May 26, 2000, 8:52 a.m.: 23 IR 2502; filed May 10, 2001, 9:22 a.m.: 24 IR 3067; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

Rule 32. Transfer of Prescriptions Between Pharmacies

856 IAC 1-32-1 Applicability of rule
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 1. This rule governs the transfer of prescription information, either originally filled or previously refilled, by one (1) pharmacy to another pharmacy for refills. *(Indiana Board of Pharmacy; 856 IAC 1-32-1; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-2 Noncontrolled and controlled substance prescription transfers
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 2. (a) Prescription information for legend drugs that are not controlled substances may be transferred at any time during the lifetime of the prescription up to one (1) year after the date of the original filling, or when the original number of authorized refills expires, whichever comes first.
(b) Except as limited by the requirement of subsection (a), prescriptions for legend drugs that are not controlled substances may be transferred any number of times.
(c) If any authorized refills remain, prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances may be transferred only once within six (6) months from the date the prescription was issued. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.
(d) Prescriptions for Schedule II controlled substances may not be transferred. *(Indiana Board of Pharmacy; 856 IAC 1-32-2; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-3 Patient's right to transfer prescriptions
Authority: IC 25-26-13-4
Affected: IC 25-26-13-16; IC 25-26-13-25

Sec. 3. A pharmacist may not legally refuse to transfer a patient's prescription or prescription information except when to do so would be against the professional judgment of the pharmacist in the manner provided for under IC 25-26-13-16. *(Indiana Board of Pharmacy; 856 IAC 1-32-3; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)*

856 IAC 1-32-4 Pharmacists' responsibilities
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 4. Transfer of prescription information under this rule must meet the following requirements:
(1) The transfer is communicated directly between two (2) licensed pharmacists or by suitable electronic device approved by the Indiana board of pharmacy, and the transferring pharmacist records the following information:
(A) Write the word "VOID" on the face of the invalidated prescription.
(B) Record on the reverse of the invalidated prescription, the name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription.

(C) Record the date of the transfer and the name of the pharmacist transferring the information.
(2) The pharmacist receiving the transferred prescription shall reduce to writing the following:
(A) Write the word "TRANSFER" on the face of the transferred prescription.
(B) Provide all information required to be on a prescription and include the following:
(i) Date of issuance of original prescription.
(ii) Original number of refills authorized on original prescriptions.
(iii) Date of original dispensing.
(iv) Number of valid refills remaining and date of last refill, and, in the event the transfer is for the second or subsequent transfer of a substance that is a Schedule III, Schedule IV, or Schedule V controlled substance, the date and location of the previous refill.
(v) Pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred.
(vi) Name of the transferor pharmacist.
(C) Both the original and transferred prescription must be maintained as required under IC 25-26-13-25.
(3) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.
(Indiana Board of Pharmacy; 856 IAC 1-32-4; filed Jun 8, 1992, 5:00 p.m.: 15 IR 2248; errata filed Jul 10, 1992, 9:00 a.m.: 15 IR 2465; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1339)

Rule 33. Counseling

856 IAC 1-33-1 Definitions
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 1. The following definitions apply throughout this rule:
(1) "Counseling" means appropriate communication, by a pharmacist, to a patient, as defined in subdivision (3), of information for the purpose of improving therapeutic outcomes by maximizing the proper use of drugs and devices dispensed pursuant to prescriptions.
(2) "Offer" means a statement that is verbal or, only if necessary for an individual patient, nonverbal, for example, printed or written, that clearly informs the patient that a pharmacist is available, at the time the offer is made, to counsel the patient, including, but not limited to, giving information to or answering questions, or both, from the patient.
(3) "Patient" means the following:
(A) The individual for whom a prescription was issued.
(B) The caregiver of the individual for whom a prescription was issued.
(C) The agent of the individual for whom a prescription was issued.
(Indiana Board of Pharmacy; 856 IAC 1-33-1; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330;)

856 IAC 1-33-1.5 Offer requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-10

Sec. 1.5. (a) The following can satisfy an offer:
(1) A pharmacist counseling the patient.
(2) A pharmacist intern/extern registered under IC 25-26-13-10 if:
(A) permitted by the pharmacist; and
(B) the counseling by the pharmacist intern/extern is followed by a bona fide offer for the pharmacist to counsel the patient and if the patient or patient's representative desires such counseling.
(3) A written notice containing the pharmacy's phone number and a bona fide offer when:
(A) a patient is not present and has not authorized the giving of information to another; or
(B) the drug or device is delivered by the United States Postal Service, parcel delivery, or hand delivery.
(4) Any personnel in the prescription department, as defined in 856 IAC 1-13-3(b)(3), making an offer to counsel, as defined in section 1(2) of this rule.
(b) The following cannot satisfy an offer:
(1) Making an offer for the patient to ask questions.
(2) Any other method that serves to shift the responsibility from the pharmacists to the patient for initiating the counseling or for selecting the informational content of the counseling.
(3) Relaying information through an intermediary, unless needed for translations, hearing impaired, or other situation beyond the control of the pharmacist.
(4) Using signs or other types of written notices or written information given to the patient with each drug dispensed.
(Indiana Board of Pharmacy; 856 IAC 1-33-1.5)

856 IAC 1-33-2 Patient counseling requirements
Authority: IC 25-26-13-4

Affected: IC 25-26-13-16

Sec. 2. (a) Upon the receipt of a prescription or upon the subsequent refilling of a prescription, and following a review of the patient's prescription medication profile, the pharmacist shall be responsible for the initiation of an offer, as set forth in section 1.5(a) of this rule, to counsel the patient on matters that, in the pharmacist's professional judgment, are significant to optimizing drug therapy. Depending upon the situation, these matters may include, but are not necessarily limited to, the following:

(1) The name and description of the medicine.
(2) The route, dosage form, dosage, route of administration, and duration of drug therapy.
(3) Special directions and precautions.
(4) Common adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance and the action required if they occur.
(5) Techniques for self-monitoring drug therapy.
(6) Proper storage.
(7) Prescription refill information.
(8) Action to be taken in the event of a missed dose.

(b) Counseling shall be in person, whenever practicable, or through access to a telephone service that is toll-free for long distance calls and be held with the patient, the patient's caregiver, or the patient's representative.

(c) Alternative forms of patient information may be used to supplement verbal counseling when appropriate. Examples include written information leaflets, pictogram labels, and video programs. Nothing in this subsection shall be construed to mean that supplements may be a substitute for verbal counseling when verbal counseling is practicable.

(d) Nothing in this rule shall be construed as requiring a pharmacist to provide counseling when a patient knowingly declines (waives) the offer to counsel.

(e) Requesting or accepting, or both, a waiver for counseling for all prescriptions both present and future is not permitted. An offer must be made with each prescription-dispensing visit.

(f) The patient's declining of counseling must be documented in either written or electronic format. The required documentation may be on the same form as or with another pharmacy-related authorization, only if it is clear to the patient that the documentation form also contains the patient's intent to decline (waive) counseling. The documentation subject to this section shall be retained in the pharmacy licensed area or in a secure area under the pharmacy's control, which is readily available for inspection, for a period of not less than two (2) years. *(Indiana Board of Pharmacy; 856 IAC 1-33-2; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-33-3 Patient profile requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13-25

Sec. 3. The pharmacist shall assure that prescription medication profiles are maintained for all patients receiving pharmaceutical care at that pharmacy. Within limits of reasonably available information, the pharmacy medication profile shall include the following:

(1) Name, address, telephone number, age or date of birth, and gender.
(2) Known drug allergies and adverse reactions.
(3) A list of current medications and relevant devices, either of which may relate to the patient's drug therapy.
(4) Known disease states.
(5) Any other information that, in the pharmacist's professional judgment, the pharmacist deems appropriate.
(6) Pharmacist's comments relevant to the individual's drug therapy.

(Indiana Board of Pharmacy; 856 IAC 1-33-3; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1176; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-33-4 Institutional patient exception
Authority: IC 25-26-13-4
Affected: IC 25-1-9

Sec. 4. The requirements for patient counseling, as described in this rule, shall not apply to patients residing in institutional facilities in Indiana as defined under 856 IAC 1-28.1-1(6). *(Indiana Board of Pharmacy; 856 IAC 1-33-4; filed Dec 1, 1992, 5:00 p.m.: 16 IR 1177; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-33-5 Patient counseling violations
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 5. Violation of this rule shall be grounds for discipline by the board under either IC 25-1-9 or 856 IAC 1-20. *(Indiana Board of Pharmacy; 856 IAC 1-33-5)*

Rule 34. Security Features for Prescriptions

856 IAC 1-34-1 Applicability

Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 1. This rule establishes minimum standards for security features for prescriptions issued by practitioners as described in IC 16-42-19-5. Practitioners licensed in Indiana must comply with this rule in order for their prescriptions to be accepted for filling in licensed Indiana pharmacies. *(Indiana Board of Pharmacy; 856 IAC 1-34-1; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-2 Security feature requirements
Authority: IC 35-48-7-8
Affected: IC 16-42-19-5

Sec. 2. (a) All controlled substance prescriptions written by licensed Indiana practitioners, as defined by IC 16-42-19-5, must contain the following security features:
(1) A latent, repetitive "void" pattern screened at five percent (5%) in reflex blue must appear across the entire face of the document when the prescription is photocopied.
(2) There shall be a custom artificial watermark printed on the back side of the base paper so that it may only be seen at a forty-five (45) degree angle. The watermark shall consist of the words "Indiana Security Prescription", appearing horizontally in a step-and-repeated format in five (5) lines on the back of the document using 12-point Helvetica bold type style.
(3) An opaque RX symbol must appear in the upper right-hand corner, one-eighth (_) of an inch from the top of the pad and five-sixteenths ($^5/_{16}$) of an inch from the right side of the pad. The symbol must be three-fourths (¾) inch in size and must disappear if the prescription copy is lightened.
(4) Six (6) quantity check-off boxes must be printed on the form and the following quantities must appear and the appropriate box be checked off for the prescription to be valid:
(A) 1–24
(B) 25–49
(C) 50–74
(D) 75–100
(E) 101–150
(F) 151 and over.
(5) No advertisements may appear on the front or back of the prescription blank.
(6) Logos, defined as a symbol utilized by an individual, professional practice, professional association, or hospital, may appear on the prescription blank. The upper left one (1) inch square of the prescription blank is reserved for the purpose of logos. Only logos, as defined by this subdivision, may appear on the prescription blank.
(7) Only one (1) prescription may be written per prescription blank. The following statement must be printed on the bottom of the pad: "Prescription is void if more than one (1) prescription is written per blank.".
(8) Refill options that can be circled by the prescriber must appear below any logos and above the signature lines on the left side of the prescription blank in the following order:
Refill NR 1 2 3 4 5 Void after_____.
(9) Practitioner name and state issued professional license number must be preprinted, stamped, or manually printed on the prescription.
(10) All prescription blanks printed under this rule shall be four and one-fourth (4¼) inches high and five and one-half (5½) inches wide.
(b) Nothing in this rule shall prevent licensed Indiana practitioners from utilizing security paper prescriptions for the prescribing of any legend drug. *(Indiana Board of Pharmacy; 856 IAC 1-34-2; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2782, eff Jan 1, 1996; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-34-3 Preprinted controlled substance prohibition
Authority: IC 35-48-7-8
Affected: IC 35-48-2; IC 35-48-7

Sec. 3. The name of any controlled substance, as defined by IC 35-48-2, may not be preprinted on any prescription forms at any time before the prescription is being prepared and executed for presentation to the patient or the patient's agent. That includes, but is not limited to, such activities as typing prescriptions in anticipation of their need, and using a rubber stamp or other similar means which would accomplish the same end. Commercially printed forms containing names of controlled substances are also prohibited. *(Indiana Board of Pharmacy; 856 IAC 1-34-3; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-4 Exemption
Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 4. Prescriptions utilized by pharmacists to record call-in prescriptions, transferred prescriptions, or facsimile prescriptions do not need to comply with this rule. *(Indiana Board of Pharmacy; 856 IAC 1-34-4; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-34-5 Approval
Authority: IC 35-48-7-8
Affected: IC 35-48-7

Sec. 5. Printers wishing to supply prescription blanks to authorized recipients must obtain a template design from the board to use as a layout guide. Printers must also submit a preprint proof to the board for approval prior to any production of prescription blanks governed by this rule. *(Indiana Board of Pharmacy; 856 IAC 1-34-5; filed Jul 5, 1995, 9:45 a.m.: 18 IR 2783, eff Jan 1, 1996; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 35. Pharmacy Technicians

856 IAC 1-35-1 Purpose and scope
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) The board is responsible for establishing standards for the competent practice of pharmacy.

(b) The use of pharmacy technicians to assist the pharmacist with nondiscretionary functions associated with the practice of pharmacy enables the pharmacist to provide pharmaceutical care to the patient.

(c) Evolved pharmacy practice demands additional time for pharmacists to counsel individual patients regarding the proper use of drugs.

(d) Only pharmacists (licensed under IC 25-26-13-11), pharmacy interns and externs (as defined in IC 25-26-13-2 and registered under IC 25-26-13-10), and pharmacy technicians as described in this section shall be permitted to participate in the activities associated with a drug order or prescription preparation.

(e) A pharmacist shall not permit a pharmacy technician to participate in the activities associated with a drug order or prescription preparation unless the pharmacy technician meets the qualifications of this section.

(f) The pharmacist is responsible for the work performed by the pharmacy technician under the pharmacist's supervision. *(Indiana Board of Pharmacy; 856 IAC 1-35-1; filed Aug 17, 1995, 8:30 a.m.: 19 IR 39; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1561)*

856 IAC 1-35-2 "Unlicensed person" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 2. (a) As used in this rule, "unlicensed person" means a pharmacy technician who, under the immediate and direct supervision of the pharmacist, assists the pharmacist in the technical and nonjudgmental functions related to the practice of pharmacy in the processing of prescriptions and drug orders.

(b) As used in subsection (a), "pharmacy technician" shall not include pharmacy intern/externs or other ancillary persons which include, but are not limited to:

(1) clerks;
(2) secretaries;
(3) cashiers; or
(4) delivery persons;

who may be present in the pharmacy. *(Indiana Board of Pharmacy; 856 IAC 1-35-2; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-35-3 "Pharmaceutical care" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. As used in this rule, "pharmaceutical care" means the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. *(Indiana Board of Pharmacy; 856 IAC 1-35-3; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-35-4 Qualifications
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. To be eligible to perform the functions and duties of a pharmacy technician, an individual must possess the following qualifications, which shall be ascertained and documented in a reasonably retrievable manner by the pharmacist that qualifies the pharmacy permit:

(1) The individual has not been convicted of a crime that has a direct bearing on the individual's ability to work with legend drugs or controlled substances.

(2) The individual must be a high school graduate or have successfully completed a General Education Development program or have been judged to be competent by the qualifying pharmacist.

(3) The individual must have successfully completed or be enrolled in and successfully complete within twelve (12) months of being hired as a technician one (1) of the following board-approved programs:
(A) A comprehensive curricular-based education and training program conducted by a pharmacy or educational organization.
(B) A technician training program utilized by the employer that includes specific training in the duties required to assist the pharmacist in the technical functions associated with the practice of pharmacy. The contents of the training program shall include, at a minimum, the following:
(i) Understanding of the duties and responsibilities of the technician and the pharmacist, including the standards of patient confidentiality and ethics governing pharmacy practice.
(ii) Tasks and technical skills, policies, and procedures related to the technician's position.
(iii) Working knowledge of pharmaceutical-medical terminology, abbreviations, and symbols commonly used in prescriptions and drug orders.
(iv) Working knowledge of the general storage, packaging, and labeling requirements of drugs, prescriptions, or drug orders.
(v) Ability to perform the arithmetic calculations required for the usual dosage determinations.
(vi) Working knowledge and understanding of the essential functions related to drug purchasing and inventory control.
(vii) The record keeping functions associated with prescriptions or drug orders.
(4) In lieu of the requirements in subdivision (3), the successful completion of a board-approved certification examination may satisfy the requirements of this section.
(5) A record of the pharmacy technician training and education must be maintained in the pharmacy where the technician is employed and shall include the following:
(A) The name of the pharmacy technician.
(B) The starting date of employment as a pharmacy technician.
(C) The starting date of the technician training program.
(D) The date of completion of the training program or proof of passing the board-approved examination if subdivision (4) applies.
(E) A copy of the training manual, if on-the-job training is used by the employer, or certificate of successful completion of another approved program, or other training program completed prior to employment.
(Indiana Board of Pharmacy; 856 IAC 1-35-4; filed Aug 17, 1995, 8:30 a.m.: 19 IR 40; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1562)

856 IAC 1-35-5 Duties that a pharmacy technician may not perform
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18
Sec. 5. A pharmacy technician may perform many technical functions associated with the practice of pharmacy. However, even under the immediate and direct supervision of a pharmacist, the pharmacy technician is prohibited from performing the following functions:
(1) Any duty required by law, regulation, or rule to be performed by a pharmacist.
(2) The provision of advice or consultation with the prescriber or other licensed health care provider regarding the patient or the interpretation and application of information contained in the prescription or drug order, medical record, or patient profile.
(3) The provision of advice or consultation with the patient regarding the interpretation of the prescription or the application of information contained in the patient profile or medical record.
(4) Dispensing of prescription drug information to the patient as required in IC 25-26-13-4.
(5) Receipt of a verbal prescription, other than a refill approval or denial, from a prescriber.
(6) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including, but not limited to, accuracy of the:
(A) drug;
(B) strength; and
(C) labeling.
(Indiana Board of Pharmacy; 856 IAC 1-35-5; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-35-6 Provision of quality assurance; duties *(Repealed)*

Sec. 6. *(Repealed by Indiana Board of Pharmacy; filed Dec 20, 2002, 12:17 p.m.: 26 IR 1562)*

856 IAC 1-35-7 Identification
Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 7. (a) The public shall be able to identify a pharmacist from a pharmacy technician while engaged in the provision of pharmaceutical care.
(b) A pharmacy technician shall:
(1) wear identification clearly stating that the person is a pharmacy technician while on duty; and
(2) identify himself or herself verbally in any telephonic or electronic communication as a pharmacy technician.
(c) No person, other than a person who has met the qualifications established in section 4 of this rule, will be permitted to wear identification using the words "pharmacy technician" or similar wording that may confuse or deceive another person. *(Indiana Board of Pharmacy; 856 IAC 1-35-7; filed Aug 17, 1995, 8:30 a.m.: 19 IR 41; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 36. Temporary Variances

856 IAC 1-36-1 Exceptions
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. A person subject to the regulations of the board may request that the board grant a temporary variance from any rule adopted by the board, except rules concerning examinations, experience hours, and requirements for licensure. *(Indiana Board of Pharmacy; 856 IAC 1-36-1; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-2 Submission of a request for temporary variance
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 2. A request for a temporary variance must be submitted to the board in writing. Each request must contain the following information:
(1) The name, address, and license or permit number of the applicant.
(2) The name of the responsible pharmacist and the specific location at which activities will be conducted under the temporary variance.
(3) The citation to the specific rule from which the applicant seeks a temporary variance.
(4) A detailed explanation of the purpose of the temporary variance.
(5) An assessment of the impact on the public if the variance is granted.
(6) A statement of the conditions which would cause the applicant to apply for renewal of the temporary variance.
(7) The beginning, midpoint, and ending dates of the proposed demonstration project.
(Indiana Board of Pharmacy; 856 IAC 1-36-2; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4534; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)

856 IAC 1-36-3 Positive impact on delivery of pharmaceutical care
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. Temporary variances shall only be granted for demonstration projects which are expected to have a positive impact on the delivery of pharmaceutical care. Justification for that expectation shall be fully explained. The board shall not grant any temporary variance which threatens public health, safety, or welfare. *(Indiana Board of Pharmacy; 856 IAC 1-36-3; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-4 Period of time
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. The board shall grant a temporary variance for a period of no more than six (6) months. Any person who receives a temporary variance shall submit to the board a written report of the effects of the demonstration project at the midpoint and at the conclusion of the temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-4; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-5 Renewal
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. A temporary variance may be renewed by the Indiana board of pharmacy (board) for an additional six (6) months. A temporary variance shall not be renewed more than five (5) times. Requests for renewal of a variance shall be submitted in writing to the board not less than thirty (30) days prior to the expiration of the variance and shall contain at least the information required by section 2 of this rule. *(Indiana Board of Pharmacy; 856 IAC 1-36-5; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Dec 2, 2001, 12:35 p.m.: 25 IR 1340)*

856 IAC 1-36-6 Revocation
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. The board may revoke any temporary variance for cause, including, but not limited to, a finding that the temporary variance poses or may pose a threat to public health, safety, or welfare. The person requesting the temporary variance has the obligation to report any such potential threat to the board immediately upon the discovery of such potential threat, or as soon as possible after such discovery. *(Indiana Board of Pharmacy; 856 IAC 1-36-6; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-7 Public notice

Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. The board shall give public notice of requests for temporary variances at not less than two (2) consecutive regular meetings before voting to grant or deny a request for a temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-7; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-8 Justification of denial
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. The board shall set forth in writing its reasons for granting or denying a temporary variance. *(Indiana Board of Pharmacy; 856 IAC 1-36-8; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

856 IAC 1-36-9 Copies of requests
Authority: IC 25-26-13-4
Affected: IC 25-26-13-5

Sec. 9. The executive director shall retain copies of all requests for temporary variances and the board's reasons for granting or denying requests as part of the record of it proceedings maintained under IC 25-26-13-5. *(Indiana Board of Pharmacy; 856 IAC 1-36-9; filed Jul 23, 1998, 4:43 p.m.: 21 IR 4535; readopted filed Nov 13, 2001, 3:55 p.m.: 25 IR 1330)*

Rule 37. Centralized Processing of Prescription Drug Orders

856 IAC 1-37-1 "Centralized prescription drug order processing" defined
Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 1. "Centralized prescription drug order processing" means the processing by a pharmacy of a request from another pharmacy to do the following:
(1) Fill or refill a prescription drug order.
(2) Perform processing functions, including the following:
(A) Dispensing.
(B) Drug utilization review.
(C) Claims adjudication.
(D) Refill authorizations.
(E) Therapeutic interventions.
(Indiana Board of Pharmacy; 856 IAC 1-37-1)

856 IAC 1-37-2 Centralized prescription processing
Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 2. A pharmacy, licensed or registered by the board, may perform or outsource centralized prescription processing services provided the parties have:
(1) the same owner; or
(2) a written contract outlining the:
(A) services to be provided; and
(B) responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;
and share a common electronic file or have appropriate technology to allow access to sufficient information necessary or required to fill or refill a prescription drug order. *(Indiana Board of Pharmacy; 856 IAC 1-37-2)*

856 IAC 1-37-3 Policy and procedures manual
Authority: IC 25-26-13-4
Affected: IC 25-26

Sec. 3. The parties performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual and documentation that implementation is occurring in a manner that shall be made available to the board for review, upon request, and that includes, but it is not limited to, the following:
(1) A description of how the parties will comply with federal and state laws and regulations.
(2) The maintenance of the following:

(A) Appropriate records to identify the responsible pharmacist or pharmacists in the dispensing and counseling processes.
(B) A mechanism for tracking the prescription drug order during each step in the dispensing process.
(C) A mechanism to identify on the prescription label all pharmacies involved in dispensing the prescription drug order.
(3)The provision of adequate security to:
(A) protect the product integrity; and
(B) prevent the illegal use or disclosure of protected health information.
(4)The maintenance of a continuous quality improvement program for centralized prescription processing pharmacy services.
(Indiana Board of Pharmacy; 856 IAC 1-37-3)

Rule 38. Credit for Returned Expired Drugs

856 IAC 1-38-1 Applicability
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 1. (a) This rule establishes the standards and procedures concerning the return of expired legend drugs by an individual or entity licensed to receive legend drugs to either of the following:
(1) A drug manufacturer.
(2) A designated agent of a drug manufacturer.
(b) This rule does not apply to the following:
(1) Vaccines that prevent influenza.
(2) Medicine used for the treatment of malignant hyperthermia.
(3) Other legend drugs as determined by the board.
(Indiana Board of Pharmacy; 856 IAC 1-38-1)

856 IAC 1-38-2 "Board" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 2. As used in this rule, "board" has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-38-2)*

856 IAC 1-38-3 "Designated agent" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. As used in this rule, "designated agent" means an individual or entity that contracts with a drug manufacturer to administer the manufacturer's drug return policy for expired legend drugs. *(Indiana Board of Pharmacy; 856 IAC 1-38-3)*

856 IAC 1-38-4 Application of return of expired drugs
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 4. Effective with all drug orders placed after December 31, 2005, all drug manufacturers or their designated agents shall make adequate provisions for the return of expired legend drugs. *(Indiana Board of Pharmacy; 856 IAC 1-38-4)*

856 IAC 1-38-5 Record keeping
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 5. Drug manufacturers or their designated agents shall do the following:
(1) Maintain records of all credits made under this rule for a period of two (2) years.
(2) Make the records available to the board or its agent upon request.
(Indiana Board of Pharmacy; 856 IAC 1-38-5)

856 IAC 1-38-6 Compliance with other relevant law
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. The return of expired legend drugs under this rule shall also be consistent with all other applicable federal, state, and local laws and regulations. *(Indiana Board of Pharmacy; 856 IAC 1-38-6)*

Rule 39. Home Medical Equipment Service Providers

856 IAC 1-39-1 "Board" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21-1

Sec. 1. As used in this rule, "board" has the meaning set forth in IC 25-26-21-1. *(Indiana Board of Pharmacy; 856 IAC 1-39-1)*

856 IAC 1-39-2 "DMEPOS" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 2. As used in this rule, "DMEPOS" means durable medical equipment, prosthetics, orthotics, and supplies. *(Indiana Board of Pharmacy; 856 IAC 1-39-2)*

856 IAC 1-39-3 "Home medical equipment" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21-2

Sec. 3. As used in this rule, "home medical equipment" has the meaning set forth in IC 25-26-21-2. The term also includes the following:
(1) Continuous passive motion (CPM) machines.
(2) Patient lift devices.
(3) Defibrillators.
(4) Manual wheelchairs.
(5) Hospital bed accessories.
(6) Electronically controlled or computerized wheel chairs and seating systems that are sold.
(Indiana Board of Pharmacy; 856 IAC 1-39-3)

856 IAC 1-39-4 "Home medical equipment services" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21-3

Sec. 4. As used in this rule, "home medical equipment services" has the meaning set forth in IC 25-26-21-3. *(Indiana Board of Pharmacy; 856 IAC 1-39-4)*

856 IAC 1-39-5 "Licensee" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 5. As used in this rule, "licensee" means the holder of a home medical equipment service provider license issued under IC 25-26-21 and this title. *(Indiana Board of Pharmacy; 856 IAC 1-39-5)*

856 IAC 1-39-6 "Provider" defined
Authority: IC 25-26-21-7
Affected: IC 25-26-21-4

Sec. 6. As used in this rule, "provider" has the meaning set forth in IC 25-26-21-4. *(Indiana Board of Pharmacy; 856 IAC 1-39-6)*

856 IAC 1-39-7 Fees
Authority: IC 25-1-8-2; IC 25-26-21-7
Affected: IC 25-26-21

Sec. 7. (a) The fee for an original licensure application shall be:
(1) one hundred fifty dollars ($150); and
(2) paid at the time of filing the initial application.

(b) The fee for a biennial renewal shall be:
(1) two hundred dollars ($200); and
(2) paid at the time of license renewal.
(Indiana Board of Pharmacy; 856 IAC 1-39-7)

856 IAC 1-39-8 Renewal
Authority: IC 25-1-8-2; IC 25-26-21-7
Affected: IC 25-26-21

Sec. 8. Home medical equipment service provider licenses shall expire on December 31 of each odd-numbered year. *(Indiana Board of Pharmacy; 856 IAC 1-39-8)*

856 IAC 1-39-9 Proof of insurance
Authority: IC 25-1-8-2; IC 25-26-21-7
Affected: IC 25-26-21

Sec. 9. Before being issued a license, each home medical equipment service provider shall obtain and maintain comprehensive business and liability insurance, consistent with minimum Medicare DMEPOS Supplier Standards. *(Indiana Board of Pharmacy; 856 IAC 1-39-9)*

856 IAC 1-39-10 Oxygen and related respiratory services
Authority: IC 25-26-21-7
Affected: IC 25-26-21; IC 25-34.5

Sec. 10. In order to provide oxygen and related respiratory services, each licensee shall employ or contract with:
(1) a respiratory care practitioner licensed under IC 25-34.5; or
(2) another duly licensed health professional with education and training in oxygen and related respiratory services.
(Indiana Board of Pharmacy; 856 IAC 1-39-10)

856 IAC 1-39-11 Training
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 11. (a) Each licensee shall conduct and document training for each employee:
(1) at the time of hire; and
(2) annually.
(b) Documentation of training shall be readily available for inspection.
(c) Training programs:
(1) shall be conducted according to industry standards; and
(2) may be subject to board approval.
(Indiana Board of Pharmacy; 856 IAC 1-39-11)

856 IAC 1-39-12 Patient records
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 12. Each licensee shall maintain patient records, relevant to services rendered, in accordance with state and federal guidelines. *(Indiana Board of Pharmacy; 856 IAC 1-39-12)*

856 IAC 1-39-13 Equipment maintenance
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 13. Each licensee shall maintain documentation of the maintenance of equipment according to industry standards. *(Indiana Board of Pharmacy; 856 IAC 1-39-13)*

856 IAC 1-39-14 Personnel policies and procedures
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 14. Each licensee shall maintain employee personnel records and policies consistent with the following:
(1) The scope of services provided.
(2) State and federal requirements.
(Indiana Board of Pharmacy; 856 IAC 1-39-14)

856 IAC 1-39-15 Safety and quality of home medical equipment services
Authority: IC 25-26-21-7

Affected: IC 25-26-21

Sec. 15. Each licensee shall:
(1) clean;
(2) repair;
(3) store;
(4) segregate; and
(5) identify;
all equipment in a manner that makes the equipment safe for use by the public according to industry standards. *(Indiana Board of Pharmacy; 856 IAC 1-39-15)*

856 IAC 1-39-16 Licenses
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 16. Each licensee shall ensure that each employee is appropriately licensed or credentialed, or both, for the services provided. *(Indiana Board of Pharmacy; 856 IAC 1-39-16)*

856 IAC 1-39-17 Physical location
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 17. Each licensee shall have a physical location from which home medical equipment services are provided. *(Indiana Board of Pharmacy; 856 IAC 1-39-17)*

856 IAC 1-39-18 Availability of licensee
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 18. Each licensee shall provide twenty-four (24) hours a day, seven (7) days a week availability to their clients consistent with the nature of the services the licensee provides. *(Indiana Board of Pharmacy; 856 IAC 1-39-18)*

856 IAC 1-39-19 Medicare DMEPOS supplier standards
Authority: IC 25-26-21-7
Affected: IC 25-26-21

Sec. 19. The board hereby incorporates by reference the Medicare supplier standards titled Special Payment Rules for Items Furnished by DMEPOS Suppliers and Issuance of DMEPOS Supplier Billing Privileges found at 42 CFR 424.57(c), effective December 11, 2000. *(Indiana Board of Pharmacy; 856 IAC 1-39-19)*

Rule 40. Electronic Prescribing

856 IAC 1-40-1 "Board" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 1. "Board" has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-40-1)*

856 IAC 1-40-2 "Electronically transmitted" or "electronic transmission" defined
Authority: IC 25-26-13-4
Affected: IC 16-18-2-106.4; IC 25-26-13-2

Sec. 3. "Electronically transmitted" or "electronic transmission" has the meaning set forth in IC 16-18-2-106.4 and IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-40-2)*

856 IAC 1-40-3 "Electronic data intermediary" or "EDI" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 3. "Electronic data intermediary" or "EDI" has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-40-3)*

856 IAC 1-40-4 "Practitioner" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 4. "Practitioner" has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-40-4)*

856 IAC 1-40-5 "Prescription" defined
Authority: IC 25-26-13-4
Affected: IC 25-26-13-2

Sec. 5. "Prescription" has the meaning set forth in IC 25-26-13-2. *(Indiana Board of Pharmacy; 856 IAC 1-40-5)*

856 IAC 1-40-6 Equipment
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 6. All electronic equipment for receipt of prescription drug orders communicated by way of electronic transmission shall be maintained so as to ensure against the following:
(1) Unauthorized access.
(2) Changes to the prescription.
(Indiana Pharmacy Board; 856 IAC 1-40-6)

856 IAC 1-40-7 Electronic transmission
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 7. Each electronic data intermediary shall ensure that the prescription electronically transmitted to the pharmacy:
(1) contains:
(A) no alterations to the:
(i) prescription;
(ii) order entry;
(iii) drug selection; or
(iv) intended drug selection;
by any electronic data intermediary;
(B) the exact information the prescription contained when originated by the authorized practitioner; and
(C) unique identifier for the practitioner, such as:
(i) a National Practitioner Identifier (NPI);
(ii) a Drug Enforcement Administration registration number;
(iii) a state issued practitioner license number; or
(iv) another board-approved identifier; and
(2) shall not interfere with the patient's freedom to choose a pharmacy.
(Indiana Board of Pharmacy; 856 IAC 1-40-7)

856 IAC 1-40-8 Electronic data intermediary requirements
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 8. An applicant for approval as an electronic data intermediary shall do the following:
(1) File an application provided by the board.
(2) Submit information regarding how the EDI shall do the following:
(A) Guarantee the security of the following:
(i) The prescription.
(ii) The practitioner's identity and privacy.
(iii) The patient's identity, privacy and confidentiality.
(B) Validate the authorized practitioner's licensure status.
(3) Appear before the board, if requested.
(Indiana Board of Pharmacy; 856 IAC 1-40-8)

856 IAC 1-40-9 Electronic data intermediary standards
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 9. Each electronic data intermediary shall do the following:
(1) Maintain policies and procedures regarding the security of the following:
(A) The prescription.
(B) The practitioner's identity and privacy.
(C) The patient's identity, privacy, and confidentiality.
(2) Validate positive identification of the practitioner.
(Indiana Board of Pharmacy; 856 IAC 1-40-9)

856 IAC 1-40-10 Electronic prescription prohibitions
Authority: IC 25-26-13-4
Affected: IC 25-26-13

Sec. 10. An electronic prescription does not include a prescription that is as follows:
(1) Transmitted via:
(A) electronic mail, without the use of an electronic data intermediary; or
(B) facsimile.
(2) Printed from a computer or electronic device.
(Indiana Board of Pharmacy; 856 IAC 1-40-10)

ARTICLE 48. CONTROLLED SUBSTANCES

IC 35-48-1
Chapter 1. Definitions

IC 35-48-1-1
(Repealed by P.L.5-1988, SEC.208.)

IC 35-48-1-2
Sec. 2. The definitions in this chapter apply throughout this article.
As added by P.L.5-1988, SEC.182.

IC 35-48-1-3
Sec. 3. "Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by:
(1) a practitioner or by his authorized agent; or
(2) the patient or research subject at the direction and in the presence of the practitioner.
As added by P.L.5-1988, SEC.183.

IC 35-48-1-4
Sec. 4. "Advisory committee" refers to the controlled substances advisory committee established under IC 35-48-2-1.
As added by P.L.5-1988, SEC.184.

IC 35-48-1-5
Sec. 5. "Agent" means an authorized person who acts on behalf of, or at the direction of, a manufacturer, distributor, or dispenser, but it does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
As added by P.L.5-1988, SEC.185.

IC 35-48-1-6
Sec. 6. "Board" refers to the Indiana state board of pharmacy.
As added by P.L.5-1988, SEC.186.

IC 35-48-1-7
Sec. 7. "Cocaine" includes coca leaves and any salt, compound, or derivative of coca leaves, and any salt, compound, isomer, derivative, or preparation which is chemically equivalent or identical to any of these substances. However, decocainized coca leaves or extraction of coca leaves that do not contain cocaine or ecgonine are not included.
As added by P.L.5-1988, SEC.187.

IC 35-48-1-8
(*Repealed by P.L.3-1989, SEC.224.)*

IC 35-48-1-9
Sec. 9. "Controlled substance" means a drug, substance, or immediate precursor in schedule I, II, III, IV, or V under:
(1) IC 35-48-2-4, IC 35-48-2-6, IC 35-48-2-8, IC 35-48-2-10, or IC 35-48-2-12, if IC 35-48-2-14 does not apply; or
(2) a rule adopted by the board, if IC 35-48-2-14 applies.
As added by P.L.5-1988, SEC.189.

IC 35-48-1-10
Sec. 10. "Counterfeit substance" means a controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the substance.
As added by P.L.5-1988, SEC.190.

IC 35-48-1-11
Sec. 11. "Delivery" means:
(1) an actual or constructive transfer from one (1) person to another of a controlled substance, whether or not there is an agency relationship; or
(2) the organizing or supervising of an activity described in subdivision (1).
As added by P.L.5-1988, SEC.191. Amended by P.L.165-1990, SEC.1.

IC 35-48-1-12
Sec. 12. "Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner and

includes the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery.
As added by P.L.5-1988, SEC.192.

IC 35-48-1-13
YAMD.1988
Sec. 13. "Dispenser" means a practitioner who dispenses.
As added by P.L.5-1988, SEC.193.

IC 35-48-1-14
Sec. 14. "Distribute" means to deliver other than by administering or dispensing a controlled substance.
As added by P.L.5-1988, SEC.194.

IC 35-48-1-15
Sec. 15. "Distributor" means a person who distributes.
As added by P.L.5-1988, SEC.195.

IC 35-48-1-16
Sec. 16. "Drug" has the meaning set forth in IC 16-42-19-2. It does not include devices or their components, parts, or accessories, nor does it include food.
As added by P.L.5-1988, SEC.196. Amended by P.L.2-1993, SEC.190.

IC 35-48-1-17
Sec. 17. "Immediate precursor" means a substance which the board has found to be and by rule designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediate used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.
As added by P.L.5-1988, SEC.197.

IC 35-48-1-18
Sec. 18. "Manufacture" means:
(1) the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. It does not include the preparation, compounding, packaging, or labeling of a controlled substance:
(A) by a practitioner as an incident to his administering or dispensing of a controlled substance in the course of his professional practice; or
(B) by a practitioner, or by his authorized agent under his supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale; or
(2) the organizing or supervising of an activity described in subdivision (1).
As added by P.L.5-1988, SEC.198. Amended by P.L.165-1990, SEC.2; P.L.17-2001, SEC.18.

IC 35-48-1-19
Sec. 19. "Marijuana" means any part of the plant genus Cannabis whether growing or not; the seeds thereof; the resin extracted from any part of the plant, including hashish and hash oil; any compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant; fiber produced from the stalks; oil or cake made from the seeds of the plant; any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom); or the sterilized seed of the plant which is incapable of germination.
As added by P.L.5-1988, SEC.199.

IC 35-48-1-20
Sec. 20. "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.
(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical to any of the substances referred to in subdivision (1) of this definition, but not including the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
As added by P.L.5-1988, SEC.200.

IC 35-48-1-21
Sec. 21. "Opiate" means a substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under IC 35-48-2, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.
As added by P.L.5-1988, SEC.201.

IC 35-48-1-22
Sec. 22. "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.
As added by P.L.5-1988, SEC.202.

IC 35-48-1-23
Sec. 23. "Poppy straw" means any part, except the seeds, of the opium poppy, after mowing.
As added by P.L.5-1988, SEC.203.

IC 35-48-1-24
Sec. 24. "Practitioner" means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in Indiana.
As added by P.L.5-1988, SEC.204.

IC 35-48-1-25
Sec. 25. "Prescription drug" means a controlled substance or a legend drug (as defined in IC 16-18-2-199).
As added by P.L.5-1988, SEC.205. Amended by P.L.2-1993, SEC.191.

IC 35-48-1-26
Sec. 26. "Production" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.
As added by P.L.5-1988, SEC.206.

IC 35-48-1-27
Sec. 27. "Ultimate user" means a person who lawfully possesses a controlled substance for the person's own use, for the use of a member of the person's household, or for administering to an animal owned by the person or by a member of the person's household.
As added by P.L.5-1988, SEC.207.

IC 35-48-2
Chapter 2. Classification of Drugs

IC 35-48-2-1
Sec. 1. (a) The board shall administer this article and may recommend to the general assembly the addition, deletion, or rescheduling of all substances listed in the schedules in sections 4, 6, 8, 10, and 12 of this chapter by submitting a report of such recommendations to the legislative council. In making a determination regarding a substance, the board shall consider the following:
(1) The actual or relative potential for abuse.
(2) The scientific evidence of its pharmacological effect, if known.
(3) The state of current scientific knowledge regarding the substance.
(4) The history and current pattern of abuse.
(5) The scope, duration, and significance of abuse.
(6) The risk to public health.
(7) The potential of the substance to produce psychic or physiological dependence liability.
(8) Whether the substance is an immediate precursor of a substance already controlled under this article.
(b) After considering the factors enumerated in subsection (a), the board shall make findings and recommendations concerning the control of the substance if it finds the substance has a potential for abuse.
(c) If the board finds that a substance is an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.
(d) If any substance is designated or rescheduled to a more restrictive schedule as a controlled substance under federal law and notice is given to the board, the board shall recommend similar control of the substance under this article in the board's report to the general assembly, unless the board objects to inclusion or rescheduling. In that case, the board shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall publish its findings.
(e) If a substance is rescheduled to a less restrictive schedule or deleted as a controlled substance under federal law, the substance is rescheduled or deleted under this article. If the board objects to inclusion, rescheduling, or deletion of the substance, the board shall notify the chairman of the legislative council not more than thirty (30) days after the federal law is changed and the substance may not be rescheduled or deleted until the conclusion of the next complete session of the general assembly. The notice from the board to the chairman of the legislative council must be published.
(f) There is established a sixteen (16) member controlled substances advisory committee to serve as a consultative and advising body to the board in all matters relating to the classification, reclassification, addition to, or deletion from of all substances classified as controlled substances in schedules I to IV or substances not controlled or yet to come into being. In addition, the advisory committee shall conduct hearings and make recommendations to the board regarding revocations, suspensions, and restrictions of registrations as provided in IC 35-48-3-4. All hearings shall be conducted in accordance with IC 4-21.5-3. The advisory committee shall be made up of:
(1) two (2) physicians licensed under IC 25-22.5, one (1) to be elected by the medical licensing board of Indiana from among its members and one (1) to be appointed by the governor;

(2) two (2) pharmacists, one (1) to be elected by the state board of pharmacy from among its members and one (1) to be appointed by the governor;
(3) two (2) dentists, one (1) to be elected by the state board of dentistry from among its members and one (1) to be appointed by the governor;
(4) the state toxicologist or the designee of the state toxicologist;
(5) two (2) veterinarians, one (1) to be elected by the state board of veterinary medical examiners from among its members and one (1) to be appointed by the governor;
(6) one (1) podiatrist to be elected by the board of podiatric medicine from among its members;
(7) one (1) advanced practice nurse with authority to prescribe legend drugs as provided by IC 25-23-1-19.5 who is:
(A) elected by the state board of nursing from among the board's members; or
(B) if a board member does not meet the requirements under IC 25-23-1-19.5 at the time of the vacancy on the advisory committee, appointed by the governor;
(8) the superintendent of the state police department or the superintendent's designee;
(9) three (3) members appointed by the governor who have demonstrated expertise concerning controlled substances; and
(10) one (1) member appointed by the governor who is a psychiatrist with expertise in child and adolescent psychiatry.
(g) All members of the advisory committee elected by a board shall serve a term of one (1) year and all members of the advisory committee appointed by the governor shall serve a term of four (4) years. Any elected or appointed member of the advisory committee, may be removed for cause by the authority electing or appointing the member. If a vacancy occurs on the advisory committee, the authority electing or appointing the vacating member shall elect or appoint a successor to serve the unexpired term of the vacating member. The board shall acquire the recommendations of the advisory committee pursuant to administration over the controlled substances to be or not to be included in schedules I to V, especially in the implementation of scheduled substances changes as provided in subsection (d).
(h) Authority to control under this section does not extend to distilled spirits, wine, or malt beverages, as those terms are defined or used in IC 7.1, or to tobacco.
(i) The board shall exclude any nonnarcotic substance from a schedule if that substance may, under the Federal Food, Drug, and Cosmetic Act or state law, be sold over the counter without a prescription.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977,
P.L.344, SEC.1; P.L.137-1985, SEC.17; P.L.200-1987, SEC.4; P.L.188-1989, SEC.4; P.L.33-1993, SEC.73; P.L.163-1994, SEC.2; P.L.177-1997, SEC.8; P.L.14-2000, SEC.77.

IC 35-48-2-1.1
(*Repealed by P.L.2-1995, SEC.140.)*

IC 35-48-2-1.5
Sec. 1.5. (a) The advisory committee shall annually elect a chairperson and any other officers that the advisory committee determines necessary from among its members.
(b) Meetings of the advisory committee may be called by:
(1) the advisory committee chairperson; or
(2) a majority of the members of the advisory committee.
(c) Seven (7) members of the committee constitute a quorum.
(d) Notwithstanding IC 1-1-4-1, if at least a quorum of its members are present at a meeting, the committee may take an action by an affirmative vote of at least a majority of the members present and voting.
(e) The advisory committee shall adopt rules under IC 4-22-2 to:
(1) set standards related to the registration and control of the manufacture, distribution, and dispensing of controlled substances, including recordkeeping requirements;
(2) set fees described in IC 25-1-8; and
(3) carry out its responsibilities under IC 35-48-2 through IC 35-48-3 and IC 35-48-6.
(f) The health professions bureau shall provide staff and facilities to the advisory committee under IC 25-1-5.
(g) Each member of the committee who is not a state employee is entitled to the minimum salary per diem provided by IC 4-10-11-2.1(b). Such a member is also entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the department of administration and approved by the state budget agency.
(h) Each member of the committee who is a state employee is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the department of administration and approved by the budget agency.
As added by P.L.200-1987, SEC.5.

IC 35-48-2-2
Sec. 2. Nomenclature. The controlled substances listed in the schedules in sections 4, 6, 8, 10 and 12 of this chapter are included by whatever official, common, usual, chemical, or trade name designated. The number placed in brackets after each substance is its federal Drug Enforcement Administration Controlled Substances Code Number which is to be used for identification purposes on certain certificates of registration.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.2.

IC 35-48-2-3
Sec. 3. (a) The board shall recommend placement of a substance in schedule I under this chapter if it finds that the substance:

(1) has high potential for abuse; and
(2) has no accepted medical use in treatment in the United States or lacks accepted safety for use in treatment under medical supervision.
(b) The board may recommend placement of a substance in schedule I under this chapter if it finds that the substance is classified as a controlled substance in schedule I under federal law.
As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.6.

IC 35-48-2-4
Sec. 4. (a) The controlled substances listed in this section are included in schedule I.
(b) Opiates. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted by rule of the board or unless listed in another schedule, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:
Acetylmethadol (9601)
Allylprodine (9602)
Alphacetylmethadol (9603)
Alphameprodine (9604)
Alphamethadol (9605)
Alphamethylfentanyl (9614)
Benzethidine (9606)
Betacetylmethadol (9607)
Betameprodine (9608)
Betamethadol (9609)
Betaprodine (9611)
Clonitazene (9612)
Dextromoramide (9613)
Diampromide (9615)
Diethylthiambutene (9616)
Difenoxin (9168)
Dimenoxadol (9617)
Dimepheptanol (9618)
Dimethylthiambutene (9619)
Dioxaphetyl butyrate (9621)
Dipipanone (9622)
Ethylmethylthiambutene (9623)
Etonitazene (9624)
Etoxeridine (9625)
Furethidine (9626)
Hydroxypethidine (9627)
Ketobemidone (9628)
Levomoramide (9629)
Levophenacylmorphan (9631)
3-Methylfentanyl [N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenyl-propanimide](9813)
MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) (9961)
Morpheridine (9632)
Noracymethadol (9633)
Norlevorphanol (9634)
Normethadone (9635)
Norpipanone (9636)
Phenadoxone (9637)
Phenampromide (9638)
Phenomorphan (9647)
Phenoperidine (9641)
PEPAP [1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine] (9663)
Piritramide (9642)
Proheptazine (9643)
Properidine (9644)
Propiram (9649)
Racemoramide (9645)
Tilidine (9750)
Trimeperidine (9646)
(c) Opium derivatives. Any of the following opium derivatives, their salts, isomers, and salts of isomers, unless specifically excepted by rule of the board or

unless listed in another schedule, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

Acetorphine (9319)
Acetyldihydrocodeine (9051)
Benzylmorphine (9052)
Codeine methylbromide (9070)
Codeine-N-Oxide (9053)
Cyprenorphine (9054)
Desomorphine (9055)
Dihydromorphine (9145)
Drotebanol (9335)
Etorphine (except hydrochloride salt) (9056)
Heroin (9200)
Hydromorphinol (9301)
Methyldesorphine (9302)
Methyldihydromorphine (9304)
Morphine methylbromide (9305)
Morphine methylsulfonate (9306)
Morphine-N-Oxide (9307)
Myrophine (9308)
Nicocodeine (9309)
Nicomorphine (9312)
Normorphine (9313)
Pholcodine (9314)
Thebacon (9315)

(d) Hallucinogenic substances. Any material, compound, mixture, or preparation which contains any quantity of the following hallucinogenic, psychedelic, or psychogenic substances, their salts, isomers, and salts of isomers, unless specifically excepted by rule of the board or unless listed in another schedule, whenever the existence of these salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 4-Bromo-2, 5-Dimethoxyamphetamine (7391). Some trade or other names: 4-Bromo-2, 5-Dimethoxy-a-methylphenethylamine; 4-Bromo-2, 5-DMA.

(2) 2, 5-Dimethoxyamphetamine (7396). Some trade or other names: 2, 5-Dimethoxy-a-methylphenethylamine; 2, 5-DMA.

(3) 4-Methoxyamphetamine (7411). Some trade or other names: 4-Methoxy-a-methylphenethylamine; Paramethoxyamphetamine; PMA.

(4) 5-methoxy-3, 4-methylenedioxy amphetamine (7401). Other Name: MMDA.

(5) 4-methyl-2, 5-dimethoxyamphetamine (7395). Some trade and other names: 4-methyl-2, 5-dimethoxy-a-methylphenethylamine; DOM; and STP.

(6) 3, 4-methylenedioxy amphetamine (7400). Other name: MDA.

(7) 3, 4-methylenedioxymethamphetamine (MDMA) (7405).

(8) 3, 4, 5-trimethoxy amphetamine (7390). Other name: TMA.

(9) Bufotenine (7433). Some trade and other names: 3-(B-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminonethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine.

(10) Dimethyltryptamine (7434). Some trade or other names: N, N-Diethyltryptamine; DET.

(11) Diethyltryptamine (7435). Some trade or other names: DMT.

(12) Ibogaine (7260). Some trade and other names: 7-Ethyl-6, 6b, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1', 2': 1, 2, azepino 4, 5-b) indole; tabernanthe iboga.

(13) Lysergic acid diethylamide (7315). Other name: LSD.

(14) Marijuana (7360).

(15) Mescaline (7381).

(16) Parahexyl (7374). Some trade or other names: 3-Hexyl-1-hydroxy-7, 8, 9, 10-Tetrahydro-6, 6, 9-trimethyl-6H-dibenzo (b,d) pyran; Snyhexyl.

(17) Peyote (7415), including:

(A) all parts of the plant that are classified botanically as lophophora williamsii lemaire, whether growing or not;

(B) the seeds thereof;

(C) any extract from any part of the plant; and

(D) every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(18) N-ethyl-3-piperidyl benzilate (7482). Other name: DMZ.

(19) N-methyl-3-piperidyl benzilate (7484). Other name: LBJ.

(20) Psilocybin (7437).

(21) Psilocyn (7438).

(22) Tetrahydrocannabinols (7370), including synthetic equivalents of the substances contained in the plant, or in the resinous extractives of Cannabis, sp. and synthetic substances,
derivatives, and their isomers with similar chemical structure and pharmacological activity such as:

(A) $.^{1}$ cis or trans tetrahydrocannabinol, and their optical isomers;

(B) $.^{6}$ cis or trans tetrahydrocannabinol, and their optical isomers; and

(C) $.^{3,4}$ cis or trans tetrahydrocannabinol, and their optical isomers.

Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of

atomic positions are covered. Other name: THC.

(23) Ethylamine analog of phencyclidine (7455). Some trade or other names: N-Ethyl-1-phenylcyclohexylamine; (1-phenylcyclohexyl) ethylamine; N-(1-phenylcyclohexyl) ethylamine; cyclohexamine; PCE.

(24) Pyrrolidine analog of phencyclidine (7458). Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine; PCP_y; PHP.

(25) Thiophene analog of phencyclidine (7470). Some trade or other names: 1-(1-(2-thienyl) cyclohexyl) piperidine; 2-Thienyl Analog of Phencyclidine; TPCP.

(e) Depressants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Gamma-hydroxybutyric acid (other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate) (2010)

Mecloqualone (2572)

Methaqualone (2565)

(f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Fenethylline (1503)

N-ethylamphetamine (1475)

Methcathinone (1237) (Some other trade names: 2-Methylamino-1-Phenylpropan-l-one; Ephedrone; Monomethylpropion; UR 1431.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.3; Acts 1981, P.L.170, SEC.2; P.L.333-1983, SEC.1; P.L.327-1985, SEC.1; P.L.156-1986, SEC.4; P.L.200-1987, SEC.7; P.L.163-1994, SEC.3; P.L.2-1996, SEC.286; P.L.288-2001, SEC.15.

IC 35-48-2-5

IC 35-48-2-5 Sec. 5. (a) The board shall recommend placement of a substance in schedule II under this chapter if it finds that:

(1) the substance has high potential for abuse;

(2) the substance has currently accepted medical use in treatment in the United States, or currently accepted medical use with severe restrictions; and

(3) the abuse of the substance may lead to severe psychological or physical dependence.

(b) The board may recommend placement of a substance in schedule II under this chapter if it finds that the substance is classified as a controlled substance in schedule II under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.8.

IC 35-48-2-6

Sec. 6. (a) The controlled substances listed in this section are included in schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrorphan, nalbuphine, naloxone, naltrexone, and their respective salts but including:

(A) raw opium (9600);

(B) opium extracts (9610);

(C) opium fluid extracts (9620);

(D) powdered opium (9639);

(E) granulated opium (9640);

(F) tincture of opium (9630);

(G) codeine (9050);

(H) ethylmorphine (9190);

(I) etorphine hydrochloride (9059);

(J) hydrocodone (9193);

(K) hydromorphone (9150);

(L) metopon (9260);

(M) morphine (9300);

(N) oxycodone (9143);

(O) oxymorphone (9652); and

(P) thebaine (9333).

(2) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (b)(1) of this section, but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Cocaine (9041).

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy) (9670).

(c) Opiates. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation:

Alfentanil (9737)

Alphaprodine (9010)

Anileridine (9020)
Bezitramide (9800)
Bulk dextropropoxyphene (nondosage forms) (9273)
Dihydrocodeine (9120)
Diphenoxylate (9170)
Fentanyl (9801)
Isomethadone (9226)
Levomethorphan (9210)
Levorphanol (9220)
Metazocine (9240)
Methadone (9250)
Methadone-Intermediate, 4-cyano-2-dimethyl-amino-4, 4-diphenyl butane (9254)
Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane- carboxylic acid (9802)
Pethidine (Meperidine) (9230)
Pethidine-Intermediate- A, 4-cyano-1-methyl-4-phenylpiperidine (9232)
Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate (9233)
Pethidine-Intermediate-C,1-methyl-4-phenylpiperidine-4-carbo xylic acid (9234)
Phenazodine (9715)
Piminodine (9730)
Racemethorphan (9732)
Racemorphan (9733)
Sufentanil (9740)

(d) Stimulants. Any material compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers (1100).
(2) Methamphetamine, including its salts, isomers, and salts of its isomers (1105).
(3) Phenmetrazine and its salts (1631).
(4) Methylphenidate (1724).

(e) Depressants. Unless specifically excepted by rule of the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital (2125)
Gamma hydroxybutyrate
Pentobarbital (2270)
Phencyclidine (7471)
Secobarbital (2315)

(f) Immediate precursors. Unless specifically excepted by rule of the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine: Phenylacetone (8501). Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.
(2) Immediate precursors to phencyclidine (PCP):
(A) 1-phenylcyclohexylamine (7460); or
(B) 1-piperidinocyclohexanecarbonitrile (PCC) (8603).

(g) Hallucinogenic substances:

Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration approved drug product (7369).

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.4; Acts 1981, P.L.170, SEC.3; P.L.333-1983, SEC.2; P.L.77-1984, SEC.13; P.L.327-1985, SEC.2; P.L.156-1986, SEC.5; P.L.329-1987, SEC.1; P.L.31-1998, SEC.9.

IC 35-48-2-7

Sec. 7. (a) The board shall recommend placement of a substance in schedule III under this chapter if it finds that:

(1) the substance has a potential for abuse less than the substances listed in schedule I and II under this chapter;
(2) the substance has currently accepted medical use in treatment in the United States; and
(3) abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

(b) The board may recommend placement of a substance in schedule III under this chapter if it finds that the substance is classified as a controlled substance in schedule III under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.9.

IC 35-48-2-8

Sec. 8. (a) The controlled substances listed in this section are included in schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any

quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on April 1, 1986, as excepted compounds under 21 CFR 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or that is the same except that it contains a lesser quantity of controlled substances (1405).

(2) Benzphetamine (1228).

(3) Chlorphentermine (1645).

(4) Clortermine (1647).

(5) Phendimetrazine (1615).

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing:

(A) amobarbital (2125);

(B) secobarbital (2315);

(C) pentobarbital (2270); or

(D) any of their salts;

and one (1) or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing:

(A) amobarbital (2125);

(B) secobarbital (2315);

(C) pentobarbital (2270); or

(D) any of their salts;

and approved by the Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid, or any salt thereof (2100).

(4) Chlorhexadol (2510).

(5) Glutethimide (2550).

(6) Lysergic acid (7300).

(7) Lysergic acid amide (7310).

(8) Methyprylon (2575).

(9) Sulfondiethylmethane (2600).

(10) Sulfonethylmethane (2605).

(11) Sulfonmethane (2610).

(12) A combination product containing tiletimine and zolazepam (Telazol) (7295).

(13) Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. 301 et seq. (2012).

(d) Nalorphine (a narcotic drug) (9400).

(e) Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following limited quantities:

(1) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium (9803).

(2) Not more than 1.8 grams of codeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9804).

(3) Not more than 300 milligrams of dihydrocodeinone, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium (9805).

(4) Not more than 300 milligrams of dihydrocodeinone, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9806).

(5) Not more than 1.8 grams of dihydrocodeine, per 100 milliliters or not more than 90 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9807).

(6) Not more than 300 milligrams of ethylmorphine, per 100 milliliters or not more than 15 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9808).

(7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts (9809).

(8) Not more than 50 milligrams of morphine, per 100 milliliters or per 100 grams with one (1) or more active nonnarcotic ingredients in recognized therapeutic amounts (9810).

(f) Anabolic steroid (as defined in 21 U.S.C. 802(41)(A) and 21 U.S.C. 802(41)(B)).

(g) The board shall except by rule any compound, mixture, or preparation containing any stimulant or depressant substance listed in subsections (b) through (e) from the application of any part of this article if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a stimulant or depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a stimulant or depressant effect on the central nervous system.

(h) Any material, compound, mixture, or preparation which contains any quantity of Ketamine.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.2, SEC.86; Acts 1979, P.L.303, SEC.5; Acts 1981, P.L.170, SEC.4; P.L.333-1983, SEC.3; P.L.200-1987, SEC.10; P.L.48-1991, SEC.76; P.L.1-1994, SEC.171; P.L.31-1998, SEC.10; P.L.288-2001, SEC.16.

IC 35-48-2-9

Sec. 9. (a) The board shall recommend placement of a substance in schedule IV under this chapter if it finds that:

(1) the substance has a low potential for abuse relative to substances in schedule III under this chapter;

(2) the substance has currently accepted medical use in treatment in the United States; and

(3) abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances in schedule III under this chapter.

(b) The board may recommend placement of a substance in schedule IV under this chapter if it finds that the substance is classified as a controlled substance in schedule IV under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.11.

IC 35-48-2-10

Sec. 10. (a) The controlled substances listed in this section are included in schedule IV.

(b) Narcotic drugs. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following limited quantities:

(1) Not more than 1 milligram of difenoxin (9618) and not less than 25 micrograms of atropine sulfate per dosage unit.

(2) Dextropropoxyphene (alpha- (+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane (9273).

(c) Depressants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Alprazolam (2882).
Barbital (2145).
Bromazepam (2748).
Camazepam (2749).
Carisoprodol
Chloral betaine (2460).
Chloral hydrate (2465).
Chlordiazepoxide (2744).
Clobazam (2751).
Clonazepam (2737).
Clorazepate (2768).
Clotiazepam (2752).
Cloxazolam (2753).
Delorazepam (2754).
Diazepam (2765).
Estazolam (2756).
Ethchlorvynol (2540).
Ethinamate (2545).
Ethyl loflazepate (2758).
Fludiazepam (2759).
Flunitrazepam (2763).
Flurazepam (2767).
Halazepam (2762).
Haloxazolam (2771).
Ketazolam (2772).
Loprazolam (2773).
Lorazepam (2885).
Lormetazepam (2774).
Mebutamate (2800).
Medazepam (2836).
Meprobamate (2820).
Methohexital (2264).
Methylphenobarbital (mephobarbital) (2250).
Midazolam (2884).
Nimetazepam (2837).
Nitrazepam (2834).
Nordiazepam (2838).
Oxazepam (2835).
Oxazolam (2839).

Paraldehyde (2585).
Petrichloral (2591).
Phenobarbital (2285).
Pinazepam (2883).
Prazepam (2764).
Quazepam (2881).
Temazepam (2925).
Tetrazepam (2886).
Triazolam (2887).
Zolpidem (Ambien) (2783).

(d) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible.

Fenfluramine (1670).

(e) Stimulants. Unless specifically excepted in a rule adopted by the board or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion (1608).
(2) Mazindol (1605).
(3) Phentermine (1640).
(4) Pemoline (including organometallic complexes and chelates thereof) (1530).
(5) Pipradrol (1750).
(6) SPA ((-)-1-dimethylamino-1,2-diphenylethane (1635).

(f) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances including its salts:

(1) Pentazocine (9709).

(g) The board may except by rule any compound, mixture, or preparation containing any depressant substance listed in subsection (b), (c), (d), (e), or (f) from the application of any part of this article if the compound, mixture, or preparation contains one (1) or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.344, SEC.2; Acts 1979, P.L.303, SEC.6; Acts 1981, P.L.170, SEC.5; P.L.333-1983, SEC.4; P.L.77-1984, SEC.14; P.L.200-1987, SEC.12; P.L.288-2001, SEC.17.

C 35-48-2-11

Sec. 11. (a) The board shall recommend placement of a substance in schedule V under this chapter if it finds that:

(1) the substance has low potential for abuse relative to the controlled substances listed in schedule IV under this chapter;
(2) the substance has currently accepted medical use in treatment in the United States; and
(3) the substance has limited physical dependence or psychological dependence liability relative to the controlled substances listed in schedule IV under this chapter.

(b) The board may recommend placement of a substance in schedule V under this chapter if it finds that the substance is classified as a controlled substance in schedule V under federal law.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.200-1987, SEC.13.

IC 35-48-2-12

Sec. 12. (a) The controlled substances listed in this section are included in schedule V.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in the following quantities, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.
(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.
(6) Not more than 0.5 milligrams of difenoxin (9168), and not less than 25 micrograms of atropine sulfate per dosage unit.

(c) Buprenorphine (9064).

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1979, P.L.303, SEC.7; Acts 1981, P.L.170, SEC.6; P.L.327-1985, SEC.3.

IC 35-48-2-13

(*Repealed by Acts 1979, P.L.303, SEC.13.)*

IC 35-48-2-14

Sec. 14. (a) The board may adopt rules under IC 4-22-2 to reclassify a controlled substance:

(1) from a more restrictive schedule to a less restrictive schedule; or

(2) as a substance that is not a controlled substance;

if the board finds that the substance qualifies for reclassification under this chapter and that the same reclassification has been made in a controlled substance schedule under federal law.

(b) If the board reclassifies a controlled substance under subsection (a), the board shall recommend the same reclassification to the general assembly under section 1 of this chapter.

(c) Notwithstanding a provision in this chapter that classifies a controlled substance in a more restrictive schedule than a rule adopted under subsection (a), a person who manufactures, distributes, dispenses, possesses, or uses a controlled substance in compliance with the requirements applicable to the less restrictive schedule to which a controlled substance is reclassified under subsection (a) does not commit an offense under this article.

(d) Notwithstanding a provision in this chapter that classifies a substance as a controlled substance, a person does not commit an offense under this article if the board has reclassified the controlled substance as a substance that is not a controlled substance.

As added by P.L.200-1987, SEC.14.

IC 35-48-3

Chapter 3. Registration and Control

IC 35-48-3-1

Sec. 1. Rules. The board may promulgate rules and charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances within this state.

As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-2

Sec. 2. (a) Any humane society, animal control agency, or governmental entity operating an animal shelter or other animal impounding facility is entitled to receive a limited permit only for the purpose of buying, possessing, and using:

(1) sodium pentobarbital to euthanize injured, sick, homeless, or unwanted domestic pets and animals;

(2) ketamine and ketamine products to anesthetize or immobilize fractious domestic pets and animals; and

(3) a combination product containing tiletimine and zolazepam as an agent for the remote chemical capture of domestic pets or animals that otherwise cannot be restrained or captured.

(b) A humane society, animal control agency, or governmental entity entitled to receive a permit under this chapter must:

(1) apply to the board according to the rules established by the board;

(2) pay annually to the board a fee set by the board for the limited permit; and

(3) submit proof, as determined by the board, that the employees of an applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance.

(c) All fees collected by the board under this section shall be credited to the state board of pharmacy account.

(d) Storage, handling, and use of controlled substances obtained according to this section are subject to the rules adopted by the board.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.193-1987, SEC.16; P.L.136-2001, SEC.1.

IC 35-48-3-3

Sec. 3. (a) Every person who manufactures or distributes any controlled substance within this state or who proposes to engage in the manufacture or distribution of any controlled substance within this state, must obtain biennially a registration issued by the board in accordance with its rules.

(b) Every person who dispenses or proposes to dispense any controlled substance within Indiana must have a registration issued by the board in accordance with its rules. A registration issued to a dispenser under this subsection expires whenever the dispenser's license as a practitioner expires. The board shall renew a dispenser's registration under this subsection concurrently with any state license authorizing the dispenser to act as a practitioner.

(c) Persons registered by the board under this article to manufacture, distribute, dispense, or conduct research with controlled substances may possess, manufacture, distribute, dispense, or conduct research with those substances to the extent authorized by their registration and in conformity with the other provisions of this chapter.

(d) The following persons need not register and may lawfully possess controlled substances under this article:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance if he is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment.

(3) An ultimate user or a person in possession of any controlled substance under a lawful order of a practitioner or in lawful possession of a schedule V substance.

(e) The board may waive by rule the requirement for registration of certain manufacturers, distributors, or dispensers if it finds it consistent with the public health and safety.

(f) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, dispenses, or possesses controlled substances.

(g) The board may inspect the establishment of a registrant or applicant for registration in accordance with the board's rules.

As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.156-1986, SEC.6.

IC 35-48-3-4

Sec. 4. Registration. (a) The board shall register an applicant to manufacture or distribute controlled substances unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the board shall consider:

(1) maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

(2) compliance with applicable state and local law;

(3) any convictions of the applicant under any federal and state laws relating to any controlled substance;

(4) past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

(5) furnishing by the applicant of false or fraudulent material in any application filed under this article;

(6) suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

(7) any other factors relevant to and consistent with the public health and safety.

(b) Registration under subsection (a) of this section does not entitle a registrant to manufacture and distribute controlled substances in schedules I or II other than those specified in the registration.

(c) Practitioners must be registered to dispense any controlled substances or to conduct research with controlled substances in schedules II through V if they are authorized to dispense or conduct research under the law of this state. The board need not require separate registration under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through V where the registrant is already registered under this chapter in another capacity, to the extent authorized by his registration in that other capacity.

(d) Registration to conduct research or instructional activities with controlled substances in schedules I through V does not entitle a registrant to conduct research or instructional activities with controlled substances other than those approved by the controlled substances advisory committee in accordance with the registration.

Compliance by manufacturers and distributors with the provisions of the federal law respecting registration (excluding fees) entitles them to be registered under this article.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.7.

IC 35-48-3-5

Sec. 5. Denial, Revocation, and Suspension of Registration. (a) An application for registration or re-registration submitted pursuant to and a registration issued under section 3 of this chapter to manufacture, distribute, or dispense a controlled substance may be denied, suspended or revoked by the board upon a finding by the advisory committee that the applicant or registrant:

(1) has furnished false or fraudulent material information in any application filed under this article;

(2) has violated any state or federal law relating to any controlled substance;

(3) has had his federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances; or

(4) has failed to maintain reasonable controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels.

(b) The board may limit revocation or suspension of a registration or the denial of an application for registration or re-registration to the particular controlled substance with respect to which grounds for revocation, suspension or denial exist.

(c) If the board suspends or revokes a registration or denies an application for re-registration, all controlled substances owned or possessed by the registrant at the time of suspension or the effective date of the revocation or denial order may be placed under seal. The board may require the removal of such substances from the premises. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court, upon application therefor, orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation or denial order becoming final, all controlled substances may be forfeited to the state.

(d) The board shall promptly notify the drug enforcement administration of all orders suspending or revoking registration, all orders denying any application for registration or re-registration, and all forfeitures of controlled substances.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1981, P.L.170, SEC.8.

IC 35-48-3-6

Sec. 6. (a) Before recommending a denial, suspension, or revocation of a registration, or before refusing a renewal of registration, the advisory committee shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended, or why the renewal should not be denied. The order to show cause shall contain a statement of the basis therefor and shall call upon the applicant or registrant to appear before the advisory committee at a time and place not less than thirty (30) days after the date of service of the order, but in the case of a denial or renewal of registration the show cause order shall be served not later than thirty (30) days before the expiration of the registration. These proceedings shall be conducted in accordance with IC 4-21.5 without regard to any criminal prosecution or other proceeding. Proceedings to refuse renewal of registration shall not abate the existing registration which shall remain in effect pending the outcome of the administrative hearing.

(b) The advisory committee may recommend suspension, and the board may suspend, without an order to show cause, any registration simultaneously with the institution of proceedings under section 4 of this chapter, or where renewal of registration is refused, if it finds that there is an imminent danger to the public health or safety which warrants this action. The suspension shall continue in effect until the conclusion of the proceedings, including judicial review thereof, unless sooner withdrawn by the board or dissolved by a court of competent jurisdiction.

(c) If an applicant for re-registration (who is doing business under a registration previously granted and not revoked nor suspended) has applied for re-registration at least forty-five (45) days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the board so issues its order. The board may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration at least forty-five (45) days before

expiration of the existing registration, with or without request by the registrant, if the board finds that such extension is not inconsistent with the public health and safety.
As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.7-1987, SEC.166.

IC 35-48-3-7
Sec. 7. Records of Registrants. Persons registered to manufacture, distribute, or dispense controlled substances under this article shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of federal law and with any additional rules the board issues.
As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-8
Sec. 8. Order Forms. Controlled substances in schedules I and II shall be distributed by a registrant to another registrant only pursuant to an order form. Compliance with the provisions of federal law respecting order forms is deemed compliance with this section.
As added by Acts 1976, P.L.148, SEC.7.

IC 35-48-3-9
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.
As added by Acts 1976, P.L.148, SEC.7. Amended by P.L.2-1993, SEC.192; P.L.163-1994, SEC.4. Amended by P.L. 204-2005, SEC.21.

IC 35-48-3-10
(*Repealed by P.L.157-1999, SEC.2.)*

IC 35-48-3-11
Sec. 11. (a) Only a physician licensed under IC 25-22.5 may treat a patient with a Schedule III or Schedule IV controlled substance for the purpose of weight reduction or to control obesity.
(b) A physician licensed under IC 25-22.5 may not prescribe, dispense, administer, supply, sell, or give any amphetamine, sympathomimetic amine drug, or compound designated as a Schedule III or Schedule IV controlled substance under IC 35-48-2-8 and IC 35-48-2-10 for a patient for purposes of weight reduction or to control obesity, unless the physician does the following:
(1) Determines:
(A) through review of:
(i) the physician's records of prior treatment of the patient; or
(ii) the records of prior treatment of the patient provided by a previous treating physician or weight loss program;
that the physician's patient has made a reasonable effort to lose weight in a treatment program using a regimen of weight reduction based on caloric restriction, nutritional counseling, behavior modification, and exercise without using controlled substances; and
(B) that the treatment described in clause (A) has been ineffective for the physician's patient.
(2) Obtains a thorough history and performs a thorough physical examination of the physician's patient before initiating a treatment plan using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity.
(c) A physician licensed under IC 25-22.5 may not begin and shall discontinue using a Schedule III or Schedule IV controlled substance for purposes of weight reduction or to control obesity after the physician determines in the physician's professional judgment that:
(1) the physician's patient has failed to lose weight using a treatment plan involving the controlled substance;
(2) the controlled substance has provided a decreasing contribution toward further weight loss for the patient unless continuing to take the controlled substance is medically necessary or appropriate for maintenance therapy;
(3) the physician's patient:
(A) has a history of; or
(B) shows a propensity for;
alcohol or drug abuse; or
(4) the physician's patient has consumed or disposed of a controlled substance in a manner that does not strictly comply with a treating physician's direction.
As added by P.L.157-1999, SEC.1. Amended by P.L.37-2001, SEC.1.

IC 35-48-4

Chapter 4. Offenses Relating to Controlled Substances

IC 35-48-4-1

Sec. 1. (a) A person who:
(1) knowingly or intentionally:
(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
cocaine, a narcotic drug, or methamphetamine, pure or adulterated, classified in schedule I or II; or
(2) possesses, with intent to:
(A) manufacture;
(B) finance the manufacture of;
(C) deliver; or
(D) finance the delivery of;
cocaine, a narcotic drug, or methamphetamine, pure or adulterated, classified in schedule I or II;
commits dealing in cocaine, a narcotic drug, or methamphetamine, a Class B felony, except as provided in subsection (b).
(b) The offense is a Class A felony if:
(1) the amount of the drug involved weighs three (3) grams or more;
(2) the person:
(A) delivered; or
(B) financed the delivery of;
the drug to a person under eighteen (18) years of age at least three (3) years junior to the person; or
(3) the person manufactured, delivered or financed the delivery of the drug:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.96; Acts 1979, P.L.303, SEC.8; P.L.296-1987, SEC.5; P.L.165-1990, SEC.3; P.L.296-1995, SEC.3; P.L.65-1996, SEC.11; P.L.17-2001, SEC.19.

IC 35-48-4-2

Sec. 2. (a) A person who:
(1) knowingly or intentionally:
(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
a controlled substance, pure or adulterated, classified in schedule I, II, or III, except marijuana, hash oil, or hashish; or
(2) possesses, with intent to:
(A) manufacture;
(B) finance the manufacture of;
(C) deliver; or
(D) finance the delivery of;
a controlled substance, pure or adulterated, classified in schedule I, II, or III, except marijuana, hash oil, or hashish;
commits dealing in a schedule I, II, or III controlled substance, a Class B felony, except as provided in subsection (b).
(b) The offense is a Class A felony if:
(1) the person:
(A) delivered; or
(B) financed the delivery of;
the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or
(2) the person delivered or financed the delivery of the substance:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.97; Acts 1979, P.L.303, SEC.9; P.L.296-1987, SEC.6; P.L.165-1990, SEC.4; P.L.296-1995, SEC.4; P.L.65-1996, SEC.12; P.L.17-2001, SEC.20.

IC 35-48-4-3

Sec. 3. (a) A person who:
(1) knowingly or intentionally:
(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
a controlled substance, pure or adulterated, classified in schedule IV; or
(2) possesses, with intent to manufacture or deliver, a controlled substance, pure or adulterated, classified in schedule IV;
commits dealing in a schedule IV controlled substance, a Class C felony, except as provided in subsection (b).
(b) The offense is a Class B felony if:
(1) the person:
(A) delivered; or
(B) financed the delivery of;
the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or
(2) the person delivered or financed the delivery of the substance:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.98; P.L.296-1987, SEC.7; P.L.165-1990, SEC.5; P.L.296-1995, SEC.5; P.L.65-1996, SEC.13; P.L.17-2001, SEC.21.

IC 35-48-4-4

Sec. 4. (a) A person who:
(1) knowingly or intentionally:
(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
a controlled substance, pure or adulterated, classified in schedule V; or
(2) possesses, with intent to:
(A) manufacture;
(B) finance the manufacture of;
(C) deliver; or
(D) finance the delivery of;
a controlled substance, pure or adulterated, classified in schedule V;
commits dealing in a schedule V controlled substance, a Class D felony, except as provided in subsection (b).
(b) The offense is a Class B felony if:
(1) the person:
(A) delivered; or
(B) financed the delivery of;
the substance to a person under eighteen (18) years of age at least three (3) years junior to the person; or
(2) the person delivered or financed the delivery of the substance:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.99; P.L.296-1987, SEC.8; P.L.165-1990, SEC.6; P.L.296-1995, SEC.6; P.L.65-1996, SEC.14; P.L.17-2001, SEC.22.

IC 35-48-4-4.5

Sec. 4.5. (a) A person who knowingly or intentionally delivers or finances the delivery of any substance, other than a controlled substance or a drug for which a prescription is required under federal or state law, that:

(1) is expressly or impliedly represented to be a controlled substance;
(2) is distributed under circumstances that would lead a reasonable person to believe that the substance is a controlled substance; or
(3) by overall dosage unit appearance, including shape, color, size, markings, or lack of markings, taste, consistency, or any other identifying physical characteristic of the substance, would lead a reasonable person to believe the substance is a controlled substance;
commits dealing in a substance represented to be a controlled substance, a Class D felony.
(b) In determining whether representations have been made, subject to subsection (a)(1), or whether circumstances of distribution exist, subject to subsection (a)(2), the trier of fact may consider, in addition to other relevant factors, the following:
(1) Statements made by the owner or other person in control of the substance, concerning the substance's nature, use, or effect.
(2) Statements made by any person, to the buyer or recipient of the substance, that the substance may be resold for profit.
(3) Whether the substance is packaged in a manner uniquely used for the illegal distribution of controlled substances.
(4) Whether:
(A) the distribution included an exchange of, or demand for, money or other property as consideration; and
(B) the amount of the consideration was substantially greater than the reasonable retail market value of the substance.
As added by Acts 1981, P.L.305, SEC.1. Amended by P.L.210-1986, SEC.1; P.L.165-1990, SEC.7.

IC 35-48-4-4.6
Sec. 4.6. (a) A person who knowingly or intentionally:
(1) manufactures;
(2) finances the manufacture of;
(3) advertises;
(4) distributes; or
(5) possesses with intent to manufacture, finance the manufacture of, advertise, or distribute;
a substance described in section 4.5 of this chapter commits a Class C felony.
(b) A person who knowingly or intentionally possesses a substance described in section 4.5 of this chapter commits a Class C misdemeanor. However, the offense is a Class A misdemeanor if the person has a previous conviction under this section.
(c) In any prosecution brought under this section it is not a defense that the person believed the substance actually was a controlled substance.
(d) This section does not apply to the following:
(1) The manufacture, financing the manufacture of, processing, packaging, distribution, or sale of noncontrolled substances to licensed medical practitioners for use as placebos in professional practice or research.
(2) Persons acting in the course and legitimate scope of their employment as law enforcement officers.
(3) The retention of production samples of noncontrolled substances produced before September 1, 1986, where such samples are required by federal law.
(e) In addition to any other penalty imposed for conviction of an offense under this section, a court shall order restitution pursuant to IC 35-50-5-3 to cover the costs of an environmental cleanup incurred by a law enforcement agency or other person as a result of the offense.
(f) The amount collected under subsection (e) shall be used to reimburse the law enforcement agency that assumed the costs associated with the environmental cleanup described in subsection (e).
As added by P.L.210-1986, SEC.2. Amended by P.L.165-1990, SEC.8; P.L.150-1999, SEC.1.

IC 35-48-4-4.1
Sec. 4.1. (a) A person who dumps, discharges, discards, transports, or otherwise disposes of:
(1) chemicals, knowing the chemicals were used in the illegal manufacture of a controlled substance or an immediate precursor; or
(2) waste, knowing that the waste was produced from the illegal manufacture of a controlled substance or an immediate precursor;
commits dumping controlled substance waste, a Class D felony.
(b) It is not a defense in a prosecution under subsection (a) that the person did not manufacture the controlled substance or immediate precursor.
As added by P.L.17-2001, SEC.23.

IC 35-48-4-5
Sec. 5. A person who:
(1) knowingly or intentionally:
(A) creates;
(B) delivers; or
(C) finances the delivery of;
a counterfeit substance; or
(2) possesses, with intent to:
(A) deliver; or
(B) finance the delivery of;
a counterfeit substance;
commits dealing in a counterfeit substance, a Class D felony.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.100; P.L.165-1990, SEC.9.

IC 35-48-4-6

Sec. 6. (a) A person who, without a valid prescription or order of a practitioner acting in the course of the practitioner's professional practice, knowingly or intentionally possesses cocaine (pure or adulterated), a narcotic drug (pure or adulterated) classified in schedule I or II, or methamphetamine (pure or adulterated) commits possession of cocaine, a narcotic drug, or methamphetamine, a Class D felony, except as provided in subsection (b).

(b) The offense is:

(1) a Class C felony if:

(A) the amount of the drug involved (pure or adulterated) weighs three (3) grams or more; or

(B) the person was also in possession of a firearm (as defined in IC 35-47-1-5);

(2) a Class B felony if the person in possession of the cocaine, narcotic drug, or methamphetamine possesses less than three (3) grams of pure or adulterated cocaine, a narcotic drug, or methamphetamine:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center; and

(3) a Class A felony if the person possesses the cocaine, narcotic drug, or methamphetamine in an amount (pure or adulterated) weighing at least three (3) grams:

(A) on a school bus; or

(B) in, on, or within one thousand (1,000) feet of:

(i) school property;

(ii) a public park;

(iii) a family housing complex; or

(iv) a youth program center.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.101; Acts 1979, P.L.303, SEC.10; P.L.138-1983, SEC.3; P.L.296-1987, SEC.9; P.L.296-1995, SEC.7; P.L.65-1996, SEC.15; P.L.188-1999, SEC.7; P.L.17-2001, SEC.24.

IC 35-48-4-7

Sec. 7. (a) A person who, without a valid prescription or order of a practitioner acting in the course of his professional practice, knowingly or intentionally possesses a controlled substance (pure or adulterated) classified in schedule I, II, III, or IV, except marijuana or hashish, commits possession of a controlled substance, a Class D felony. However, the offense is a Class C felony if the person in possession of the controlled substance possesses the controlled substance:

(1) on a school bus; or

(2) in, on, or within one thousand (1,000) feet of:

(A) school property;

(B) a public park;

(C) a family housing complex; or

(D) a youth program center.

(b) A person who, without a valid prescription or order of a practitioner acting in the course of his professional practice, knowingly or intentionally obtains:

(1) more than four (4) ounces of schedule V controlled substances containing codeine in any given forty-eight (48) hour period unless pursuant to a prescription;

(2) a schedule V controlled substance pursuant to written or verbal misrepresentation; or

(3) possession of a schedule V controlled substance other than by means of a prescription or by means of signing an exempt narcotic register maintained by a pharmacy licensed by the Indiana state board of pharmacy; commits a Class D felony.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.102; P.L.138-1983, SEC.4; P.L.327-1985, SEC.4; P.L.296-1987, SEC.10; P.L.296-1995, SEC.8; P.L.65-1996, SEC.16; P.L.17-2001, SEC.25.

IC 35-48-4-8

(*Repealed by Acts 1980, P.L.115, SEC.5.)*

IC 35-48-4-8.1

Sec. 8.1. (a) A person who manufactures, finances the manufacture of, or designs an instrument, a device, or other object that is intended to be used primarily for:

(1) introducing into the human body a controlled substance;

(2) testing the strength, effectiveness, or purity of a controlled substance; or

(3) enhancing the effect of a controlled substance;

in violation of this chapter commits a Class A infraction for manufacturing paraphernalia.

(b) A person who:

(1) knowingly or intentionally violates this section; and

(2) has a previous judgment for violation of this section;

commits manufacture of paraphernalia, a Class D felony.
As added by Acts 1980, P.L.115, SEC.2. Amended by P.L.202-1989, SEC.3; P.L.165-1990, SEC.10.

IC 35-48-4-8.2
(*Repealed by P.L.1-1991, SEC.205.)*

IC 35-48-4-8.3
Sec. 8.3. (a) A person who possesses a raw material, an instrument, a device, or other object that the person intends to use for:
(1) introducing into the person's body a controlled substance;
(2) testing the strength, effectiveness, or purity of a controlled substance; or
(3) enhancing the effect of a controlled substance;
in violation of this chapter commits a Class A infraction for possessing paraphernalia.
(b) A person who:
(1) knowingly or intentionally violates subsection (a); and
(2) has a previous judgment or conviction under this section;
commits possession of paraphernalia, a Class D felony.
(c) A person who recklessly possesses a raw material, an instrument, a device, or other object that is to be used primarily for:
(1) introducing into the person's body a controlled substance;
(2) testing the strength, effectiveness, or purity of a controlled substance; or
(3) enhancing the effect of a controlled substance;
in violation of this chapter commits reckless possession of paraphernalia, a Class A misdemeanor. However, the offense is a Class D felony if the person has a previous judgment or conviction under this section.
As added by Acts 1980, P.L.115, SEC.4. Amended by P.L.202-1989, SEC.5; P.L.166-1990, SEC.2.

IC 35-48-4-8.5
Sec. 8.5. (a) A person who keeps for sale, offers for sale, delivers, or finances the delivery of a raw material, an instrument, a device, or other object that is intended to be or that is designed or marketed to be used primarily for:
(1) ingesting, inhaling, or otherwise introducing into the human body marijuana, hash oil, hashish, or a controlled substance;
(2) testing the strength, effectiveness, or purity of marijuana, hash oil, hashish, or a controlled substance;
(3) enhancing the effect of a controlled substance;
(4) manufacturing, compounding, converting, producing, processing, or preparing marijuana, hash oil, hashish, or a controlled substance;
(5) diluting or adulterating marijuana, hash oil, hashish, or a controlled substance by individuals; or
(6) any purpose announced or described by the seller that is in violation of this chapter;
commits a Class A infraction for dealing in paraphernalia.
(b) A person who:
(1) knowingly or intentionally violates subsection (a); and
(2) has a previous judgment or conviction under this section;
commits dealing in paraphernalia, a Class D felony.
(c) A person who recklessly keeps for sale, offers for sale, or delivers an instrument, a device, or other object that is to be used primarily for:
(1) ingesting, inhaling, or otherwise introducing into the human body marijuana, hash oil, hashish, or a controlled substance;
(2) testing the strength, effectiveness, or purity of marijuana, hash oil, hashish, or a controlled substance;
(3) enhancing the effect of a controlled substance;
(4) manufacturing, compounding, converting, producing, processing, or preparing marijuana, hash oil, hashish, or a controlled substance;
(5) diluting or adulterating marijuana, hash oil, hashish, or a controlled substance by individuals; or
(6) any purpose announced or described by the seller that is in violation of this chapter;
commits reckless dealing in paraphernalia, a Class A misdemeanor. However, the offense is a Class D felony if the person has a previous judgment or conviction under this section.
(d) This section does not apply to the following:
(1) Items marketed for use in the preparation, compounding, packaging, labeling, or other use of marijuana, hash oil, hashish, or a controlled substance as an incident to lawful research, teaching, or chemical analysis and not for sale.
(2) Items marketed for or historically and customarily used in connection with the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, or inhaling of tobacco or any other lawful substance.
As added by P.L.1-1991, SEC.206.

IC 35-48-4-9
(*Repealed by Acts 1980, P.L.115, SEC.5.)*

IC 35-48-4-10
Sec. 10. (a) A person who:
(1) knowingly or intentionally:

(A) manufactures;
(B) finances the manufacture of;
(C) delivers; or
(D) finances the delivery of;
marijuana, hash oil, or hashish, pure or adulterated; or
(2) possesses, with intent to:
(A) manufacture;
(B) finance the manufacture of;
(C) deliver; or
(D) finance the delivery of;
marijuana, hash oil, or hashish, pure or adulterated;
commits dealing in marijuana, hash oil, or hashish, a Class A misdemeanor, except as provided in subsection (b).
(b) The offense is:
(1) a Class D felony if:
(A) the recipient or intended recipient is under eighteen (18) years of age;
(B) the amount involved is more than thirty (30) grams but less than ten (10) pounds of marijuana or two (2) grams but less than three hundred (300) grams of hash oil or hashish; or
(C) the person has a prior conviction of an offense involving marijuana, hash oil, or hashish; and
(2) a Class C felony if the amount involved is ten (10) pounds or more of marijuana or three hundred (300) or more grams of hash oil or hashish or the person delivered or financed the delivery of marijuana, hash oil, or hashish:
(A) on a school bus; or
(B) in, on, or within one thousand (1,000) feet of:
(i) school property;
(ii) a public park;
(iii) a family housing complex; or
(iv) a youth program center.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.105; Acts 1979, P.L.303, SEC.11; Acts 1982, P.L.204, SEC.38; P.L.296-1987, SEC.11; P.L.165-1990, SEC.12; P.L.296-1995, SEC.9; P.L.65-1996, SEC.17; P.L.17-2001, SEC.26.

IC 35-48-4-11
Sec. 11. A person who:
(1) knowingly or intentionally possesses (pure or adulterated) marijuana, hash oil, or hashish;
(2) knowingly or intentionally grows or cultivates marijuana; or
(3) knowing that marijuana is growing on his premises, fails to destroy the marijuana plants;
commits possession of marijuana, hash oil, or hashish, a Class A misdemeanor. However, the offense is a Class D felony (i) if the amount involved is more than thirty (30) grams of marijuana or two (2) grams of hash oil or hashish, or (ii) if the person has a prior conviction of an offense involving marijuana, hash oil, or hashish.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.106; Acts 1979, P.L.303, SEC.12; P.L.138-1983, SEC.5.

IC 35-48-4-12
Sec. 12. If a person who has no prior conviction of an offense under this article or under a law of another jurisdiction relating to controlled substances pleads guilty to possession of marijuana or hashish as a Class A misdemeanor, the court, without entering a judgment of conviction and with the consent of the person, may defer further proceedings and place him in the custody of the court under such conditions as the court determines. Upon violation of a condition of the custody, the court may enter a judgment of conviction. However, if the person fulfills the conditions of the custody, the court shall dismiss the charges against him. There may be only one (1) dismissal under this section with respect to a person.
As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.107.

IC 35-48-4-13
Sec. 13. (a) A person who knowingly or intentionally visits a building, structure, vehicle, or other place that is used by any person to unlawfully use a controlled substance commits visiting a common nuisance, a Class B misdemeanor.
(b) A person who knowingly or intentionally maintains a building, structure, vehicle, or other place that is used one (1) or more times:
(1) by persons to unlawfully use controlled substances; or
(2) for unlawfully:
(A) manufacturing;
(B) keeping;
(C) offering for sale;
(D) selling;
(E) delivering; or
(F) financing the delivery of;
controlled substances, or items of drug paraphernalia as described in IC 35-48-4-8.5;
commits maintaining a common nuisance, a Class D felony.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.108; P.L.210-1986, SEC.4; P.L.165-1990, SEC.13; P.L.1-1991, SEC.207; P.L.31-1998, SEC.11; P.L.17-2001, SEC.27.

IC 35-48-4-14

Sec. 14. (a) A person who:

(1) is subject to IC 35-48-3 and who recklessly, knowingly, or intentionally distributes or dispenses a controlled substance in violation of IC 35-48-3;

(2) is a registrant and who recklessly, knowingly, or intentionally:

(A) manufactures; or

(B) finances the manufacture of;

a controlled substance not authorized by his registration or distributes or dispenses a controlled substance not authorized by his registration to another registrant or other authorized person;

(3) recklessly, knowingly, or intentionally fails to make, keep, or furnish a record, a notification, an order form, a statement, an invoice, or information required under this article; or

(4) recklessly, knowingly, or intentionally refuses entry into any premises for an inspection authorized by this article;

commits a Class D felony.

(b) A person who knowingly or intentionally:

(1) distributes as a registrant a controlled substance classified in schedule I or II, except under an order form as required by IC 35-48-3;

(2) uses in the course of the:

(A) manufacture of;

(B) the financing of the manufacture of; or

(C) distribution of;

a controlled substance a federal or state registration number that is fictitious, revoked, suspended, or issued to another person;

(3) furnishes false or fraudulent material information in, or omits any material information from, an application, report, or other document required to be kept or filed under this article; or

(4) makes, distributes, or possesses a punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or a likeness of any of the foregoing on a drug or container or labeling thereof so as to render the drug a counterfeit substance;

commits a Class D felony.

(c) A person who knowingly or intentionally acquires possession of a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, alteration of a prescription order, concealment of a material fact, or use of a false name or false address commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection.

(d) A person who knowingly or intentionally affixes any false or forged label to a package or receptacle containing a controlled substance commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection. This subsection does not apply to law enforcement agencies or their representatives while engaged in enforcing IC 16-42-19 or this chapter (or IC 16-6-8 before its repeal).

(e) A person who duplicates, reproduces, or prints any prescription pads or forms without the prior written consent of a practitioner commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction of an offense under this subsection. This subsection does not apply to the printing of prescription pads or forms upon a written, signed order placed by a practitioner or pharmacist, by legitimate printing companies.

As added by Acts 1976, P.L.148, SEC.7. Amended by Acts 1977, P.L.340, SEC.109; P.L.131-1986, SEC.3; P.L.165-1990, SEC.14; P.L.2-1993, SEC.193.

IC 35-48-4-14.5

Sec. 14.5. (a) As used in this section, "chemical reagents or precursors" refers to one (1) or more of the following:

(1) Ephedrine.

(2) Pseudoephedrine.

(3) Phenylpropanolamine.

(4) The salts, isomers, and salts of isomers of a substance identified in subdivisions (1) through (3).

(5) Anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1).

(6) Organic solvents.

(7) Hydrochloric acid.

(8) Lithium metal.

(9) Sodium metal.

(10) Ether.

(11) Sulfuric acid.

(12) Red phosphorous.

(13) Iodine.

(14) Sodium hydroxide (lye).

(15) Potassium dichromate.

(16) Sodium dichromate.

(17) Potassium permanganate.

(18) Chromium trioxide.

(19) Benzyl cyanide.

(20) Phenylacetic acid and its esters or salts.

(21) Piperidine and its salts.
(22) Methylamine and its salts.
(23) Isosafrole.
(24) Safrole.
(25) Piperonal.
(26) Hydriodic acid.
(27) Benzaldehyde.
(28) Nitroethane.
(29) Gamma-butyrolactone.
(30) White phosphorus.
(31) Hypophosphorous acid and its salts.
(32) Acetic anhydride.
(33) Benzyl chloride.
(34) Ammonium nitrate.
(35) Ammonium sulfate.
(36) Hydrogen peroxide.
(37) Thionyl chloride.
(38) Ethyl acetate.
(39) Pseudoephedrine hydrochloride.

(b) A person who possesses more than ten (10) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, pure or adulterated, commits a Class D felony. However, the offense is a Class C felony if the person possessed:

(1) a firearm while possessing more than ten (10) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, pure or adulterated; or

(2) more than ten (10) grams of ephedrine, pseudoephedrine, or phenylpropanolamine, pure or adulterated, in, on, or within one thousand (1,000) feet of:

(A) school property;
(B) a public park;
(C) a family housing complex; or
(D) a youth program center.

(c) A person who possesses anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1) with the intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6, commits a Class D felony. However, the offense is a Class C felony if the person possessed:

(1) a firearm while possessing anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1) with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6; or

(2) anhydrous ammonia or ammonia solution (as defined in IC 22-11-20-1) with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6 in, on, or within one thousand (1,000) feet of:

(A) school property;
(B) a public park;
(C) a family housing complex; or
(D) a youth program center.

(d) Subsection (b) does not apply to a:

(1) licensed health care provider, pharmacist, retail distributor, wholesaler, manufacturer, warehouseman, or common carrier or an agent of any of these persons if the possession is in the regular course of lawful business activities; or

(2) person who possesses more than ten (10) grams of a substance described in subsection (b) if the substance is possessed under circumstances consistent with typical medicinal or household use, including:

(A) the location in which the substance is stored;
(B) the possession of the substance in a variety of:
(i) strengths;
(ii) brands; or
(iii) types; or
(C) the possession of the substance:
(i) with different expiration dates; or
(ii) in forms used for different purposes.

(e) A person who possesses two (2) or more chemical reagents or precursors with the intent to manufacture:

(1) Methcathinone, a schedule I controlled substance under IC 35-48-2-4;
(2) Methamphetamine, a schedule II controlled substance under IC 35-48-2-6;
(3) Amphetamine, a schedule II controlled substance under IC 35-48-2-6; or
(4) Phentermine, a schedule IV controlled substance under IC 35-48-2-10;

commits a Class D felony.

(f) An offense under subsection (e) is a Class C felony if the person possessed:

(1) a firearm while possessing two (2) or more chemical reagents or precursors with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-6; or

(2) two (2) or more chemical reagents or precursors with intent to manufacture methamphetamine, a schedule II controlled substance under IC 35-48-2-

6 in, on, or within one thousand (1,000) feet of:
(A) school property;
(B) a public park;
(C) a family housing complex; or
(D) a youth program center.
(g) A person who sells, transfers, distributes, or furnishes a chemical reagent or precursor to another person with knowledge or the intent that the recipient will use the chemical reagent or precursors to manufacture methamphetamine, methcathinone, amphetamine, or phentermine commits unlawful sale of a precursor, a Class D felony.
As added by P.L.150-1999, SEC.2. Amended by P.L.17-2001, SEC.28. Amended by P.L. 192-2005, SEC.8.

IC 35-48-4-14.7
Sec. 14.7. (a) This section does not apply to the following:
(1) Ephedrine or pseudoephedrine dispensed pursuant to a prescription.
(2) The sale of a drug containing ephedrine or pseudoephedrine to a licensed health care provider, pharmacist, retail distributor, wholesaler, manufacturer, or an agent of any of these persons if the sale occurs in the regular course of lawful business activities. However, a retail distributor, wholesaler, or manufacturer is required to report a suspicious order to the state police department in accordance with subsection (f).
(3) The sale of a drug containing ephedrine or pseudoephedrine by a person who does not sell exclusively to walk-in customers for the personal use of the walk-in customers. However, if the person described in this subdivision is a retail distributor, wholesaler, or manufacturer, the person is required to report a suspicious order to the state police department in accordance with subsection (f).
(b) The following definitions apply throughout this section:
(1) "Constant video monitoring" means the surveillance by an automated camera that:
(A) records at least one (1) photograph or digital image every ten (10) seconds;
(B) retains a photograph or digital image for at least seventy-two (72) hours;
(C) has sufficient resolution and magnification to permit the identification of a person in the area under surveillance; and
(D) stores a recorded photograph or digital image at a location that is immediately accessible to a law enforcement officer.
(2) "Convenience package" means a package that contains a drug having as an active ingredient not more than one hundred twenty (120) milligrams of ephedrine or pseudoephedrine, or both.
(3) "Ephedrine" means pure or adulterated ephedrine.
(4) "Pseudoephedrine" means pure or adulterated pseudoephedrine.
(5) "Suspicious order" means a sale or transfer of a drug containing ephedrine or pseudoephedrine if the sale or transfer:
(A) is a sale or transfer that the retail distributor, wholesaler, or manufacturer is required to report to the United States Drug Enforcement Administration;
(B) appears suspicious to the retail distributor, wholesaler, or manufacturer in light of the recommendations contained in Appendix A of the report to the United States attorney general by the suspicious orders task force under the federal Comprehensive Methamphetamine Control Act of 1996; or
(C) is for cash or a money order in a total amount of at least two hundred dollars ($200).
(6) "Unusual theft" means the theft or unexplained disappearance from a particular retail store of drugs containing ten (10) grams or more of ephedrine, pseudoephedrine, or both in a twenty-four (24) hour period.
(c) This subsection does not apply to a convenience package. A person may sell a drug that contains the active ingredient of ephedrine, pseudoephedrine, or both only if the person complies with the following conditions:
(1) The person does not sell the drug to a person less than eighteen (18) years of age.
(2) The person does not sell drugs containing more than three (3) grams of ephedrine or pseudoephedrine, or both in one (1) transaction.
(3) The person requires:
(A) the purchaser to produce a state or federal identification card;
(B) the purchaser to complete a paper or an electronic log in a format approved by the state police department with the purchaser's name, address, and driver's license or other identification number; and
(C) the clerk who is conducting the transaction to initial or electronically record the clerk's identification on the log.
Records from the completion of a log must be retained for at least two (2) years, and may be inspected by a law enforcement officer in accordance with state and federal law. A retailer who in good faith releases information maintained under this subsection is immune from civil liability unless the release constitutes gross negligence or intentional, wanton, or willful misconduct. This subdivision expires June 30, 2008.
(4) The person stores the drug:
(A) behind a counter in an area inaccessible to a customer or in a locked display case that makes the drug unavailable to a customer without the assistance of an employee; or
(B) directly in front of the pharmacy counter in the direct line of sight of an employee at the pharmacy counter, in an area under constant video monitoring, if the drug is sold in a retail establishment that:
(i) is a pharmacy; or
(ii) contains a pharmacy that is open for business.
(d) A person may not purchase drugs containing more than three (3) grams of ephedrine, pseudoephedrine, or both in one (1) week.
(e) This subsection only applies to convenience packages. A person may not sell drugs containing more than one hundred twenty (120) milligrams of ephedrine or pseudoephedrine, or both in any one (1) transaction if the drugs are sold in convenience packages. A person who sells convenience packages must secure the convenience packages in at least one (1) of the following ways:
(1) The convenience package must be stored not more than thirty (30) feet away from a checkout station or counter and must be in the direct line of

sight of an employee at the checkout station or counter.

(2) The convenience package must be protected by a reliable anti-theft device that uses package tags and detection alarms designed to prevent theft.

(3) The convenience package must be stored in restricted access shelving that permits a purchaser to remove not more than one (1) package every fifteen (15) seconds.

(4) The convenience package must be stored in an area that is under constant video monitoring, and a sign placed near the convenience package must warn that the area is under constant video monitoring.

(f) A retail distributor, wholesaler, or manufacturer shall report a suspicious order to the state police department in writing.

(g) Not later than three (3) days after the discovery of an unusual theft at a particular retail store, the retailer shall report the unusual theft to the state police department in writing. If three (3) unusual thefts occur in a thirty (30) day period at a particular retail store, the retailer shall, for at least one hundred eighty (180) days after the date of the last unusual theft, locate all drugs containing ephedrine or pseudoephedrine at that particular retail store behind a counter in an area inaccessible to a customer or in a locked display case that makes the drug unavailable to customers without the assistance of an employee.

(h) A unit (as defined in IC 36-1-2-23) may not adopt an ordinance after February 1, 2005, that is more stringent than this section.

(i) A person who knowingly or intentionally violates this section commits a Class C misdemeanor. However, the offense is a Class A misdemeanor if the person has a prior unrelated conviction under this section.

(j) Before June 30, 2007, the state police department shall submit a report to the legislative council detailing the effectiveness of this section in reducing the illicit production of methamphetamine. The report must describe the number of arrests or convictions that are attributable to the identification and logging requirements contained in this section, and must include recommendations for future action. The report must be in an electronic format under IC 5-14-6.

Amended by P.L. 192-2005, SEC92.

IC 35-48-4-15

Sec. 15. (a) If a person is convicted of an offense under section 1, 2, 3, 4, 5, 6, 7, 10, or 11 of this chapter, or conspiracy to commit an offense under section 1, 2, 3, 4, 5, 6, 7, 10, or 11 of this chapter, the court shall, in addition to any other order the court enters, order that the person's:

(1) operator's license be suspended;

(2) existing motor vehicle registrations be suspended; and

(3) ability to register motor vehicles be suspended;

by the bureau of motor vehicles for a period specified by the court of at least six (6) months but not more than two (2) years.

(b) If a person is convicted of an offense described in subsection (a) and the person does not hold an operator's license or a learner's permit, the court shall order that the person may not receive an operator's license or a learner's permit from the bureau of motor vehicles for a period of not less than six (6) months.

As added by P.L.67-1990, SEC.13. Amended by P.L.107-1991, SEC.3; P.L.129-1993, SEC.2; P.L.64-1994, SEC.6.

IC 35-48-4-16

Sec. 16. (a) For an offense under this chapter that requires proof of:

(1) delivery of cocaine, a narcotic drug, methamphetamine, or a controlled substance;

(2) financing the delivery of cocaine, a narcotic drug, methamphetamine, or a controlled substance; or

(3) possession of cocaine, narcotic drug, methamphetamine, or controlled substance;

within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center, the person charged may assert the defense in subsection (b) or (c).

(b) It is a defense for a person charged under this chapter with an offense that contains an element listed in subsection (a) that:

(1) a person was briefly in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center; and

(2) no person under eighteen (18) years of age at least three (3) years junior to the person was in, on, or within one thousand (1,000) feet of the school property, public park, family housing complex, or youth program center at the time of the offense.

(c) It is a defense for a person charged under this chapter with an offense that contains an element listed in subsection (a) that a person was in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center at the request or suggestion of a law enforcement officer or an agent of a law enforcement officer.

(d) The defense under this section applies only to the element of the offense that requires proof that the delivery, financing of the delivery, or possession of cocaine, a narcotic drug, methamphetamine, or a controlled substance occurred in, on, or within one thousand (1,000) feet of school property, a public park, a family housing complex, or a youth program center.

As added by P.L.17-2001, SEC.29.

IC 35-48-7

Chapter 7. Central Repository for Controlled Substances Data

IC 35-48-7-1

Sec. 1. As used in this chapter, "advisory committee" refers to the controlled substances advisory committee established by IC 35-48-2-1.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-2

Sec. 2. As used in this chapter, "central repository" refers to the central repository designated by the advisory committee under section 10 of this chapter.
As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.1.

IC 35-48-7-3

Sec. 3. As used in this chapter, "dispenser" has the meaning set forth in IC 35-48-1-13. However, the term does not include the following:

(1) A Type II pharmacy (as defined in IC 25-26-13-17) operated by a hospital licensed under IC 16-21.

(2) A nurse registered or licensed under IC 25-23 or a medication aide who administers a controlled substance at the direction of a physician licensed under IC 25-22.5.

(3) A person who administers or dispenses a controlled substance ordered for a bona fide patient in a facility licensed under IC 16-28.

(4) A pharmacy licensed under IC 25-26-13 when it dispenses prescriptions ordered for bona fide enrolled patients in facilities licensed under IC 16-28.

(5) A practitioner who dispenses not more than a forty-eight (48) hour supply of a controlled substance listed in either schedule II, III, or IV as set forth in IC 35-48-3-9.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-4

Sec. 4. As used in this chapter, "exception report" means a record of data concerning:

(1) a practitioner practicing a particular specialty or field of health care;

(2) a dispenser doing business in a particular location; or

(3) a recipient;

that indicates dispensing or receiving of controlled substances outside norms for dispensing or receiving controlled substances established by the advisory committee under this chapter.
As added by P.L.163-1994, SEC.5.

IC 35-48-7-5

Sec. 5. As used in this chapter, "identification number" refers to the following:

(1) The unique number contained on any of the following:

(A) A valid driver's license of a recipient or a recipient's representative issued under Indiana law or the law of any other state.

(B) A recipient's or a recipient representative's valid military identification card.

(C) A valid identification card of a recipient or a recipient's representative issued by:

(i) the bureau of motor vehicles ~~and~~ as described in IC 9-24-16-3; or

(ii) any other state and that is similar to the identification card issued by the bureau of motor vehicles.

(D) If the recipient is an animal:

(i) the valid driver's license issued under Indiana law or the law of any other state;

(ii) the valid military identification card; or

(iii) the valid identification card issued by the bureau of motor vehicles and described in IC 9-24-16-3 or a valid identification card of similar description that is issued by any other state;

of the animal's owner.

(2) The identification number or phrase designated by the central repository.
Amended by P.L. 204-2005, SEC.22.

IC 35-48-7-5.2

Sec. 5.2. As used in this chapter, "INSPECT" means the Indiana scheduled prescription electronic collection and tracking program established by IC 25-1-13-4.

IC 35-48-7-5.4

Sec. 5.4. As used in this chapter, "interoperability" refers to the INSPECT program electronically sharing reported information with another state concerning the dispensing of a controlled substance:

(1) to a recipient who resides in the other state; or

(2) prescribed by a practitioner whose principal place of business is located in another state.

IC 35-48-7-5.6

Sec. 5.6. As used in this chapter, "patient" means an individual who has requested or received health care services from a provider for the examination, treatment, diagnosis, or prevention of a physical or mental condition.

IC 35-48-7-5.8

Sec. 5.8. As used in this chapter, "practitioner" means a physician, dentist, veterinarian, podiatrist, nurse practitioner, scientific investigator, pharmacist, hospital, or other institution or individual licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in the United States.

IC 35-48-7-6

Sec. 6. As used in this chapter, "recipient" means an individual for whom a controlled substance is dispensed.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-7

Sec. 7. As used in this chapter, "recipient representative" means the individual to whom a controlled substance is dispensed if the recipient is either less than eighteen (18) years of age or unavailable to receive the controlled substance.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-7.5

Sec. 7.5. As used in this chapter, "state" means any state of the United States or the District of Columbia.

IC 35-48-7-8

Sec. 8. (a) The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the central repository the following information:

(A) The recipient's name.

(B) The recipient's or the recipient representative's identification number or the identification number or phrase designated by the central repository.

(C) The recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(2) The information required to be transmitted under this section must be transmitted not more than fifteen (15) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) an electronic device compatible with the receiving device of the central repository;

(B) a computer diskette;

(C) a magnetic tape; or

(D) a pharmacy universal claim form;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

(b) This section expires July 1, 2007.

Amended by P.L. 204-2005, SEC.23.

IC 35-48-7-8.1

Sec. 8.1. (a) This section applies after June 30, 2007.

(b) The advisory committee shall provide for a controlled substance prescription monitoring program that includes the following components:

(1) Each time a controlled substance designated by the advisory committee under IC 35-48-2-5 through IC 35-48-2-10 is dispensed, the dispenser shall transmit to the INSPECT program the following information:

(A) The controlled substance recipient's name.

(B) The controlled substance recipient's or the recipient representative's identification number or the identification number or phrase designated by the INSPECT program.

(C) The controlled substance recipient's date of birth.

(D) The national drug code number of the controlled substance dispensed.

(E) The date the controlled substance is dispensed.

(F) The quantity of the controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) The dispenser's United States Drug Enforcement Agency registration number.

(I) The prescriber's United States Drug Enforcement Agency registration number.

(J) An indication as to whether the prescription was transmitted to the pharmacist orally or in writing.

(K) Other data required by the advisory committee.

(2) The information required to be transmitted under this section must be transmitted not more than seven (7) days after the date on which a controlled substance is dispensed.

(3) A dispenser shall transmit the information required under this section by:

(A) uploading to the INSPECT web site;

(B) a computer diskette; or

(C) a CD-ROM disk;

that meets specifications prescribed by the advisory committee.

(4) The advisory committee may require that prescriptions for controlled substances be written on a one (1) part form that cannot be duplicated. However, the advisory committee may not apply such a requirement to prescriptions filled at a pharmacy with a Type II permit (as described in IC 25-26-13-17) and operated by a hospital licensed under IC 16-21, or prescriptions ordered for and dispensed to bona fide enrolled patients in facilities licensed under IC 16-28. The committee may not require multiple copy prescription forms and serially numbered prescription forms for any prescriptions written. The advisory committee may not require different prescription forms for any individual drug or group of drugs. Prescription forms required under this subdivision must be jointly approved by the committee and by the Indiana board of pharmacy established by IC 25-26-13-3.

(5) The costs of the program.

IC 35-48-7-9

Sec. 9. (a) The health professions bureau or the central repository is responsible for the costs of the program, including the following costs:

(1) Telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository.

(2) Purchase of modems and other hardware required for program participation.

(3) Software and software modifications to allow dispensers to participate in the program.

(b) A dispenser may not be penalized for failure to comply with the program if the health professions bureau or the central repository cannot secure adequate funding to implement the program and cover the costs under subsection (a).

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.3.

IC 35-48-7-10

Sec. 10. (a) The advisory committee shall designate a central repository for the collection of information transmitted under section 8 of this chapter.

(b) The central repository shall do the following:

(1) Create a data base for information required to be transmitted under section 8 of this chapter in the form required under rules adopted by the advisory committee, including search capability for the following:

(A) A recipient's name.

(B) A recipient's or recipient representative's identification number.

(C) A recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.

(F) The quantities of a controlled substance dispensed.

(G) The number of days of supply dispensed.

(H) A dispenser's United States Drug Enforcement Agency registration number.

(I) A prescriber's United States Drug Enforcement Agency registration number.

(J) Whether a prescription was transmitted to the pharmacist orally or in writing.

(2) Provide advisory committee with continuing twenty-four (24) hour a day on-line access to the data base maintained by the central repository.

(3) Secure the information collected by the central repository and the data base maintained by the central repository against access by unauthorized persons.

(4) If the relationship between the advisory committee and the central repository is terminated by statute, provide to the state police department and the advisory committee, within a reasonable time, all collected information and the data base maintained by the central repository.

(c) The advisory committee, may execute a contract with a vendor designated by the advisory committee as the central repository under this section, or the advisory committee may act as the central repository under this chapter.

(d) The central repository may gather prescription data from the Medicaid retrospective drug utilization review program (DUR) established by IC 12-15-35.

(e) The advisory committee may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the central repository.

(f) This section expires July 1, 2007.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.4.

IC 35-48-7-10.1

Sec. 10.1. (a) This section applies after June 30, 2007.

(b) The INSPECT program must do the following:

(1) Create a data base for information required to be transmitted under section 8.1 of this chapter in the form required under rules adopted by the advisory committee, including search capability for the following:

(A) A controlled substance recipient's name.

(B) A controlled substance recipient's or recipient representative's identification number.

(C) A controlled substance recipient's date of birth.

(D) The national drug code number of a controlled substance dispensed.

(E) The dates a controlled substance is dispensed.
(F) The quantities of a controlled substance dispensed.
(G) The number of days of supply dispensed.
(H) A dispenser's United States Drug Enforcement Agency registration number.
(I) A prescriber's United States Drug Enforcement Agency registration number.
(J) Whether a prescription was transmitted to the pharmacist orally or in writing.
(2) Provide the advisory committee with continuing twenty-four (24) hour a day online access to the data base.
(3) Secure the information collected and the data base maintained against access by unauthorized persons.
(c) The advisory committee may execute a contract with a vendor designated by the advisory committee to perform any function associated with the administration of the INSPECT program.
(d) The INSPECT program may gather prescription data from the Medicaid retrospective drug utilization review (DUR) program established under IC 12-15-35.
(e) The advisory committee may accept and designate grants, public and private financial assistance, and licensure fees to provide funding for the INSPECT program.

IC 35-48-7-11
Sec. 11. (a) Information received by the central repository under section 8 of this chapter is confidential.
(b) The advisory committee shall carry out a program to protect the confidentiality of the information described in subsection (a). The advisory committee may disclose the information to another person only under subsection (c), (d), or (f).
(c) The advisory committee may disclose confidential information described in subsection (a) to any person who is engaged in receiving, processing, or storing the information.
(d) The advisory committee may release confidential information described in subsection (a) to the following persons:
(1) A member of the board, the committee, or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.
(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:
(A) an investigation;
(B) an adjudication; or
(C) a prosecution;
of a violation under any state or federal law that involves a controlled substance.
(3) A law enforcement officer who is:
(A) authorized by the state police department to receive information of the type requested;
(B) approved by the advisory committee to receive information of the type requested; and
(C) engaged in the investigation or prosecution of a violation under any state or federal law that involves a controlled substance.
(e) Before the advisory committee releases confidential information under subsection (d), the applicant must demonstrate to the advisory committee that:
(1) the applicant has reason to believe that a violation under any state or federal law that involves a controlled substance has occurred; and
(2) the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation described in subdivision (1).
(f) The advisory committee may release to:
(1) a member of the board, the advisory committee, or another governing body that licenses practitioners;
(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or
(3) a law enforcement officer who is:
(A) authorized by the state police department to receive the type of information released; and
(B) approved by the advisory committee to receive the type of information released;
confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.
(g) The information described in subsection (f) may not be released until it has been reviewed by a member of the advisory committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data and until that member has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (h).
(h) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (f) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:
(1) A proceeding under IC 16-42-20.
(2) A proceeding under any state or federal law that involves a controlled substance.
(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.
(i) The advisory committee may compile statistical reports from the information described in subsection (a). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.
(j) This section expires July 1, 2007.
As added by P.L.163-1994, SEC.5.

IC 35-48-7-11.1

Sec. 11.1. (a) This section applies after June 30, 2007.

(b) Information received by the INSPECT program under section 8.1 of this chapter is confidential.

(c) The advisory committee shall carry out a program to protect the confidentiality of the information described in subsection (b). The advisory committee may disclose the information to another person only under subsection (d), (e), or (h).

(d) The advisory committee may disclose confidential information described in subsection (b) to any person who is authorized to engage in receiving, processing, or storing the information.

(e) Except as provided in subsections (f) and (g), the advisory committee may release confidential information described in subsection (b) to the following persons:

(1) A member of the board, the advisory committee, or another governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a prosecution of a violation under any state or federal law that involves a controlled substance.

(2) An investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general, who is engaged in:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution;

of a violation under any state or federal law that involves a controlled substance.

(3) A law enforcement officer who is an employee of:

(A) a local, state, or federal law enforcement agency; or

(B) an entity that regulates controlled substances or enforces controlled substances rules or laws in another state;

that is certified to receive information from the INSPECT program.

(4) A practitioner or practitioner's agent certified to receive information from the INSPECT program.

(5) A controlled substance monitoring program in another state with which Indiana has established an interoperability agreement.

(f) Information provided to an individual under:

(1) subsection (e)(3) is limited to information:

(A) concerning an individual or proceeding involving the unlawful diversion or misuse of a schedule II, III, IV, or V controlled substance; and

(B) that will assist in an investigation or proceeding; and

(2) subsection (e)(4) may be released only for the purpose of:

(A) providing medical or pharmaceutical treatment; or

(B) evaluating the need for providing medical or pharmaceutical treatment to a patient.

(g) Before the advisory committee releases confidential information under subsection (e), the applicant must be approved by the INSPECT program in a manner prescribed by the advisory committee.

(h) The advisory committee may release to:

(1) a member of the board, the advisory committee, or another governing body that licenses practitioners;

(2) an investigator for the consumer protection division of the office of the attorney general, a prosecuting attorney, the attorney general, a deputy attorney general, or an investigator from the office of the attorney general; or

(3) a law enforcement officer who is:

(A) authorized by the state police department to receive the type of information released; and

(B) approved by the advisory committee to receive the type of information released;

confidential information generated from computer records that identifies practitioners who are prescribing or dispensing large quantities of a controlled substance.

(i) The information described in subsection (h) may not be released until it has been reviewed by:

(1) a member of the advisory committee who is licensed in the same profession as the prescribing or dispensing practitioner identified by the data; or

(2) the advisory committee's designee;

and until that member or the designee has certified that further investigation is warranted. However, failure to comply with this subsection does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (j).

(j) An investigator or a law enforcement officer receiving confidential information under subsection (d), (e), or (h) may disclose the information to a law enforcement officer or an attorney for the office of the attorney general for use as evidence in the following:

(1) A proceeding under IC 16-42-20.

(2) A proceeding under any state or federal law that involves a controlled substance.

(3) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(k) The advisory committee may compile statistical reports from the information described in subsection (b). The reports must not include information that identifies any practitioner, ultimate user, or other person administering a controlled substance. Statistical reports compiled under this subsection are public records.

(l) This section may not be construed to require a practitioner to obtain information about a patient from the data base.

(m) A practitioner is immune from civil liability for an injury, death, or loss to a person solely due to a practitioner seeking or not seeking information from the INSPECT program. The civil immunity described in this subsection does not extend to a practitioner if the practitioner receives information directly from the INSPECT program and then negligently misuses this information. This subsection does not apply to an act or omission that is a result of gross negligence or intentional misconduct.

(n) The advisory committee may review the records of the INSPECT program. If the advisory committee determines that a violation of the law may have

occurred, the advisory committee shall notify the appropriate law enforcement agency or the relevant government body responsible for the licensure, regulation, or discipline of practitioners authorized by law to prescribe controlled substances.

IC 35-48-7-12

Sec. 12. (a) The advisory committee shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the central repository, including the controlled substances to be included in the program required under section 8 of this chapter.

(2) Design for the creation of the data base required under section 10 of this chapter.

(3) Requirements for the development and installation of on-line electronic access by the advisory committee to information collected by the central repository.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8 of this chapter without a written prescription or on a form other than a form specified in section 8(a)(4) of this chapter.

(b) This section expires July 1, 2007.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-12.1

Sec. 12.1. (a) This section applies after June 30, 2007.

(b) The advisory committee shall adopt rules under IC 4-22-2 to implement this chapter, including the following:

(1) Information collection and retrieval procedures for the INSPECT program, including the controlled substances to be included in the program required under section 8.1 of this chapter.

(2) Design for the creation of the data base required under section 10.1 of this chapter.

(3) Requirements for the development and installation of online electronic access by the advisory committee to information collected by the INSPECT program.

(4) Identification of emergency situations or other circumstances in which a practitioner may prescribe, dispense, and administer a prescription drug specified in section 8.1 of this chapter without a written prescription or on a form other than a form specified in section 8.1(b)(4) of this chapter.

(c) The advisory committee may:

(1) Set standards for education courses for individuals authorized to use the INSPECT program.

(2) Identify treatment programs for individuals addicted to controlled substances monitored by the INSPECT program.

(3) Work with impaired practitioner associations to provide intervention and treatment.

IC 35-48-7-13

Sec. 13. (a) The controlled substances data fund is established to fund the operation of the central repository. The fund shall be administered by the Indiana professional licensing agency.

(b) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and sixteen percent (16%) of the controlled substances registration fees imposed under IC 35-48-3-1.

(c) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(d) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

(e) This section expires July 1, 2007.

As added by P.L.163-1994, SEC.5. Amended by P.L.107-1999, SEC.5.

IC 35-48-7-13.1

Sec. 13.1. (a) This section applies after June 30, 2007.

(b) The controlled substances data fund is established to fund the operation of the INSPECT program. The fund shall be administered by the Indiana professional licensing agency.

(c) Expenses of administering the fund shall be paid from money in the fund. The fund consists of grants, public and private financial assistance, and sixteen percent (16%) of the controlled substances registration fees imposed under rules adopted under IC 35-48-3-1.

(d) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

IC 35-48-7-14

Sec. 14. A person who knowingly or intentionally violates this chapter commits a Class A misdemeanor.

As added by P.L.163-1994, SEC.5.

IC 35-48-7-15

(*Repealed by P.L.214-2001, SEC.1.)*

The following are repealed [effective July 1, 2007]: IC 35-48-7-2; IC 35-48-7-9

ARTICLE 2. CONTROLLED SUBSTANCE MONITORING

Rule 1. Electronic Prescription Monitoring Program

858 IAC 2-1-1 Definitions
Authority: IC 35-48-7-12
Affected: IC 35-48-2; IC 35-48-7-3

Sec. 1. (a) As used in this article, "department" refers to the Indiana state police department.
(b) As used in this article, "dispense" means the actual or constructive transfer from one (1) person to another whether or not there is an agency relationship.
(c) As used in this article, "dispenser" has the meaning set forth in IC 35-48-7-3.
(d) As used in this article, "Schedule II controlled substance" means a controlled substance classified in Schedule II:
(1) under IC 35-48-2-6; or
(2) by rule adopted under IC 35-48-2-14.
(e) As used in this article, "Schedule III controlled substance" means a controlled substance classified in Schedule III:
(1) under IC 35-48-2-8; or
(2) by rule adopted under IC 35-48-2-14.
(f) As used in this article, "Schedule IV controlled substance" means a controlled substance classified in Schedule IV:
(1) under IC 35-48-2-10; or
(2) by rule adopted under IC 35-48-2-14.
(g) As used in this article, "Schedule V controlled substance" means a controlled substance classified in Schedule V:
(1) under IC 35-48-2-12; or
(2) by rule adopted under IC 35-48-2-14.
(h) As used in this article, "universal claim form" means a nationally recognized standard form developed by the National Council for Prescription Drug Programs used for billing drug claims to insurance plans. *(Controlled Substances Advisory Committee; 858 IAC 2-1-1; filed Oct 6, 1994, 1:30 p.m.: 18 IR 266; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1383; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344; filed Apr 16, 2004, 10:07 a.m.: 27 IR 2731)*

858 IAC 2-1-2 Applicability
Authority: IC 35-48-7-12
Affected: IC 35-48-7-8

Sec. 2. This article shall apply to Schedule II, III, IV, and V controlled substances and shall not apply to any other drug. *(Controlled Substances Advisory Committee; 858 IAC 2-1-2; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344; filed Apr 16, 2004, 10:07 a.m.: 27 IR 2731)*

858 IAC 2-1-3 Prescription monitoring program
Authority: IC 35-48-7-12
Affected: IC 35-48-7-8

Sec. 3. (a) Each time a Schedule II, III, IV, or V controlled substance is dispensed, the dispenser shall transmit to the central repository information outlined in IC 35-48-7-8.
(b) Dispensers reporting more than twenty (20) Schedule II, III, IV, or V prescriptions in any given month must transmit to the central repository information outlined in IC 35-48-7-8 utilizing one (1) of the following:
(1) An electronic device compatible with the receiving device of the central repository.
(2) A computer diskette.
(3) A magnetic tape.
(c) Dispensers reporting less than twenty (20) Schedule II, III, IV, or V prescriptions in any given month may submit data utilizing a universal claim form or transmit the information utilizing the ways outlined in subsection (b).
(d) The committee may grant a waiver to a dispenser which is unable to transmit the required data in accordance with subsection (b) for a period of one hundred eighty (180) days from the effective date of this rule which one hundred eighty (180) day period may be extended by the committee at its discretion. During the effective period of the waiver and any extension granted by the committee, the dispenser shall submit the required data in a format acceptable to the committee. *(Controlled Substances Advisory Committee; 858 IAC 2-1-3; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344; filed Apr 16, 2004, 10:07 a.m.: 27 IR 2731)*

858 IAC 2-1-4 Application for payment of pharmacy costs
Authority: IC 35-48-7-12
Affected: IC 35-48-7-9

Sec. 4. (a) Before the department will pay for the purchase of hardware to comply with the program, an applicant must file an application provided by the department and provide the following information:

(1) The dispenser's name, address, and Indiana license number.

(2) A detailed description of the dispenser's current computer hardware, including the name and manufacturer of all components.

(3) A detailed description of the hardware the dispenser intends to purchase and two (2) price quotes from computer hardware vendors.

(4) The reason why the dispenser believes the computer hardware will be necessary to comply with the program.

(5) The number of Schedule II, III, IV, and V prescriptions the pharmacy dispenses in any given month.

(b) Upon receipt of an application requesting that the department pay for computer hardware, the committee shall evaluate the dispenser's current technology in determining whether the dispenser would be required to purchase new computer hardware. The committee shall take into account the ability of the dispenser to utilize any one (1) of the methods outlined in section 3 of this rule.

(c) The central repository shall provide grants to software vendors to update software in order for dispensers to comply with the program as outlined in contract form.

(d) The department and the central repository shall pay for telephone access charges, line charges, and switch charges for transmission of data by dispensers to the central repository. *(Controlled Substances Advisory Committee; 858 IAC 2-1-4; filed Oct 6, 1994, 1:30 p.m.: 18 IR 267; filed Jan 27, 2000, 7:49 a.m.: 23 IR 1384; readopted filed Nov 30, 2001, 2:47 p.m.: 25 IR 1344; filed Apr 16, 2004, 10:07 a.m.: 27 IR 2732)*

ARTICLE 2. CONTROLLED SUBSTANCES

Rule 1. Definitions

856 IAC 2-1-1 Definitions
Authority: IC 35-48-3-1
Affected: IC 4-21.5; IC 35-48-2-1

Sec. 1. Definitions. As used herein, the following terms shall have the meanings specified:
(a) The term "Act" means the Indiana Uniform Controlled Substances Act of 1973. IC 1971, 35-24.1 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.
(b) The term "basic class" means, as to controlled substances listed in Schedules I and II *[856 IAC 2-2-2 and 856 IAC 2-2-3]*:
(1) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in Section 2.11(b) *[856 IAC 2-2-2(b)]* of this chapter;
(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in Section 2.11(c) *[856 IAC 2-2-2(c)]* of this part;
(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in Section 2.11(d) *[856 IAC 2-2-2(d)]* of this part;
(4) Each of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(ii) Apomorphine;
(iii) Codeine;
(iv) Ethylmorphine;
(v) Hydrocodone;
(vi) Hydromorphone;
(vii) Metopon;
(viii) Morphine;
(ix) Oxycodone;
(x) Oxymorphone;
(xi) Thebaine;
(xii) Mixed alkaloids of opium listed in Section 2.12(b)(2) *[856 IAC 2-2-3(b)(2)]* of this part;
(xiii) Cocaine; and
(xiv) Ecgonine;
(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation, listed in Section 2.12(c) *[856 IAC 2-2-3(c)]* as amended, of this part;
(6) Methamphetamine, including salts, isomers, and salts of isomers.
(7) Amphetamine, its salts, optical isomers and salts of its optical isomers;
(8) Phenmetrazine and its salts; and
(9) Methylphenidate.
(c) The term "Administration" means the Drug Enforcement Administration, formerly the Bureau of Narcotics and Dangerous Drugs.
(d) The term "agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.
(e) The term "controlled premises" means—
(1) Places where original or other records or documents required under the Act *[IC 35-48]* are kept or required to be kept, and
(2) Places including factories, warehouses, or other establishments, conveyances, where persons registered under the Act *[IC 35-48]* or exempted from registration under the Act *[IC 35-48]* may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of controlled substances.
(f) The term "Administrator" means the Director of the Federal Drug Enforcement Administration who has been delegated authority under the Controlled Substances Act of 1970 (84 Stat. 1242; 21 U.S.C. 801) by the Attorney General of the United States (28 C.F.R. 0.100), as amended.
(g) The term "hearing" means any hearing held pursuant to the provisions of IC 1971, 4-22-1 through 4-22-1-30 *[Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]* as amended and 4-22-2, for the purpose of granting, denying, or revoking, or suspending a registrant or application for registrant or a hearing amending these rules pursuant to IC 1971, 35-24.1 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.
(h) The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted by the State of Indiana or the United States, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.
(i) The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the state of Indiana or the United States, to dispense a controlled substance in the course of practice, but does not include a pharmacy.
(j) The term "person" includes any individual, corporation, government or governmental subdivision or agency, business, trust partnership, association or other legal entity.

(k) The term “pharmacist” means any practitioner licensed as a pharmacist by the State of Indiana to dispense controlled substances and shall include pharmacist interns licensed by the State of Indiana, to dispense controlled substances under the supervision of a pharmacist licensed by the State of Indiana.
(l) The term “prescription” means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user. (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).
(m) The terms “register” and “registration” refers only to registration required and permitted by IC 1971, 35-24.1-3-2 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.
(n) The term “registrant” means any person who is registered or exempted from registration pursuant to IC 1971, 35-24.1-3-2 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.
(o) Any term not defined in this section shall have the definition set forth in IC 1971, 35-24.1-1-1 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.
(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-1-2 Controlled substances advisory committee; function; hearings
Authority: IC 35-48-3-1
Affected: IC 4-21.5; IC 35-48-2-1

Sec. 2. Function. The Controlled Substances Advisory Committee shall serve as a consultative and advisory body to the Board in all matters relative to additions, deletions and transfers of substances to or among schedules of control established by IC 1971, 35-24.1 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended.

In addition, the advisory committee may, as representatives of the Board, conduct hearings regarding control of substances, and it shall, as representatives of the Board, conduct hearings and make recommended findings in matters affecting the denial, suspension, or revocation of registrations. All adjudicatory hearings shall be conducted in a manner consistent with the provision of IC 1971, 35-24.1-3-4 through IC 1971, 35-24.1-3-5 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48]*, and IC 1971, 4-22-1 *[Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]*as amended. *(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.11; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-1-3 Meetings; organization
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 3. Meetings and Organization. The controlled substances advisory committee shall meet not later than sixty (60) days after the appointment of their entire membership and thereafter shall meet upon the request of the Board. The committees shall select, from among their members, a chairman, vice-chairman, and secretary who shall serve terms of one year from the date of selection. In any case in which a committee officer shall be unable to serve a full term, the committee shall select another to serve in his own right a full term. *(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-1-4 Duties of officers
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 4. Duties of Officers. The chairman of the committee, or the vice-chairman in the absence of the chairman, shall preside at all meetings of the committee. In addition, the chairman or his designee shall preside over all hearings conducted by the committee on behalf of the Board.

The secretary of the committee shall be responsible for keeping the minutes of all meetings and he shall further be charged with the responsibility of assuring that a complete and accurate record is made of all hearings conducted before the committee. To this end, he may, with the consent of the Board, arrange for the attendance of such stenographers or court reporters as are necessary for the recording of such hearings. *(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.13; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-1-5 Rulemaking powers
Authority: IC 35-48-3-1
Affected: IC 4-22-2; IC 35-48-2-1

Sec. 5. Rules of Conduct. The advisory committee may, with the approval of the Board, make such other rules regulating its conduct and procedure as are necessary and proper for the orderly conduct of its business.

All such rules, when they may affect procedure or substance of matters which may come before the Board for adjudication, after promulgation in accordance with IC 1971, 4-22-2 as amended, shall be in writing and shall be made available upon request to parties appearing before the committee. *(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.14; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-1-6 Recommendations and findings
Authority: IC 35-48-3-1

Affected: IC 35-48-2-1

Sec. 6. Recommendations and findings. Recommendations and findings to be in writing. Whenever, in the discharge of its duties, the advisory committee shall be required to make recommendations or findings upon matters heard before the committee, such recommendations to the Board shall be in writing and shall include a summary of relevant evidence, opinions, and laws upon which such recommendations or findings are based. *(Indiana Board of Pharmacy; Reg 28,Ch I,Sec 1.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

Rule 2. Controlled Substances Code Number Schedules I through IV

856 IAC 2-2-1 Controlled substances code numbers
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 1. Controlled Substances Code Number. (a) Each controlled substance, or basic class thereof, listed in Schedules I through IV *[856 IAC 2-2-2 — 856 IAC 2-2-5]* has been assigned a "Controlled Substances Code Number" for purposes of identification of the substances or class on certain Certificates of Registration issued by the Indiana State Board of Pharmacy pursuant to Section 3.42 *[856 IAC 2-3-19]* of the Chapter. Certain applicants for registration must include the appropriate numbers on the application as required in Section 3.32(d) *[856 IAC 2-3-13(d)]* of this Chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Controlled Substances Code Number for any purpose. *(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-2-2 Schedule I
Authority: IC 35-48-2-14; IC 35-48-3-1
Affected: IC 35-48-2-4

Sec. 2. (a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the controlled substances code number set forth opposite it.

(b) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

(1) Acetylmethadol 9601
(2) Allylprodine 9602
(3) Alphacetylmethadol (except levo-alphalmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM) 9603
(4) Alphameprodine 9604
(5) Alphamethadol 9605
(6) Benzethidine 9606
(7) Betacetylmethadol 9607
(8) Betameprodine 9608
(9) Betamethadol 9609
(10) Betaprodine 9611
(11) Clonitazene 9612
(12) Dextromoramide 9613
(13) Dextrorphan 9614
(14) Diampromide 9615
(15) Diethylthiambutene 9616
(16) Difenoxin 9168
(17) Dimenoxadol 9617
(18) Dimepheptanol 9618
(19) Dimethylthiambutene 9619
(20) Dioxaphetyl butyrate 9621
(21) Dipipanone 9622
(22) Ethylmethylthiambutene 9623
(23) Etonitazene 9624
(24) Etoxeridine 9625
(25) Furethidine 9626
(26) Hydroxypethidine 9627
(27) Ketobemidone 9628
(28) Levomoramide 9629
(29) Levophenacylmorphan 9631
(30) Morpheridine 9632
(31) Noracymethadol 9633
(32) Norlevorphanol 9634

(33) Normethadone 9635
(34) Norpipanone 9636
(35) Phenadoxone 9637
(36) Phenampromide 9638
(37) Phenomorphan 9647
(38) Phenoperidine 9641
(39) Piritramide 9642
(40) Proheptazine 9643
(41) Properidine 9644
(42) Propiram 9649
(43) Racemoramide 9645
(44) Trimeperidine 9646

(c) Opium derivatives. Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Acetrophine 9319
(2) Acetyldihydrocodeine 9051
(3) Benzylmorphine 9052
(4) Codeine methylbromide 9070
(5) Codeine-N-Oxide 9053
(6) Cyprenorphine 9054
(7) Desomorphine 9055
(8) Dihydromorphine 9145
(9) Drotebanol 9335
(10) Etorphine (Except Hydrochloride Salt) 9056
(11) Heroin 9200
(12) Hydromorphinol 9301
(13) Methyldesorphine 9302
(14) Methylidihydromorphine 9304
(15) Morphine methylbromide 9305
(16) Morphine methylsufonate 9306
(17) Morphine-N-Oxide 9307
(18) Myrophine 9308
(19) Nicocodeine 9309
(20) Nicomorphine 9312
(21) Normorphine 9313
(22) Pholcodine 9314
(23) Thebacon 9315

(d) Hallucinogenic substances. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (for purposes of this subsection only, “isomer” includes the optical, position, and geometric isomers):

(1) 4-Bromo-2, 5-Dimethoxyamphetamine 7391
Some trade or other names:
4-Bromo-2, 5-Dimethoxy-a-methylphenethylamine; 4-Bromo-2, 5-DMA
(2) 2, 5-Dimethoxyamphetamine 7396
Some trade or other names:
2, 5-Dimethoxy-a-methylphenethylamine; 2,5-DMA
(3) 4-Methoxyamphetamine 7411
Some trade or other names:
4-Methoxy-a-methylphenethylamine: Paramethoxyamphetamine: PMA
(4) 5-methoxy-3, 4-methylenedioxy amphetamine 7401
(5) 4-methyl-2, 5-dimethoxyamphetamine 7395
Some trade and other names:
4-methyl-2,5-dimethoxy-a-methylphenethylamine: “DOM”; and “STP”.
(6) 3, 4-methylenedioxy amphetamine 7400
(7) 3, 4, 5-trimethoxy amphetamine 7390
(8) Bufotenine 7433
Some trade and other names:
3-(B-Dimethylaminoethyl)-5-hydroxyindol; 3-(2-Dimethylaminoethyl)-5-indolo; N, N-dimenthylserotonin; 5-hydroxy-N, N-dimethyltryptamine; mappine.
(9) Diethyltryptamine 7434
Some trade and other names: N, N-Diethyltryptamine, DET.

(10) Dimethyltryptamine 7435
Some trade or other names: DMT
(11) Ibogaine 7260
Some trade and other names:
7-Ethyl-6, 6a, 7, 8, 9, 10, 12, 13-octahydro-2-methoxy-6, 9-methano-5H-pyrido (1', 2': 1, 2) azepino 4, 5-b) indole; tabernanthe iboga.
(12) Lysergic acid diethylamide 7315
(13) Marihuana 7360
(14) Mescaline 7381
(15) Peyote 7415
Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not; the seeds thereof; any extract from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or extracts.
(Interprets 21 U.S.C. 812(c), Schedule I(c) (12))
(16) N-ethyl-3-piperidyl benzilate 7482
(17) N-methyl-3-piperidyl benzilate 7484
(18) Psilocybin 7437
(19) Psilocyn 7438
(20) Tetrahydrocannabinols 7370
Synthetic equivalents of the substances contained in plant, or in the resinous extractives of Cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
$_^{1}$ cis or trans tetrahydrocannabinol, and their optical isomers.
$_^{6}$ cis or trans tetrahydrocannabinol and their optical isomers.
$_^{3, 4}$ cis or trans tetrahydrocannabinol, and its optical isomers.
(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.)
(21) Thiophene Analog of Phencyclidine 7470
Some trade or other names:
1-(1-(2-thienyl) cyclohexyl) piperidine); 2-Thienyl Analog of Phencyclidine, TPCP.
(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Mecloqualone 2572
(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.11; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 31, 1994, 5:00 p.m.: 17 IR 2335; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-3 Schedule II
Authority: IC 35-48-2-14; IC 35-48-3-1
Affected: IC 35-48-2-6

Sec. 3. (a) Schedule II shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the controlled substances code number set forth opposite it.
(b) Substances, vegetable origin, or chemical synthesis. Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naloxone and its salts and naltrexone and its salts but including the following:
(A) Raw opium 9600
(B) Opium extracts 9610
(C) Opium fluid extracts 9620
(D) Powdered opium 9639
(E) Granulated opium 9640
(F) Tincture of opium 9630
(G) Apomorphine 9030
(H) Codeine 9050
(I) Ethylmorphine 9190
(J) Etorphine hydrochloride 9059
(K) Hydrocodone 9193
(L) Hydromorphone 9194
(M) Metopon 9260
(N) Morphine 9300
(O) Oxycodone 9143
(P) Oxymorphone 9652

(Q) Thebaine 9333
(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subdivision (1), except that these substances shall not include the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw (9650).
(4) Coca Leaves (9040) and salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (9041) or ecgonine (9180).
(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrine alkaloids of the opium poppy) 9670.

(c) Opiates. Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:
(1) Alphaprodine 9010
(2) Anileridine 9020
(3) Benzitramide 9800
(4) Dihydrocodeine 9120
(5) Diphenoxylate 9170
(6) Fentanyl 9801
(7) Isomethadone 9226
(8) Levo-alphacetylmethadol 9648
Some trade and other names:
levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM.
(9) Levomethorphan 9210
(10) Levorphanol 9220
(11) Metazocine 9240
(12) Methadone 9250
(13) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-dyphenyl butane 9254
(14) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid 9802
(15) Pethidine 9230
(16) Pethidine-Intermediate-A,4-cyano-1- methyl-4-phenylpiperidine 9232
(17) Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate 9233
(18) Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-4-carboxylic acid 9234
(19) Phenazocine 9715
(20) Piminodine 9730
(21) Racemethorphan9732
(22) Racemorphan 9733

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:
(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
(2) Methamphetamine, including its salts, isomers, and salts of isomers 1105
(3) Phenmetrazine and its salts 1631
(4) Methylphenidate 1724

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:
(1) Methaqualone 2565
(2) Amobarbital 2125
(3) Secobarbital 2315
(4) Pentobarbital 2270
(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.12; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 31, 1994, 5:00 p.m.: 17 IR 2336; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-4 Schedule III
Authority: IC 35-48-3-1
Affected: IC 35-48-2-8

Sec. 4. (a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II, which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under 1308.32, and any other drug of the quantitative composition shown in that list for those drugs or that is the same, except that it contains a lesser quantity of controlled substances 1405
(2) Benzphetamine 1228
(3) Chlorphentermine 1645
(4) Clortermine 1647
(5) Mazindol 1605
(6) Phendimetrazine 1615

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system:
(1) Any compound, mixture, or preparation containing:
(A) Amobarbital 2125
(B) Secobarbital 2315
(C) Pentobarbital 2270
or any salt thereof and one (1) or more other active medicinal ingredient that are not listed in any schedule.
(2) Any suppository dosage form containing:
(A) Amobarbital 2125
(B) Secobarbital 2315
(C) Pentobarbital 2270
or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
(3) Any substance that contains any quantity of a derivative of barbituric acid or any salt thereof 2100
(4) Chlorhexadol 2510
(5) Ketamine, its salts, isomers, and salts of isomers 7285
Some other names for ketamine: (-2(2-chlorophenyl) -2- (methylamino) - cyclohexanone
(6) Lysergic acid 7300
(7) Lysergic acid amide 7310
(8) Methyprylon 2575
(9) Sulfondiethylmethane 2600
(10) Sulfonethylmethane 2605
(11) Sulfonmethane 2610

(d) Nalorphine (a narcotic drug) 9400

(e) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:
(1) Not more than one and eight-tenths (1.8) grams of codeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803
(2) Not more than one and eight-tenths (1.8) grams of codeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9804
(3) Not more than three hundred (300) milligrams of dihydrocodeinone, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium 9805
(4) Not more than three hundred (300) milligrams of dihydrocodeinone, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients, in recognized therapeutic amounts 9806
(5) Not more than one and eight-tenths (1.8) grams of dihydrocodeine, per one hundred (100) milliliters or not more than ninety (90) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9807
(6) Not more than three hundred (300) milligrams of ethylmorphine, per one hundred (100) milliliters or not more than fifteen (15) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808
(7) Not more than five hundred (500) milligrams of opium per one hundred (100) milliliters or per one hundred (100) grams or not more than twenty-five (25) milligrams per dosage unit, with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9809
(8) Not more than fifty (50) milligrams of morphine, per one hundred (100) milliliters or per one hundred (100) grams with one (1) or more active, nonnarcotic ingredients in recognized therapeutic amounts 9810

(f) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any quantity of anabolic steroids, including its salts, isomers, and salts of isomers whenever the existence of such salts of isomers is possible within the specific chemical designation 4000

(g) For hallucinogenic substances, dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a United States Food and Drug Administration-approved drug product 7369
(Some other names for dronabinol: (6aR-trans) - 6a, 7, 8, 10a - tetrahydro-6,6,9 - trimethyl - 3-pentyl- 6H - dibenzo[b,d]pyrano-1-ol, or (1) $_{9}$ - (trans) - tetrahydrocan-nabinol.) *(Indiana Board of Pharmacy; Reg 28, Ch II, Sec 2.13; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jun 9, 1977, 8:55 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2503; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-2-5 Schedule IV
Authority: IC 35-48-3-1
Affected: IC 35-48-2-10

Sec. 5. (a) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Barbital 2145
(2) Chloral betaine 2460
(3) Chloral hydrate 2465
(4) Chlordiazepoxide 2744
(5) Clonazepam 2737
(6) Clorazepate 2768
(7) Diazepam 2765
(8) Ethchlorvynol 2540
(9) Ethinamate 2545
(10) Flurazepam 2767
(11) Mebutamate 2800
(12) Meprobamate 2820
(13) Methohexital 2264
(14) Methylphenobarbital 2250
(15) Oxazepam 2835
(16) Paraldehyde 2585
(17) Petrichloral 2591
(18) Phenobarbital 2285

(c) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine 1670

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Diethylpropion 1608
(2) Phentermine 1640
(3) Pemoline (including organometallic complexes and chelates thereof) 1530

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.14; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-6 Schedule V

Authority: IC 35-48-3-1
Affected: IC 35-48-2-12

Sec. 6. (a) Schedule V shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.

(b) Narcotic drugs containing nonnarcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs or salts thereof, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone:

(1) Not more than 200 milligrams of codeine, per 100 milliliters or per 100 grams.
(2) Not more than 100 milligrams of dihydrocodeine, per 100 milliliters or per 100 grams.
(3) Not more than 100 milligrams of ethylmorphine, per 100 milliliters or per 100 grams.
(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-7 Application for exception of stimulant or depression compound; revocation

Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 7. Application for exception of a stimulant or depressant compound. (a) Any person seeking to have any compound, mixture, or preparation containing any depressant or stimulant substance listed in Chapter 2, Section 2.13(b) or (c) *[856 IAC 2-2-4(b) or (c)]* or in Section 2.14 *[856 IAC 2-2-5]* excepted from the application of all or any part of the Act *[IC 35-48]* pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended, may apply to the Indiana Board of Pharmacy for such exception.

(b) An application for an exception under this section shall be approved by the Board, provided that such application shall contain a copy of the Administration's approval for such request for an exception from the Federal Controlled Substances Act.

(c) Within a reasonable period of time after the receipt of an application for an exception under this section, the Indiana State Board of Pharmacy shall notify the applicant of its acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Indiana State Board of Pharmacy need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section.

(d) The Indiana Board of Pharmacy may at any time revoke any exception granted pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]*, as amended, upon a finding that such exception from the Federal Controlled Substances Act was terminated, suspended or revoked. The revocation of the exception granted under this Act *[IC 35-48]* shall become effective upon the Board's notifying the person to whom such exception was granted by certified mail of such revocation. *(Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.21; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)*

856 IAC 2-2-8 Excepted stimulant or depressant compounds

Authority: IC 35-48-3-1

Affected: IC 35-48-2-8; IC 35-48-2-10

Sec. 8. The Indiana Board of Pharmacy may except any compound, mixture, or preparation containing any depressant or stimulant substance listed in Section 2.13(b) or (c) *[856 IAC 2-2-4(b) or (c)]*, or in Section 2.14 *[856 IAC 2-2-5]* from the application of all or any part of the Act pursuant to IC 1971, 35-24.1-2-8(e) or 10(c) *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended, the drugs which were excepted by the Bureau or Administration on April 1, 1973 under section 202(d) of the Federal Controlled Substances Act (21 U.S.C. 812(d)) have been excepted by the Indiana State Board of Pharmacy from the application of IC 1971, 25-24.1-3, 6 and 8 *[Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.]* as amended, and the application of Section 3.74(d) *[856 IAC 2-3-33(d)]* (rule) for administrative purposes only. The excepting of these drugs by the Indiana State Board of Pharmacy should not be construed as an adoption or rejection of the criteria by which these drugs were originally excepted. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

The following is a list of the excepted stimulant or depressant compounds under these regulations *[856 IAC 2-2]*.

The Excepted Prescription Drugs Table is not on tape. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.22; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-9 Application for exclusion of stimulant or depression compound; revocation
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 9. Application for exclusion of a stimulant or depressant compound. (a) Any person seeking to have any non-narcotic substance which may, under the Federal Food, Drug, and Cosmetic Act or state law, be lawfully sold over-the-counter without a prescription, excluded from any schedule, pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, may apply to the Indiana Board of Pharmacy for such exclusion.

(b) An application for an exclusion under this section shall be approved by the Board, provided that such application shall contain a copy of the Administration's approval for such request for an exclusion from the Federal Controlled Substances Act.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Indiana State Board of Pharmacy shall notify the applicant of its acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Indiana State Board of Pharmacy need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of paragraph (b) of this section.

(d) The Indiana State Board of Pharmacy may at any time revoke any exclusion granted pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, upon a finding that such exclusion from the Federal Controlled Substances Act was terminated, suspended or revoked. The revocation of the exclusion granted under this Act [IC 35-48] shall become effective upon the board's notifying the person to whom such exclusion was granted by certified mail of such revocation. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.23; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-10 Excluded nonnarcotic substances, stimulant or depressant compounds
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 10. Excluded non-narcotic substances, stimulant, or depressant compounds. (a) The Indiana Board of Pharmacy may exclude any non-narcotic substance from a schedule if such substance may, under the Federal Food, Drug and Cosmetic Act or state law, be lawfully sold over-the-counter without a prescription pursuant to IC 1971, 35-24.1-2-1(g) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, the drugs which were excluded by the Bureau or Administration on January 1, 1974 under section 201(g)(1) of the Federal Controlled Substances Act (21 U.S.C. 811(g) (1)) have been excluded by the Indiana State Board of Pharmacy from the schedules of IC 1971, 35-24.1-2-4, 6, 8, 10, and 12 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended. The exclusion of these drugs by the Indiana State Board of Pharmacy should not be construed as an adoption or rejection of the criteria by which these drugs were originally excluded. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exclusion in order for that drug to be excluded. The following is a list of the presently excluded non-narcotic substances under these regulations. The Excluded Over-the-Counter Drugs Table is not on tape. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.24; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-11 Exempt chemical preparations
Authority: IC 35-48-3-1
Affected: IC 35-48-2-1

Sec. 11. Exempt Chemical Preparations. (a) The chemical preparations and mixtures specifically listed in subparagraph (b) of this Section have been exempted by the Indiana Board of Pharmacy from the application of IC 1971, 35-24.1-3-2, 3, 6 and 8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, which preparation or mixture is intended for laboratory, industrial, educational or special research purposes and not for general administration to a human being or other animal. The exemption to be valid must be in strict compliance with the requirements imposed for the preparation or mixture prescribed in Part 1308, Section 1308.24 of Title 21 of the Code of Federal Regulations, effective January 1, 1973, and no exemption granted pursuant to this Section affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation. Distribution, possession and use of an exempt chemical preparation are lawful for registrants and non-registrants only as long as such distribution, possession or use is intended for laboratory, industrial or educational purposes and not for immediate or subsequent administration to a human being or other animal.

(b) The following preparations and mixtures in the form and quantity listed in the application submitted (indicated as the “date of application”) are designated as exempt chemical preparations for the purposes set forth in this Section. & The Exempt Chemical Preparations Table is not on tape. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.25; filed Jul 9, 1974, 9:29 am: Unpublished; filed Jun 9, 1977, 8:55 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-12 Rulemaking hearings
Authority: IC 35-48-3-1
Affected: IC 4-22-2; IC 35-48-3-1

Sec. 12. Hearings for rule making. In any case where the Indiana Board of Pharmacy shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, the procedures for such hearing and accompanying proceedings shall be governed generally by the rule making procedures set forth in IC 1971, 4-22-2 as amended, and such procedures, if relating to standards and schedules, be of record in accordance with IC 1971, 35-24.1-2-1 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-13 Purpose of public hearings
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 13. Purpose of hearing. Whenever proceedings are initiated pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, of this chapter, the Indiana Board of Pharmacy shall hold a hearing of record for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to IC 1971, 35-24.1-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.
On the date set for hearing any interested party in person or by attorney shall be afforded an adequate opportunity to participate in the formulation of the proposed rule or rules through the presentation of facts or argument or the submission of written data or views. All relevant matter presented shall be given full consideration by the Board.
The Board may adopt procedures in addition to those required by this Act [IC 35-48] including the holding of conferences and inviting and permitting the submission of suggestions, facts, argument and views of interested persons in advance of the drafting of the proposed rule or rules. (Indiana Board of Pharmacy; Reg 28,Ch II,Sec 2.32; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-2-14 Exempt anabolic steroid products
Authority: IC 35-48-2-14
Affected: IC 35-48-2

Sec. 14. The following anabolic steroid containing compounds, mixtures, or preparations have been exempted from this rule and are not controlled substances:

Trade Name	Composition	Company
Androgyn L.A.	Vial; testosterone nathate 90 mg-ml; estradiol valerate 4 mg-ml	Forest Pharmaceuticals St. Louis, MO
Andro-estro 90-4	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Rugby Laboratories Rockville Centra, NY
depANDROGYN	Vial; testosterone cypionate 50 mg-ml;estradiol cypionate 2 mg-ml	Forest Pharmaceuticals St. Louis, MO
DEPO-T.E.	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Quality Researchuticals Carmel, IN
deptestROGEN	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Martica Pharmaceuticals Phoenix, AZ
Duomone	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Wintec Pharmaceuticals Pacific, MO
DURAtestRIN	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	W.E. Hauck Alpharetta, GA
DUO-SPAN II	Vial; testosterone cypionate 50 mg-ml; Esterified cypionate 2 mg-ml	Primedics Laboratories Gardena, CA
Estratest	Tablet; esterified estrogens 1.25 mg; methyltestosterone 2.5 mg	Solvay Pharmaceuticals Marietta, GA
Estratest HS	Tablet; esterified estrogens 0.625 mg; methyltestosterone 1.25 mg	Solvay Pharmaceuticals

PAN estra test	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Pan American Labs Covington, LA
Premarin with methyltestosteron	Tablet; conjugated estrogens 1.25 mg; methyltestosterone 10.0 mg	Ayerst Labs, Inc. New York, NY
Premarin with methyltestosteron	Tablet; conjugated estrogens 0.625 mg; methyltestosterone 5.0 mg	Ayerst Labs, Inc. New York, NY
Test-ESTRO cypi	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Rugby Laboratories Rockville Center, NY
Testosterone Cyp estradiol Cyp 2	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	I.D.E. - Interstate Amityville, NY
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Best Generics No. Miami Beach, FL
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Goldline Labs Ft. Lauderdale, FL
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Scein Pharmaceuticals Port Washington, NY
Testosterone	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Steris Labs, Inc. Phoenix, AZ
Testosterone tion	Vial; testosterone enanthate 90 mg-ml; estradiol valerate 4 mg-ml	Steris Labs, Inc. Phoenix, AZ

(Indiana Board of Pharmacy; 856 IAC 2-2-14; filed May 31, 1994, 5:00 p.m.: 17 IR 2337; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 3. Registration Information—Special Instructions

856 IAC 2-3-1 Registration information furnished upon request
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 1. Information; special instructions. Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Indiana State Board of Pharmacy. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.02; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-2 Persons required to register
Authority: IC 35-48-3-1
Affected: IC 35-48-3-3

Sec. 2. Persons required to register. Every person who manufactures, distributes, or dispenses any controlled substance or who proposes to engage in the manufacture, distribution, or dispensing of any controlled substance shall obtain annually a registration unless exempted by law or pursuant to sections 3.14—3.17 [856 IAC 2-3-5 — 856 IAC 2-3-8] of this chapter. Only persons actually engaged in such activities are required to obtain registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration).
As soon after the effective date of these rules as is practicable, the Board shall issue a provisional certificate to all persons when in possession of a valid State of Indiana or Federal certificate of registration authorizing such persons to manufacture, distribute, dispense, prescribe or possess controlled substances. The provisional certificates shall be valid until the Board shall declare that applications for annual renewals shall begin and until such applications have been acted upon by the Board. During the first renewal period, when it is instituted, applications shall be required from all prospective registrants in alphabetically ordered increments according to a schedule to be adopted by the Board. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.11; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-3 Independent activities; separate registration required; exceptions

Authority: IC 35-48-3-1
Affected: IC 35-48-3-3; IC 35-48-3-4

Sec. 3. Separate registration for independent activities. (a) The following groups of activities are deemed to be independent of each other:
(1) Manufacturing controlled substances;
(2) Distributing controlled substances;
(3) Dispensing controlled substances listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6];
(4) Conducting research (other than research described in sub-paragraph (6) of this paragraph) with controlled substances listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6];
(5) Conducting instructional activities with controlled substances listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6];
(6) Conducting research with narcotic drugs listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] for the purpose of continuing the dependence on such drugs of a narcotic drug dependent person in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program pursuant to a Notice of Claimed Investigational Exemption for a New Drug approved by the Food and Drug Administration;
(7) Conducting research and instructional activities with controlled substances listed in Schedule I [856 IAC 2-2-2]; and
(8) Conducting chemical analysis with controlled substances listed in any Schedule.
(b) Every person who engages in more than one group of independent activities shall obtain a separate registration for each group of activities except as provided in this paragraph. Any person, when registered to engage in the group of activities described in each subparagraph in this paragraph, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities, provided that, unless specifically exempted, he complies with all requirements and duties prescribed by law for persons registered to engage in such coincident activities:
(1) A person registered to manufacture any controlled substance or basic class of controlled substance shall be authorized to distribute that substance or class, but no other substance or class which he is not registered to manufacture;
(2) A person registered to manufacture any controlled substance listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] shall be authorized to conduct chemical analysis and pre-clinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;
(3) A person registered to conduct research with a basic class of controlled substance listed in Schedule I [856 IAC 2-2-2] shall be authorized to manufacture such class if and to the extent that such manufacture is set forth in a research protocol federally approved by the Drug Enforcement Administration and to distribute such class to other persons registered or authorized to conduct research with such class or registered or authorized to conduct chemical analysis with controlled substances;
(4) A person registered or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture such substances for analytical or instructional purposes, to distribute such substances to other persons registered or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from registration pursuant to section 3.16 [856 IAC 2-3-7], and to conduct instructional activities with controlled substances; and
(5) A person registered or authorized to conduct research (other than research described in paragraph (a)(6) of this section) with controlled substances listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research, to manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration, to distribute such substances to other persons registered or authorized to conduct chemical analysis, exempted from registration pursuant to Section 3.16 [856 IAC 2-3-7], and to conduct instructional activities with controlled substances;
(6) A person registered to dispense controlled substances listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] shall be authorized to conduct research (other than research described in
paragraph (a) (6) of this section) and to conduct instructional activities with those substances.
(7) A person registered as a manufacturer shall be authorized to conduct one, all or several of the activities and coincident activities enumerated and described in paragraphs (b)(1), (b)(2), (b)(3), (b)(4), and (b)(5) under a single registration if set forth in his application and pertaining to those controlled substances or schedules as set forth in his application. (For example, a manufacturer under a single registration may perform all or any of the following activities, by way of illustration and not limitation; (a) manufacture and distribute any controlled substance or basic class, (b) chemical analysis, (c) Schedule I [856 IAC 2-2-2] research pursuant to a federally approved protocol, (d) Schedule II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] research, and (e) instructional activity if set forth in his application and for those controlled substances or schedules as set forth for each activity.
(c) A single registration to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities. A person registered to conduct research with controlled substances listed in Schedule I [856 IAC 2-2-2] may conduct research with any substance listed in Schedule I [856 IAC 2-2-2] for which he has filed and had approved a research protocol, by the Federal Drug Enforcement Administration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-4 Separate registrations for separate locations; exceptions
Authority: IC 35-48-3-1
Affected: IC 16-1-39-2; IC 16-1-40; IC 35-48
Sec. 4. Separate registrations for separate locations. (a) A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, dispensed, or possessed by a person.
(b) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed, or dispensed:

(1) A warehouse where controlled substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to registered locations other than the registered location from which the substances were delivered or to persons not required to register by virtue of IC 1971, 35-24.1-3-2(c)(2) [Repealed by P.L.26-1977, SECTION 25. Compare IC 35-48-3-3.] as amended.
(2) An office used by agents of a registrant where sales of controlled substances are solicited, made, or supervised but which neither contains such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders; and
(3) An office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(c) The requirement of registration is waived for ambulances as defined by IC 16-1-39-2 and 836 IAC 1-1-1 operated by an ambulance service provider also defined at 836 IAC 1-1-1 which holds certification as a provider organization as this term is defined in IC 16-1-40 from the Indiana Emergency Medical Services Commission, providing that the pharmacies of the supervising or sponsoring hospitals hold a valid Indiana Board of Pharmacy permit and valid Indiana and Federal Controlled Substances Registration. (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.13; filed Jul 9, 1974, 9:29 am: unpublished; filed Feb 11, 1981, 9:05 am: 4 IR 377; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-5 Exemption of agents or employees; affiliated practitioners; paramedics

Authority: IC 35-48-3-1
Affected: IC 16-1-40; IC 35-48-3-3

Sec. 5. Exemption of agents and employees; affiliated practitioners. (a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his business or employment.

(b) An individual practitioner (other than an intern, resident, or foreign-trained physician) who is an agent or employee of another practitioner registered to dispense controlled substances may, when acting in the usual course of his employment, administer, and dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he practices, under the registration of the employer or principal practitioner in lieu of being registered himself. (For example, a pharmacist employed by a pharmacy need not be registered individually to fill a prescription for controlled substances in a pharmacy if so registered).

(c) An individual practitioner who is an intern, resident, or foreign-trained physician may dispense, administer, and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom he is employed in lieu of being registered himself, provided that:

(1) Such dispensing or prescribing is done in the usual course of his professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he is practicing;
(3) The hospital or other institution by whom he is employed has determined that the individual practitioner is so permitted to dispense, administer, or prescribe drugs by the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his employment with the hospital or institution;
(5) The hospital or other institution authorizes the intern, resident, or foreign-trained physician to dispense or prescribe under the hospital registration and designates a specific internal code number for each intern, resident, or foreign-trained physician so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., AP 0123456-10 or AP 0123456-A12); and
(6) A current list of internal codes and the corresponding individual practitioner is kept by the hospital or other institution and is made available to the public upon request for the purpose of verifying the authority of the prescribing individual practitioner.

(d) The requirement of registration is waived for advanced emergency medical technicians and emergency paramedics as described in IC 16-1-40 and 836 IAC 2-1-1 insofar as they administer controlled substances within the applicable requirements and standards of IC 16-1-40 as well as the rules and regulations promulgated thereunder by the Indiana Emergency Medical Services Commission. (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.14; filed Jul 9, 1974, 9:29 am: unpublished; filed Feb 11, 1981, 9:05 am: 4 IR 378; errata, 4 IR 536; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-6 Exemption of military or public health service personnel

Authority: IC 35-48-3-1
Affected: IC 35-48-3-3

Sec. 6. Exemption of certain military and other personnel. (a) The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of his official duties. Such officials shall follow procedures set forth in Part 6 [856 IAC 2-6] of this chapter regarding prescriptions, but shall state the branch of service or agency (e.g., “U.S. Army” or “Public Health Service”) and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his Social Security identification number.

(b) If any official exempted by this section also engages as a private individual in any activity or group of activities for which registration is required, such official shall obtain a registration for such private activities. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.15; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-7 Exemption of law enforcement officers; registration of law enforcement laboratories

Authority: IC 35-48-3-1
Affected: IC 35-48-3-3

Sec. 7. Exemption of law enforcement officials. (a) The requirement of registration is waived for the following persons in the circumstances described in this section:
(1) Any officer or employee of the Drug Enforcement Administration, any officer of the U.S. Bureau of Customs, any officer or employee of the United States Food and Drug Administration, and any other Federal officer who is lawfully engaged in the enforcement of any Federal law relating to controlled substances, drugs or customs, and is duly authorized to possess controlled substances in the course of his official duties; and
(2) Any officer or employee of any State, or any political subdivision or agency thereof, who is engaged in the enforcement of any State or local law relating to controlled substances and is duly authorized to possess controlled substances in the course of his official duties.

(b) Any official exempted by this section may, when acting in the course of his official duties, possess any controlled substance and distribute any such substance to any other official who is also exempted by this section and acting in the course of his official duties.

(c) Any official exempted by this section may procure any controlled substance in the course of an inspection, in accordance with IC 1971, 35-24.1-5-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, or in the course of any criminal investigation involving the person from whom the substance was procured.

(d) In order to enable law enforcement agency laboratories to obtain and transfer controlled substances for use as standards in chemical analysis, such laboratories must obtain annually a registration to conduct chemical analysis. Such laboratories shall be exempted from payment of a fee for registration. Laboratory personnel, when acting in the scope of their official duties, are deemed to be officials exempted by this section and within the activity described in IC 1971, 35-24.1-5-6(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. For the purpose of this paragraph, laboratory activities shall not include field or other preliminary chemical tests by officials exempted by this section. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.16; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-8 Exemption of civil defense officials
Authority: IC 35-48-3-1
Affected: IC 35-48-3-3

Sec. 8. Exemption of civil defense officials. (a) The requirement of registration is waived for any offical of a civil defense or disaster relief organization who, in the course of his official duties, is authorized to:

(1) Maintain, and distribute for such maintenance, controlled substances held for emergency use; or
(2) Procure controlled substances for the purpose of maintaining supplies for emergency use, provided that all of such procurement is from the U.S. General Services Administration and in accordance with the rules of the U.S. Office of Emergency Preparedness.

(b) The requirement of registration is waived for any official of a civil defense or disaster relief organization during a state of emergency or disaster within his jurisdiction proclaimed by the President or by a concurrent resolution of the Congress, which official, in the course of his official duties during such emergency or disaster, is authorized to:

(1) Dispense controlled substances; or
(2) Procure or distribute controlled substances, provided that all such procurement is on a special “Civil Defense Emergency Order Form,” as described in this section.

(c) Civil Defense Emergency Order Forms shall be furnished by the U.S. Office of Emergency Preparedness and will contain the name of the civil defense or disaster relief organization. Such forms may be used and are valid only during a state of emergency or disaster proclaimed by the President or by a concurrent resolution of the Congress for the area in which the organization using such forms has civil defense or disaster relief jurisdiction, who shall state his position and the nature and legal designation of the emergency or disaster. Such forms may be filled by any person registered under the Act [IC 35-48]. The Organization shall, upon the execution of a Civil Defense Emergency Order Form, be deemed to be registered under the Act [IC 35-48] for purposes or recordkeeping pursuant to Part 4 [856 IAC 2-4]. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.17; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-9 Registration fees
Authority: IC 25-26-13-4
Affected: IC 25-26-13-4

Sec. 9. (a) For each registration or reregistration to manufacture controlled substances, the registrant shall pay a fee of one hundred dollars ($100).

(b) For each registration or reregistration to distribute controlled substances, the registrant shall pay a fee of one hundred dollars ($100).

(c) For each registration or reregistration to dispense or to conduct research or instructional activities with controlled substances listed in 856 IAC 2-2-3 through 856 IAC 2-2-6, the registrant shall pay a fee of one hundred dollars ($100).

(d) For each registration or reregistration to conduct research or instructional activities with controlled substances listed in 856 IAC 2-2-2, the registrant shall pay a fee of one hundred dollars ($100).

(e) For each registration or reregistration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee of one hundred dollars ($100).

(f) For each registration or reregistration for a practitioner seeking to prescribe, administer, or dispense controlled substances, the registrant shall pay a fee of sixty dollars ($60). (Indiana Board of Pharmacy; Reg 28, Ch III, Sec 3.21; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed Jul 8, 1981, 9:00 a.m.: 4 IR 1499; filed Jul 20, 1984, 10:00 a.m.: 7 IR 2379; filed Aug 21, 1986, 10:30 a.m.: 10 IR 63; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3106; readopted filed Oct 17, 2001, 3:25 p.m.: 25 IR 940)

856 IAC 2-3-10 Time and method of payment; refund (Repealed)

Sec. 10. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-11 Persons exempt from fee
Authority: IC 35-48-3-1
Affected: IC 35-48-3-1

Sec. 11. Persons exempt from fee. (a) The Indiana State Board of Pharmacy shall exempt from payment of a fee for registration or re-registration the following persons:
(1) Any official or agency of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Veterans' Administration or Public Health Service who or which is authorized to procure or purchase controlled substances for official use; and
(2) Any official, employee, or other civil officer or agency of the United States, or any State, or any political subdivision or agency thereof, who or which is authorized to purchase controlled substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct research, instructional activities, or chemical analysis with such substances, or any combination thereof, in the course of his or its official duties or employment.
(b) In order to claim exemption from payment of a registration or re-registration fee, the registrant shall have completed the certification on the appropriate form, wherein the registrant's superior (if an individual) or officer (if an agency) certifies to the status and address of the registrant and to the authority of the registrant to acquire, possess, or handle controlled substances.
(c) Exemption from payment of a registration or re-registration fee does not relieve the registrant of any other requirements or duties prescribed by law. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.23; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-12 Time for registration or re-registration application
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 12. Time for application for registration; expiration date. (a) Any person who is required to be registered and who is not so registered may apply for registration at any time. No person required to be registered shall engage in any activity for which registration is required until the application for registration is granted by the Indiana Board of Pharmacy.
(b) Any person who is registered may apply to be re-registered not more than 60 days, before the expiration date his registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-13 Application forms; reregistration forms
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 13. (a) If any person is required to be registered, and is not so registered and is applying for registration, the following apply:
(1) To manufacture and perform other coincident activities (see 856 IAC 2-3-3(b)(7) [section 3(b)(7) of this rule]) with controlled substances, he or she shall apply on Form CSR-1A.
(2) To dispense, or to conduct research (other than research described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule]) with, or to conduct instructional activities with, controlled substances listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, he or she shall apply on Form CSR-1.
(3) To conduct research with narcotic drugs listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, as described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule], he or she shall apply on Form CSR-1.
(4) To conduct research with controlled substances listed in Schedule I under 856 IAC 2-2-2, he or she shall apply on Form CSR-1 in accordance with an approved Schedule I under 856 IAC 2-2-2 research protocol. Such protocol shall be subject to inspection by the Indiana board of pharmacy.
(5) To conduct instructional activities with controlled substances listed in Schedule I under 856 IAC 2-2-2, he or she shall apply as a researcher on Form CSR-1 with two (2) copies of a statement describing the nature, extent, and duration of such instructional activities attached to the form.
(6) To conduct chemical analysis with controlled substances listed in any schedule, he or she shall apply on Form CSR-1.
(7) To distribute controlled substances, he or she shall apply on Form CSR-1.
(b) If any person is registered and is applying for reregistration, the following apply:
(1) To manufacture and perform other coincident activities (see 856 IAC 2-3-3(b)(7)[section 3(b)(7) of this rule]), with controlled substances, he or she shall apply on Form CSRII-A.
(2) To dispense, or to conduct research (other than research described in 856 IAC 2-3-3(a)(6)[section 3(a)(6) of this rule]) with, or to conduct instructional activities with, controlled substances listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, he or she shall apply on Form CSR-II.
(3) To conduct research with narcotic drugs listed in Schedules II through V under 856 IAC 2-2-3 through 856 IAC 2-2-6, as described in 856 IAC 2-3-3(a)(6) [section 3(a)(6) of this rule], he or she shall apply on Form CSR-II.
(4) To continue to conduct research with controlled substances listed in Schedule I under 856 IAC 2-2-2 under one (1) or more approved research protocols, by the Drug Enforcement Administration, he or she shall apply on Form CSR-II.
(5) To continue to conduct instructional activities with controlled substances listed in Schedule I under 856 IAC 2-2-2 under one (1) or more approved instructional statements, he or she shall apply as a researcher on Form CSR-II.
(6) To conduct chemical analysis with controlled substances listed in any schedule, he or she shall apply on Form CSR-II.
(7) To distribute controlled substances, he or she shall apply on Form CSR-II.

(c) Applications for registration may be obtained by writing to the controlled substance division of the Indiana board of pharmacy. Applications for reregistration will be mailed, as applicable, to each registered person approximately sixty (60) days before the expiration date of his or her registration; if any registered person does not receive such forms within forty-five (45) days before the expiration date of his or her registration, he or she must promptly give notice of such fact and request such forms by writing to the controlled substance division of the Indiana board of pharmacy.

(d) Each application for registration to handle any basic class of controlled substance listed in Schedule I under 856 IAC 2-2-2 (except to conduct chemical analysis with such classes), and each application for registration to manufacture a basic class of controlled substance listed in Schedule II under 856 IAC 2-2-3, or to conduct research with any narcotic controlled substance listed in Schedule II under 856 IAC 2-2-3, shall include the controlled substances code number, as set forth in Part I [856 IAC 2-1], for each basic class or substance to be covered by such registration.

(e) Each application shall include all information called for on the form unless the item is not applicable, in which case this fact shall be indicated.

(f) Each application, attachment, or other document filed as part of an application shall be signed by:

(1) the applicant, if an individual;

(2) a partner of the applicant, if a partnership; or

(3) an officer or authorized representative of the applicant, if a corporation, corporate division, association, t trust, or other entity.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.32; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1342)

856 IAC 2-3-14 Filing of application; joint filing (Repealed)

Sec. 14. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-15 Acceptance for filing; defective applications; requests for additional information (Repealed)

Sec. 15. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-3-16 Additional information; failure to supply

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 16. Additional information. The Indiana State Board of Pharmacy may require an applicant to submit such documents or written statements of fact relevant to the application as the Board deems necessary and as provided by IC 1971, 35-24.1-3-3(a) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable period of time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Indiana State Board of Pharmacy in granting or denying the application. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.35; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-17 Amendment or withdrawal of application

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 17. Amendments to and withdrawal of applications. An application may be amended or withdrawn without permission of the Indiana Board of Pharmacy at any time. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.36; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-18 Inspection and review of application by board

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 18. Administrative review generally. The Indiana Board of Pharmacy may inspect, or cause to be inspected, the establishment of an applicant or registrant, pursuant to IC 1971, 35-24.1-5-2 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. The Indiana Board of Pharmacy shall review the application for registration and other information regarding an applicant in order to determine whether the applicable standards of IC 1971, 35-24.1-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, have been met by the applicant. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.41; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-19 Certificate of registration; denial of registration

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 19. Certificate of registration; denial of registration. (a) The Indiana State Board of Pharmacy shall issue a Certificate of Registration Form CSR-3 to an applicant if the issuance of registration or re-registration is required under the applicable provisions of IC 1971, 35-24.1-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. In the event that the issuance of registration or re-registration is not required, the Indiana State Board of Pharmacy may deny the application. Before denying any application, the Indiana State Board of Pharmacy shall issue

an order to show cause pursuant to Section 3.46 [856 IAC 2-3-23] and, if requested by the applicant, shall hold a hearing on the application pursuant to Section 3.51, through Section 3.53 [856 IAC 2-3-24 — 856 IAC 2-3-26].

(b) The Certificate of Registration shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Controlled Substances Code Number (as set forth in Part 2 [856 IAC 2-2] of this Act) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the Certificate of Registration in a readily retrievable manner and shall permit inspection of the Certificate of Registration and shall permit inspection of the certificate by any official, agent, or employee of the Board or any agency engaged in enforcement of laws relating to controlled substances. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.42; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-20 Suspension or revocation of registration

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 20. Suspension or revocation of registration. (a) The Indiana Board of Pharmacy may suspend any registration pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, for any period of time he determines.

(b) The Indiana Board of Pharmacy may revoke any registration pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(c) Before revoking or suspending any registration, the Indiana Board of Pharmacy shall issue an order to show cause, such order shall be sent by certified mail to address of the registrant, advising registrant of his rights to a hearing, Form CSR-4, pursuant to section 3.46 [856 IAC 2-3-23]. Notwithstanding the requirements of this section, however, the Indiana Board of Pharmacy may suspend any registration pending a final order pursuant to section 3.44 [856 IAC 2-3-21].

(d) Upon service of the final order of the Indiana Board of Pharmacy following a hearing or waiver thereof suspending or revoking registration, the registrant shall immediately deliver his Certificate of Registration to the Indiana Board of Pharmacy. Also, upon service of the final order of the Indiana Board of Pharmacy suspending or revoking registration, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver all controlled substances in his possession to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy; or

(2) Place all controlled substances in his possession under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(e) In the event that revocation or suspension is limited to a particular controlled substance or substances, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required to be paid for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the Indiana Board of Pharmacy. Also, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy all of the particular controlled substance or substances affected by the revocation or suspension which are in his possession; or

(2) Place all of such substances under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.43; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-21 Suspension pending final order

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 21. Suspension of registration pending final order. (a) The Indiana Board of Pharmacy may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registration should not be revoked or suspended, in any case where it finds that there is an imminent danger to the public health or safety. If the Indiana Board of Pharmacy so suspends, it shall serve with the order to show cause pursuant to section 3.46 [856 IAC 2-3-23] an order of immediate suspension which shall contain a statement of its findings regarding the danger to public health or safety.

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the Indiana Board of Pharmacy. Also, upon service of the order of the Indiana Board of Pharmacy immediately suspending registration, the registrant shall, as instructed by the Indiana Board of Pharmacy:

(1) Deliver all affected controlled substances in his possession to the Indiana Board of Pharmacy or to authorized agents of the Indiana Board of Pharmacy; or

(2) Place all of such substances under seal as described in IC 1971, 35-24.1-3-4(c) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended.

(c) Any suspension shall continue in effect until the conclusion of all preceedings upon the revocation or suspension, including any judicial review thereof, unless sooner withdrawn by the Indiana Board of Pharmacy or dissolved by a court of competent jurisdiction. Any registrant whose registration is suspended under this section may request a hearing on the revocation or suspension of his registration at a time earlier than specified in the order to show cause pursuant to section 3.46 [856 IAC 2-3-23], which request shall be granted by the Indiana Board of Pharmacy who shall fix a date for such hearing as early as reasonably possible. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.44; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-22 Extension of registration pending re-registration order

Authority: IC 35-48-3-1

Affected: IC 35-48-3-5

Sec. 22. Extension of registration pending final order. In the event that an applicant for re-registration (who is doing business under a registration previously granted and not revoked or suspended) has applied for re-registration at least 30 days before the date on which the existing registration is due to expire, the existing registration of the applicant shall automatically be extended and continue in effect until the date on which the Indiana Board of Pharmacy so issues its final order. The Indiana Board of Pharmacy may extend any other existing registration under the circumstances contemplated in this section even though the registrant failed to apply for re-registration at least 30 days before expiration of the existing registration, with or without request by the registrant, if the Indiana Board of Pharmacy finds that such extension is not inconsistent with the public health and safety. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.45; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-23 Order to show cause
Authority: IC 35-48-3-1
Affected: IC 35-48-3-5

Sec. 23. Order to show cause. (a) If, upon examination of the application for registration from any applicant and other information regarding the applicant, the Indiana Board of Pharmacy is unable to make the determinations required by the applicable provisions of IC 1971, 35-24.1-3-3 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, to register the applicant, the Indiana Board of Pharmacy shall serve upon the applicant an order to show cause why the registration should not be denied.

(b) If, upon information regarding any registrant, the Indiana Board of Pharmacy determines that the registration of such registrant is subject to suspension or revocation pursuant to IC 1971, 35-24.1-3-4 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.], as amended, the Indiana Board of Pharmacy shall serve upon the registrant an order to show cause why a registration should not be revoked or suspended.

(c) The order to show cause shall call upon the applicant or registrant to appear before the Indiana Board of Pharmacy at a time and place stated in the order, which shall not be less than 30 days after the date of receipt of the order. The order to show cause shall also contain a statement of the legal basis for such hearing and for the denial, revocation, or suspension of registration and a summary of the matters of fact and law asserted.

(d) The Indiana Board of Pharmacy shall hold a hearing at the time and place stated in the order, pursuant to section 3.51 [856 IAC 2-3-24].

(e) When authorized by the section 3.51 [856 IAC 2-3-24] any agent of the Indiana Board of Pharmacy may serve the order to show cause. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.46; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-24 Evidentiary hearing
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 24. The controlled substances advisory committee shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the denial, revocation, or suspension of any registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.51; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-3-25 Hearing procedures
Authority: IC 35-48-3-1
Affected: IC 4-21.5; IC 35-48-3-6

Sec. 25. Hearing for granting, denial, revocation, or suspension of application. (a) In any case where the advisory committee shall hold a hearing on any registration or application therefor, the procedures for such hearing shall be governed generally by the adjudication procedures of IC 1971, 4-22-1-1 to 4-22-1-30 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.], as amended, and by sections 3.52-3.53 [this section and 856 IAC 2-3-26].

(b) Any hearing under this part shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under the Act [IC 35-48] or any other law of this State.

(c) At any such hearing the advisory committee shall designate one of its members as presiding officer.

(d) At any such hearing a quorum of the advisory committee consisting of a majority of its membership shall hear the evidence and the disputed issues of law and they shall after the conclusion of the hearing, prepare for the Board recommended findings, facts, and conclusions of law.

(e) The committee's recommended findings and facts and conclusions of law shall be acted on by the Board in the manner required by IC 1971, 4-22-1 [Repealed by P.L.18-1986, SECTION 2. See IC 4-21.5.]. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.52; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-26 Modification or waiver of rules
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 26. Waiver or modification of rules.The presiding officer at the advisory committee hearings or of the Indiana Board of Pharmacy (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines than no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served and if all parties consent. Such notice of modification or waiver shall be made a part of the record of the hearing. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.53; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-27 Modification of registration
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 27. Modification in registration. Any registrant may apply to modify his registration to authorize the handling of additional controlled substances or to change his name or address by submitting a letter of request to the Indiana Board of Pharmacy. The letter shall contain the registrant's name, address, registration number, and the substances and/or schedule to be added to his registration or the name or address and shall be signed by the same person who signed the most recent application for registration or re-registration. If the registrant is seeking to handle additional controlled substances listed in Schedule I [856 IAC 2-2-2] for the purpose of research or instructional activities, a Federally approved research protocol describing each research project involving the additional substances shall be subject to inspection by the Indiana Board of Pharmacy or he shall attach two copies of a statement describing the nature, extent, and duration of such instructional activities, as appropriate. No fee shall be required to be paid for the modification. The request for modification shall be handled in the same manner as an application for registration.
If the modification of registration is approved, the Indiana Board of Pharmacy shall issue a new certificate of registration to the registrant, who shall maintain it with the old certificate of registration until the expiration date. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.61; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-28 Termination of registration; notice to board
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 28. Termination of registration. The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall notify the Indiana Board of Pharmacy promptly of such fact. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.62; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-29 Transfer of registration
Authority: IC 35-48-3-1
Affected: IC 35-48-3-6

Sec. 29. Transfer of registration. No registration or any authority conferred thereby shall be assigned or otherwise transferred except upon such conditions as the Indiana Board of Pharmacy may specifically designate and then only pursuant to its written consent. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.63; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-30 Security requirements; approval of security system
Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 30. Security requirements generally. (a) All applicants and registrants shall provide and maintain effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Indiana Board of Pharmacy shall use the security requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 — 856 IAC 2-3-35] as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Sections 3 .72 [856 IAC 2-3-31], 3.73 [856 IAC 2-3-32], and 3.75 [856 IAC 2-3-34] may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in Sections 3.72-3.76 [856 IAC 2-3-31 — 856 IAC 2-3-35] may be deemed sufficient by the Indiana Board of Pharmacy after evaluation of the overall security system and needs of a registrant or applicant. In evaluating the overall security system of a registrant or applicant, the Indiana Board of Pharmacy may consider any of the following factors as it may deem relevant to the need for strict compliance with security requirements:
(1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.);
(2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units usable powders or nonusable powders);
(3) The quantity of controlled substance handled;
(4) The location of the premises and the relationship such location bears on security needs;
(5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
(6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
(7) The type of closures on vaults, safes, and secure enclosures;
(8) The adequacy of key control systems and/or combination lock control systems;
(9) The adequacy of electric detection and alarm systems, if any including use of supervised transmittal lines and standby power sources;
(10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
(11) The adequacy of supervision over employees having access to manufacturing and storage areas;
(12) The procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel;
(13) The availability of local police protection or of the registrant's or applicant's security personnel, and;

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

(c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule, or as a result of a non-controlled substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 — 856 IAC 2-3-35] when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in Sections 3.72-3.76 [856 IAC 2-3-31 — 856 IAC 2-3-35] may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the Indiana Board of Pharmacy.

(e) Approval by the Drug Enforcement Administration of any security system, proposed security system, plans, blueprints, sketches or other material as being in substantial compliance with the requirements as set forth in 301.72-301.76 of Title 21 of the Code of Federal Regulations shall be deemed in compliance with Sections 3.71 through 3.75 [856 IAC 2-3-30 — 856 IAC 2-3-34] of these regulations, where applicable.

(f) Physical security controls of locations registered under the Harrison Narcotic Act or the Narcotics Manufacturing Act of 1960 on April 20, 1971, shall be deemed to comply substantially with the standards set forth in Sections 3.71 [this section], 3.72 [856 IAC 2-3-31], 3.73 [856 IAC 2-3-32], and 3.75 [856 IAC 2-3-34]. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.71; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-31 Storage areas; security controls for nonpractitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 31. Physical security controls for nonpractitioners: Storage Areas. (a) Schedules I and II [856 IAC 2-2-2 and 856 IAC 2-2-3]. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II [856 IAC 2-2-2 or 856 IAC 2-2-3] shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe or steel cabinet.

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques.

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve.

(2) A vault constructed before, or under construction on October 1, 1973, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after October 1, 1973:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with “day-gate” which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Indiana Board of Pharmacy or the Drug Enforcement Administration.

(b) Schedules III, IV, and V [856 IAC 2-2-4 — 856 IAC 2-2-6]. Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V [856 IAC 2-2-4 — 856 IAC 2-2-6] shall be stored in one of the following secure storage areas:

(1) Where small quantities permit, a safe which complies with the requirements set forth in paragraph (a)(1) of this section;

(2) A vault which complies with the requirements set forth in either paragraph (a)(2) or (3) of this section or

(3) A building or area located within a building, which building or area:

(i) Has walls or perimeter fences of sufficient height and construction to provide security from burglary;

(ii) Has substantial doors which may be securely locked during non-working hours by a multiple-position combination or key lock;

(iii) Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond or a 24-hour control station operated by the registrant or such other protection as the Indiana Board of Pharmacy or the Drug Enforcement Administration may approve; and controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.

(c) Multiple storage areas. Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (e.g., returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this section.

(d) Accessibility to storage areas. The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(e) Compliance with the requirements prescribed in Part 301, Section 301.72 of Title 21 of the Code of Federal Regulations, effective April 1, 1973, shall be deemed in compliance with this section. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.72; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-32 Manufacturing areas; security controls for nonpractitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 32. Physical security controls for nonpractitioners: Manufacturing areas. All manufacturing activities (including processing, packaging, and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

(a) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing such substances shall be securely locked, with adequate security for the area or building. If such security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or a local or State Police agency which has a legal duty to respond, or a 24-hour control station operated by registrant.

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area. “Limited access” may be provided in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted: Provided: that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.

(c) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, non-employee maintenance personnel, business guests, or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

(d) Compliance with the requirements prescribed in Part 301, Section 301.73 of Title 21 of the Code of Federal Regulations, effective April 1, 1973, shall be deemed in compliance with this section.

(Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.73; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-33 Additional security controls for nonpractitioners

Authority: IC 35-48-3-1

Affected: IC 35-48-3-7

Sec. 33. Other security controls for nonpractitioners: (a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance the registrant shall make a good faith inquiry either with the Indiana Board of Pharmacy or with the D.E.A. to determine that the person is registered to possess the controlled substance.

(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Indiana Board of Pharmacy of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

(c) The registrant shall notify in writing the Indiana Board of Pharmacy of any theft or significant loss of any controlled substances upon discovery of such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

(d) The registrant shall not distribute any controlled substance listed in Schedules II through V [856 IAC 2-2-3 — 856 IAC 2-2-6] as a complimentary sample to any potential or current customer (1) without the prior written request of the customer, (2) to be used only for satisfying the legitimate medical needs of patients of the customer, and (3) only in reasonable quantities. Such request must contain the name, address and state and federal registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of Part 3.5 [856 IAC 2-3-24 — 856 IAC 2-3-26] hereof shall be complied with for any distribution of a controlled substance listed in Schedule II [856 IAC 2-2-3]. For purposes of this paragraph, the term “customer” includes a person to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the person.

(e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will

provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in Section 3.72 [856 IAC 2-3-31]. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.

(f) When distributing controlled substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.74; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-34 Storage; security controls for practitioners
Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 34. Physical security controls for practitioners. (a) Controlled substances listed in Schedule I [856 IAC 2-2-2] shall be stored in a securely locked substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V [856 IAC 2-2-3 — 856 IAC 2-2-6] shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners (as defined) in Chapter I, 1.01 [856 IAC 2-1-1] may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.
Controlled substances (institutional practitioners—ward and floor stock) listed in Schedule II [856 IAC 2-2-3] and narcotic drugs in Schedule III [856 IAC 2-2-4] shall be stored in a securely locked substantially constructed cabinet or device. Controlled substances (institutional practitioners ward and floor stock) listed in Schedules III, IV, and V [856 IAC 2-2-4 — 856 IAC 2-2-6] may be dispersed in their ward or floor stock in such a manner as to obstruct theft or diversion of these controlled substances.

(c) This section shall also apply to nonpractitioners authorized to conduct research or chemical analysis under another registration. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.75; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-3-35 Additional security controls for practitioners
Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 35. Other security controls for practitioners. (a) The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, or has been convicted of a violation of State or Federal law relative to the manufacture, distribution, dispensing or possession of controlled substances.

(b) The registrant shall notify the Indiana Board of Pharmacy of the theft or significant loss of any controlled substances upon discovery of such loss or theft. (Indiana Board of Pharmacy; Reg 28,Ch III,Sec 3.76; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 4. Records and Inventories of Registrants

856 IAC 2-4-1 Records and inventories
Authority: IC 35-48-3-1
Affected: IC 35-48-3-7

Sec. 1. (a) Every registrant shall keep records and maintain inventories in conformance with the record keeping and inventorying requirements of federal law and regulation.

(b) For purposes of this section, “readily retrievable” means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, red-lined, or in some manner visually identifiable apart from other items appearing on the records. Manufacturers, distributors, and research records or electronic data processing printouts shall be made available within five (5) working days after a request by the Indiana board of pharmacy for such records or information on controlled substances transactions.

(c) Each registered pharmacy shall maintain, for a period of two (2) years, its prescriptions of controlled substances by maintaining any of the following:

(1) Three (3) separate files as follows:
(A) A file for Schedule II drugs dispensed.
(B) A file for Schedules III, IV, and V drugs dispensed.
(C) A file for prescriptions for all other drugs dispensed.
(2) Two (2) separate files as follows:
(A) A file for all noncontrolled drugs dispensed.
(B) Another file for all controlled drugs dispensed in Schedules II, III, IV, and V. If this method is used, the prescriptions in the file for Schedules III, IV, and V must be stamped with the letter “C” in red ink, not less than one (1) inch high, in the lower right-hand corner.
(3) Two (2) separate files as follows:
(A) A file for Schedule II drugs dispensed.
(B) Another file for Schedules III, IV, and V drugs, including all other noncontrolled drugs dispensed. If this method is used, the prescriptions in the file of Schedules III, IV, and V drugs must be stamped with the letter “C” in red ink, not less than one (1) inch high, in the lower right-hand corner. However, if a

pharmacy employs an automated data processing system or other electronic record keeping system for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" under subdivisions (2) and (3) is waived. (Indiana Board of Pharmacy; Reg 28, Ch IV, Sec 4.01; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2504; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 5. Order Forms

856 IAC 2-5-1 Order form requirements
Authority: IC 35-48-3-1
Affected: IC 35-48-3-8

Sec. 1. Order Form Requirements Generally. Compliance with the requirements prescribed in section 308 of the Federal Controlled Substances Act (21 U.S.C. 828), and in Part 305 of Title 21 of the Code of Federal Regulations, effective April 1, 1973 shall be deemed compliance with the requirements of IC 1971, 35-24.1-3-7 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch V,Sec 5.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 6. Issuance, Filling and Filing Prescriptions

856 IAC 2-6-1 Scope of rules governing prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 1. Scope of Part 6. Rules governing the issuance, filling and filing of prescriptions pursuant to IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, are set forth generally in that section and specifically by the sections of this part [856 IAC 2]. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.01; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-2 Persons entitled to issue prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 2. (a) A prescription for a controlled substance may be issued only by an individual practitioner who is:
(1) authorized to prescribe controlled substances by the state; and
(2) either registered or exempted from registration pursuant to 856 IAC 2-3-5(b) or 856 IAC 2-3-6.
(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an individual practitioner or a practitioner's authorized agent.
(c) Controlled substances prescriptions issued by individual practitioners in adjoining states to Indiana or other states are considered valid prescriptions if the practitioner issuing the prescription has a current and valid Drug Enforcement Administration certificate registration number. It is the pharmacist's responsibility as with all controlled substances prescriptions, to be sure beyond reasonable doubt in his or her professional judgment that the practitioner is issuing the prescription in good faith and has a valid Drug Enforcement Administration certificate of registration. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.02; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-6-3 Purpose of prescription; prohibitions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 3. Purpose of issue of prescription. (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose in a reasonable quantity by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription, within the meaning and intent of IC 1971, 35-24.1-3-8 [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his dependence upon such drugs in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.03; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-4 Issuance of prescriptions; information required

Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 4. Manner of issuance of prescriptions. (a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, and the name, address, and Federal Controlled Substance registration number of the practitioner. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these regulations.

(b) An intern, resident, or foreign-trained physician exempted from registration under section 3.14(c) [856 IAC 2-3-5(c)], shall include on all prescriptions issued by him the Federal Controlled Substance registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in section 3.14(c) [856 IAC 2-3-5(c)], in lieu of the registration number of the practitioner required by this section. Each prescription shall have the name of the intern, resident, or foreign-trained physician stamped or printed on it, as well as the signature of the physician.

(c) An official exempted from registration under section 3.15 [856 IAC 2-3-6] shall include on all prescriptions issued by him, his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the Federal Controlled Substance registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, typed, or hand-printed on it, as well as the signature of the officer. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.04; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-5 Persons entitled to fill prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 5. Persons entitled to fill prescriptions. A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or by a registered institutional practitioner. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.05; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-6 Dispensing of narcotics for maintenance purposes
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 6. Dispensing of narcotic drugs for maintenance purposes. The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of treatment of his dependence upon such drugs in the course of conducting a clinical investigation authorized by State or Federal law in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his professional practice or research" in IC 1971, 35-24.1-1-1(u) [Repealed by Acts 1976, P.L.148, SECTION 24; Acts 1977, P.L.26, SECTION 25. See IC 35-48.] as amended. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.06; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-7 Schedule II controlled substances; prescription required; exceptions
Authority: IC 35-48-3-1
Affected: IC 35-48

Sec. 7. (a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in subsection (d).

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription subject to section 6 of this rule.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by subsection (e), a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided the following:
(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner).
(2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in section 4 of this rule, except for the signature of the prescribing individual practitioner.
(3) If the prescribing individual practitioner is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his or her phone number as listed in the telephone directory and/or other good faith efforts to assure his or her identity.

(4) Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of section 4 of this rule, the prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven (7) day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Indiana board of pharmacy if the prescribing individual fails to deliver a written prescription to him or her, failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing individual practitioner.

(e) For the purpose of authorizing an oral prescription of a controlled substance listed in Schedule II of IC 35-48 as amended, "emergency situation" means those situations in which the prescribing practitioner determines the following:

(1) That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user.

(2) That no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under Schedule II of IC 35-48 as amended.

(3) That it is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing.

(Indiana Board of Pharmacy; Reg 28, Ch VI,Sec 6.11; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 26, 2000, 8:52 a.m.: 23 IR 2505; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-8 Schedule II controlled substances; refilling prescriptions

Authority: IC 35-48-3-1

Affected: IC 35-48-3-9

Sec. 8. Refilling prescriptions—Schedule II [856 IAC 2-2-3]. The refilling of a prescription for a controlled substance listed in Schedule II [856 IAC 2-2-3] is prohibited. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.12; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-9 Schedule II controlled substances; partial filling of prescriptions

Authority: IC 35-48-3-1

Affected: IC 35-48-2-6; IC 35-48-3-9

Sec. 9. (a) The partial filling of a prescription for a controlled substance listed in Schedule II under IC 35-48-2-6, as amended, is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond seventy-two (72) hours without a new prescription.

(b) A prescription for a Schedule II controlled substance written for patients in long term care facilities may be filled in partial quantities to include individual dosage units. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of a Schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A Schedule II prescription, for a patient in a long term care facility, shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication.

(c) A prescription for a Schedule II controlled substance written for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. The pharmacist has a responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription the patient is "terminally ill". A prescription that is partially filled and does not contain the notation "terminally ill" shall be deemed to have been filled in violation of this section. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of a Schedule II controlled substance dispensed in all partial fillings must not exceed the total quantity prescribed. A Schedule II prescription for a patient with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.13; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 8, 1986, 9:55 a.m.: 9 IR 2205; filed Mar 31, 1992, 5:00 p.m.: 15 IR 1391; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-10 Schedule II controlled substances; label information; exceptions

Authority: IC 35-48-3-1

Affected: IC 35-48-3-9

Sec. 10. Labeling of substances. (a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II [856 IAC 2-2-3] shall affix to the package a label showing date of filling, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and the cautionary statement, "Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed", any others if any, contained in such prescription or required by law.

(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule II [856 IAC 2-2-3] is prescribed for administration to an ultimate user who is institutionalized; Provided, That:
(1) Not more than 7-day supply of the controlled substance listed in Schedule II [856 IAC 2-2-3] is dispensed at one time;
(2) The controlled substance listed in schedule II [856 IAC 2-2-3] is not in the possession of the ultimate user prior to the administration; and
(3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in schedule II [856 IAC 2-2-3]; and
(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.14; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-11 Schedule II controlled substances; retention of prescriptions (Repealed)

Sec. 11. (Repealed by Indiana Board of Pharmacy; filed Nov 30, 2001, 11:00 a.m.: 25 IR 1344)

856 IAC 2-6-12 Schedules III and IV controlled substances
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 12. (a) A pharmacist may dispense a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5, which is a prescription drug as determined under the federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner or a practitioner's authorized agent and promptly reduced to writing by the pharmacist containing all information required in 856 IAC 2-6-4 [section 4 of this rule], except for the signature of the prescribing individual practitioner.
(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5 in the course of his or her professional practice without a prescription, subject to 856 IAC 2-6-6 [section 6 of this rule].
(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV under 856 IAC 2-2-4 or 856 IAC 2-2-5 pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in 856 IAC 2-6-4 [section 4 of this rule], except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to 856 IAC 2-6-6 [section 6 of this rule]. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.21; filed Jul 9, 1974, 9:29 a.m.: Unpublished; readopted filed Nov 30, 2001, 11:00 a.m.: 25 IR 1343)

856 IAC 2-6-13 Schedules III, IV, and V controlled substances; refilling prescriptions; retrievable information
Authority: IC 35-48-3-1
Affected: IC 35-48-2; IC 35-48-3-9

Sec. 13. (a) No prescription for a controlled substance listed in Schedule III (IC 35-48-2-8), Schedule IV (IC 35-48-2-10), or Schedule V (IC 35-48-2-12) shall be filled or refilled more than six (6) months after the date on which such prescription was issued, and no such prescription shall be authorized to be refilled more than five (5) times.
(b) Each refill of a prescription shall be recorded by one (1) of the following methods:
(1) On the back of the original prescription and, if used, a uniformly maintained, readily retrievable record such as a medication record or patient profile.
(2) In the storage memory of an electronic data processing system if such board approved system is used in the pharmacy.
(c) The following prescription information shall be retrievable by using or entering the serial number of the prescription:
(1) The name (and strength if applicable) and dosage form of the controlled substance.
(2) The date on which the prescription was written or phoned and reduced to writing by the pharmacist.
(3) The date of original filling and the date or dates of all refills.
(4) A notation or notations for the original filling and each and every subsequent refilling sufficient to identify the dispensing pharmacist.
(5) The total number of refills originally authorized and remaining for each individual prescription.
If the pharmacist does nothing more than date and initial the prescription to indicate a refill has been dispensed, the pharmacist shall be deemed to have dispensed a refill for the full face amount (that is the originally prescribed amount) of the prescription.
(d) Additional refills for prescriptions for controlled substances listed in Schedule III (IC 35-48-2-8), Schedule IV (IC 35-48-2-10), or Schedule V (IC 35-48-2-12) may be added to the original prescription on an oral authorization transmitted to the pharmacist by the original prescribing practitioner providing the following conditions are met:
(1) The total quantity authorized does not exceed the original face amount of the prescription and five (5) total refills, and none of the refills is for more dose units or a larger quantity than the original face amount of the prescription.
(2) No dispensing takes place pursuant to the original prescription more than six (6) months after the date of the original issue of the prescription.
(3) The pharmacist receiving the oral authorization records that authorization on the reverse of the original prescription, or in a readily retrievable record, and the following information:
(A) The date of the authorization.
(B) The number of the dose units or quantity authorized.
(C) The number of additional refills authorized.
(D) The initials of the pharmacist receiving the oral authorization.

(e) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five (5) refill, six (6) month limitation. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.22; filed Jul 9, 1974, 9:29 a.m.: Unpublished; filed May 20, 1988, 9:30 a.m.: 11 IR 3564; filed Jul 5, 1995, 10:00 a.m.: 18 IR 2783; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-14 Schedules III, IV and V controlled substances; partial filling of prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 14. The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V in the Controlled Substance Act, IC 35-48 as amended is permissible, provided that:
(a) each partial filling is recorded in the same manner as a refilling,
(b) the total quantity dispensed pursuant to an individual prescription including the original and all subsequent partial refills does not exceed the total quantity prescribed, and
(c) no dispensing occurs more than six (6) months after the date on which the prescription was issued.
(Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.23; filed Jul 9, 1974, 9:29 am: Unpublished; filed May 20, 1988, 9:30 am: 11 IR 3565; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-15 Schedules III and IV controlled substances; label information; exceptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 15. Labeling of substances. (a) The pharmacist filling a prescription for a controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statement, “Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed”, and other if any, contained in such prescription as required by law.
(b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is prescribed for administration to an ultimate user who is institutionalized: Provided, That:
(1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is dispensed at one time;
(2) The controlled substance listed in schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5] is not in the possession of the ultimate user prior to administration;
(3) The institution maintains appropriate safeguards and records, the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III or IV [856 IAC 2-2-4 or 856 IAC 2-2-5]; and
(4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.
(Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.24; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-16 Schedules III and IV controlled substances; retention of prescriptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 16. Filing prescriptions. All prescriptions for controlled substances listed in Schedules III and IV [856 IAC 2-2-4 or 856 IAC 2-2-5] shall be kept in accordance with section 4.01 [856 IAC 2-4-1] of these regulations. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.25; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-17 Schedule V controlled substances; prescription requirements; refilling; exceptions
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 17. Requirement of prescription. (a) A pharmacist may dispense a controlled substance listed in Schedule V [856 IAC 2-2-6] pursuant to a prescription as required for controlled substances listed in Schedules III and IV [856 IAC 2-2-4 and 856 IAC 2-2-5] in section 6.21 [856 IAC 2-6-12]. A prescription for a controlled substance listed in Schedule V [856 IAC 2-2-6] may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with section 6.24 [856 IAC 2-6-15] and file the prescription in accordance with section 6.25 [856 IAC 2-6-16].
(b) An individual practitioner may administer or dispense a controlled substance listed in Schedule V [856 IAC 2-2-6] in the course of his professional practice without a prescription, subject to section 6.24 [856 IAC 2-6-15].
(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule V [856 IAC 2-2-6] only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in section 6.04 [856 IAC 2-6-4] except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate

administration to the ultimate user, subject to section 6.24 [856 IAC 2-6-15]. (Indiana Board of Pharmacy; Reg 28,Ch VI,Sec 6.31; filed Jul 9, 1974, 9:29 am: Unpublished; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

856 IAC 2-6-18 Dispensing without prescription; delivery of devices
Authority: IC 35-48-3-1
Affected: IC 35-48-3-9

Sec. 18. (a) A controlled substance listed in Schedule V in the Controlled Substance Act, IC 35-48 which does not require a prescription under federal, state or local law or a device known as a hypodermic syringe and/or needle for human use may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:
(1) such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the direct supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in his [sic.] section, the actual cash, credit transaction, or delivery may be completed by a non-pharmacist);
(2) no more than:
(i) 240 cc. (8 ounces) or 48 dosage units of any substance containing opium;
(ii) 120 cc. (4 ounces) or 24 dosage units of any other substance nor more than 48 dosage units may be dispensed at retail to the same purchaser in any given 48-hour period;
(3) the purchaser is at least eighteen (18) years of age. However, if the item being purchased is a device known as a hypodermic syringe and/or needle for human use, the age restriction shall not apply;
(4) the pharmacist requires every purchaser of a controlled substance or device as described in 856 IAC 2-6-18(a) not known to the pharmacist to furnish suitable identification (including proof of age where appropriate); and
(5) separate bound record books for dispensing of:
(i) controlled substances; and
(ii) devices under this section; are maintained by the pharmacist. These books shall contain the name and address of the purchaser, the name and quantity of controlled substance or devices purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance or devices to the purchaser these books shall be maintained in accordance with the recordkeeping requirements of 856 IAC 2-4-1.
(b) Delivery of devices, as described above, to inpatients of institutions is exempt from this section.
(c) The delivery of a device known as a hypodermic syringe-needle other than by a pharmacist in a licensed pharmacy or a licensed practitioner in his lawful place of practice is prohibited. (Indiana Board of Pharmacy; Reg 28, Ch VI, Sec 6.32; filed Jul 9, 1974, 9:29 am: Unpublished; filed May 20, 1988, 9:30 am: 11 IR 3565; readopted filed Nov 14, 2001, 2:45 p.m.: 25 IR 1341)

Rule 7. Limited Permits

856 IAC 2-7-1 Application
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 1. (a) A humane society, animal control agency, or governmental entity that intends to operate an animal shelter or other animal impounding facility for the purpose of buying, possessing, and using drugs authorized by IC 35-48-3-2 shall apply for a limited permit in the form and manner required by the board.
(b) The applicant shall provide the following:
(1) Name and address of the facility.
(2) Type of facility.
(3) Documentation describing the ownership of the facility.
(4) Fees set by the board in this rule.
(5) Information about the substances that the facility intends to administer.
(6) Written policies relating to storage, security, and procedures for access, handling, and administration of drugs.
(7) Proof that the employees of the applicant who will handle a controlled substance are sufficiently trained to use and administer the controlled substance.
(8) Proof that a licensed Indiana veterinarian holding a valid Indiana controlled substances registration and federal DEA registration has been retained to provide technical advice to the facility.
(c) No humane society, animal control agency, or governmental entity that intends to operate an animal shelter or other animal impounding facility for the purpose of buying, possessing, and using drugs authorized by IC 35-48-3-2 shall engage in any activity for which a permit is required until the permit is granted by the board. *(Indiana Board of Pharmacy; 856 IAC 2-7-1; filed Aug 21,2003, 4:45 p.m.: 27 IR 181)*

856 IAC 2-7-2 Permit fees
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 2. The board shall charge and collect the following fees:
(1) Application for a limited permit, fifty dollars ($50).
(2) Annual renewal of limited permit, twenty-five dollars ($25).

(Indiana Board of Pharmacy; 856 IAC 2-7-2; filed Aug 21, 2003, 4:45 p.m.: 27 IR 182)

856 IAC 2-7-3 Renewal of permit
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 3. The renewal of the limited permits issued under this section shall be on the same schedule as other humane societies, animal control agencies, or governmental entities that hold controlled substance registrations issued by the board. *(Indiana Board of Pharmacy; 856 IAC 2-7-3; filed Aug 21, 2003, 4:45 p.m.: 27 IR 182)*

856 IAC 2-7-4 Storage, handling, and use of controlled substances
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 4. (a) Limited permit holders and their agents, representatives, and employees must comply with the requirements of this rule for the storage and handling of controlled substances.

(b) All facilities at which controlled substances are stored, handled, or used shall:

(1) be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas large enough to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of controlled substances that are:

(A) outdated, damaged, deteriorated, misbranded, or adulterated; or

(B) in immediate or sealed secondary containers that have been opened;

(4) be maintained in a clean and orderly condition; and

(5) be free from infestation by insects, rodents, birds, or vermin of any kind.

(c) All facilities used for storage of controlled substances by registrants under this section shall comply with the security requirements as provided by 856 IAC 2-3-31.

(d) All controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such controlled substances or with requirements in the current edition of an official compendium of drug information.

(e) If no storage requirements are established for a controlled substance, the controlled substance may be held at a controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(f) Controlled substances that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other controlled substances until they are destroyed by a designated agent of the board or returned to their supplier.

(g) Any controlled substance whose immediate or sealed outer or sealed secondary containers have been opened or used shall be:

(1) identified as such; and

(2) quarantined and physically separated from other controlled substances until they are either destroyed by a designated agent of the board or returned to the supplier.

(h) Limited permit holders shall establish and maintain inventories and records of all controlled substances stored or used at the facility.

(i) Inventories and records shall be made available for inspection and photocopying by any authorized official of any governmental agency charged with enforcement of this rule for a period of two (2) years following disposition of the controlled substances.

(j) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of any governmental agency charged with enforcement of this rule. *(Indiana Board of Pharmacy; 856 IAC 2-7-4; filed Aug 21, 2003, 4:45 p.m.: 27 IR 182)*

856 IAC 2-7-5 Training of staff
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 5. (a) Only employees of the limited permit holder are eligible for training to store, handle, and use controlled substances. Volunteers are prohibited from storing, handling, or using controlled substances.

(b) The following training is required:

(1) Completion of a comprehensive training program approved by the controlled substance advisory committee.

(2) Any additional training as required by the supervising veterinarian or site administrator.

(c) A veterinarian licensed to practice in Indiana, holding a valid Indiana controlled substances registration and federal DEA registration, must verify in writing that the employee has been trained adequately to store, handle, or use controlled substances. The written verification must be maintained at the facility in a reasonably retrievable manner.

(d) The limited permit holder or site administrator shall maintain documentary proof of training in a reasonably retrievable manner at the facility for review by an authorized official of any governmental agency charged with enforcement of this rule.
(Indiana Board of Pharmacy; 856 IAC 2-7-5; filed Aug 21, 2003, 4:45 p.m.: 27 IR 183)

856 IAC 2-7-6 Protocol for administration of controlled substances
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 6. In the event the consulting veterinarian is not physically present during the administration of controlled substances by employees of the limited permit holder, the veterinarian shall be available for consultation by telephonic or other electronic device.
(Indiana Board of Pharmacy; 856 IAC 2-7-6; filed Aug 21, 2003, 4:45 p.m.: 27 IR 183)

856 IAC 2-7-7 Limitations on permit
Authority: IC 35-48-3-2
Affected: IC 35-48-3-2

Sec. 7. (a) Except as provided in subsection (b), only controlled substances for which the humane society, animal control agency, or governmental entity has received a permit may be stored, handled, and used at the facility.

(b) A licensed veterinarian who stores, handles, or uses controlled substances at the humane society, animal control agency, or governmental entity other than those authorized under the facility.s limited permit, must apply for and obtain a controlled substance registration for the facility in the veterinarian.s name.

(c) The veterinarian who holds the registration noted in subsection (b) is responsible for the proper storage, handling, and use of the controlled substances authorized for use under the veterinarian.s controlled substance registration.
(Indiana Board of Pharmacy; 856 IAC 2-7-7; filed Aug 21, 2003, 4:45 p.m.: 27 IR 183)

IC 25-1-4 Continuing Education

IC 35-1-4-0.2
Approved Organization

Sec. 0.2. As used in this chapter, "approved organization" refers to the following:

(1) United States Department of Education.
(2) Council on Post-Secondary Education.
(3) Joint Commission on Accreditation of Hospitals.
(4) Joint Commission on Healthcare Organizations.
(5) Federal, state, and local government agencies.
(6) A college or other teaching institution accredited by the United States Department of Education or the Council on Post-Secondary Education.
(7) A national organization of practitioners whose members practicing in Indiana are subject to regulation by a board or agency regulating a profession or occupation under this title or IC 15.
(8) A national, state, district, or local organization that operates as an affiliated entity under the approval of an organization listed in subdivisions (1) through (7).
(9) An internship or a residency program conducted in a hospital that has been approved by an organization listed in subdivisions (1) through (7).
(10) Any other organization or individual approved by the board.

IC 25-1-4-0.3
"Board" defined

Sec. 0.3. As used in section 3 of this chapter, "board" means any of the following:

((1) Indiana board of accountancy (IC 25-2.1-2-1).
(2) Board of registration for architects and landscape architects (IC 25-4-1-2)
(3) Indiana athletic trainers board (IC 25-5.1-2-1).
(4) Indiana auctioneer commission (IC 25-6.1-2-1).
(5) State board of barber examiners (IC 25-7-5-1).
(6) State boxing commission (IC 25-9-1).
(7) Board of chiropractic examiners (IC 25-10-1).
(8) State board of cosmetology examiners (IC 25-8-3-1).
(9) State board of dentistry (IC 25-14-1).
(10) Indiana dietitians certification board (IC 25-14.5-2-1).
(11) State board of registration for professional engineers (IC 25-31-1-3).
(12) Board of environmental health specialists (IC 25-32).
(13) State board of funeral and cemetery service (IC 25-15-9).
(14) Indiana state board of health facility administrators (IC 25-19-1).
(15) Committee on hearing aid dealer examiners(IC 25-20-1-1.5).
(16) Home inspectors licensing board (IC 25-20.2-3-1).
(17) Indiana hypnotist committee (IC 25-20.5-1-7).
(18) State board of registration for land surveyors (IC 25-21.5-2-1).
(19) Manufactured home installer licensing board (IC 25-23.7).
(20) Medical licensing board of Indiana (IC 25-22.5-2).
(21) Indiana state board of nursing (IC 25-23-1).
(22) Occupational therapy committee (IC 25-23.5).
(23) Indiana optometry board (IC 25-24).
(24) Indiana board of pharmacy (IC 25-26).
(25) Indiana physical therapy committee (IC 25-27-1).
(26) Physician assistant committee (IC 25-27.5).
(27) Indiana plumbing commission (IC 25-28.5-1-3).
(28) Board of podiatric medicine (IC 25-29-2-1).
(29) Private detectives licensing board (IC 25-30-1-5.1).
(30) State psychology board (IC 25-33).
(31) Indiana real estate commission (IC 25-34.1-2).
(32) Real estate appraiser licensure and certification board (IC 25-34.1-8).
(33) Respiratory care committee (IC 25-34.5).
(34) Social worker, marriage and family therapist, and mental health counselor board (IC 25-23.6).
(35) Speech-language pathology and audiology board (IC 25-35.6-2).
(36) Indiana board of veterinary medical examiners (IC 15-5-1.1).

As added by P.L.269-2001, SEC.2.

IC 25-1-4-0.5

"Continuing Education" defined

Sec. 0.5. As used in this chapter, "continuing education" means an orderly process of instruction that is approved by an approved organization or the board and that is designed to directly enhance the practitioner's knowledge and skill in providing services relevant to the practitioner's profession or occupation.

IC 25-1-4-0.6

"Practitioner" defined

Sec. 0.6. As used in section 3 of this chapter, "practitioner" means an individual who holds:

(1) an unlimited license, certificate, or registration;
(2) a limited or probationary license, certificate, or registration;
(3) a temporary license, certificate, registration, or permit;
(4) an intern permit; or
(5) a provisional license;

issued by the board regulating the profession in question.

As added by P.L.269-2001, SEC.3.

IC 25-1-4-1

Requirement

Sec. 1. No board or agency regulating a profession or occupation under this title or under IC 15, IC 16, or IC 22 may require continuing education as a condition of certification, registration, or licensure unless so specifically authorized or mandated by statute.

As added by Acts 1981, P.L.222, SEC.1.

IC 25-1-4-2

Promotion

Sec. 2. A board or agency regulating a profession or occupation under this title or under IC 15, IC 16, or IC 22 may cooperate with members of the profession or occupation it regulates to promote continuing education within the profession or occupation.

As added by Acts 1981, P.L.222, SEC.1.

IC 25-1-4-3

Sworn statements of compliance; retention of copies of certificates of completion; audits

Sec. 3. (a) Notwithstanding any other law, a board that is specifically authorized or mandated to require continuing education as a condition to renew a registration, certification, or license must require a practitioner to comply with the following renewal requirements:

(1) The practitioner shall provide the board with a sworn statement executed by the practitioner that the practitioner has fulfilled the continuing education requirements required by the board.

(2) The practitioner shall retain copies of certificates of completion for continuing education courses for three (3) years from the end of the licensing period for which the continuing education applied. The practitioner shall provide the board with copies of the certificates of completion upon the board's request for a compliance audit.

(b) Following every license renewal period, the board shall randomly audit for compliance more than one percent (1%) but less than ten percent (10%) of the practitioners required to take continuing education courses.

As added by P.L.269-2001, SEC.4.

IC 25-1-4-3.2

Distance learning methods

Sec. 3.2. A board or agency regulating a profession or occupation under this title or under IC 15, IC 16, or IC 22 shall require that at least one-half (50%) of all continuing education requirements must be allowed by distance learning methods, except for doctors, nurses, chiropractors, optometrists and dentists.

As added by P.L.227-2001, SEC.1.

IC 25-1-4-4

Waiver

Sec. 4. A board, a commission, a committee, or an agency regulating a profession or occupation under this title or under IC 15, IC 16, or IC 22 may grant an applicant a waiver from all or part of the continuing education requirement for a renewal period if the applicant was not able to fulfill the requirement due to a hardship that resulted from any of the following:

(1) Service in the armed forces of the United States during a substantial part of the renewal period.
(2) An incapacitating illness or injury.
(3) Other circumstances determined by the board or agency.

As added by P.L.274-2004, SEC. 1.

IC 25-1-4-5

Sec. 5. (a) Notwithstanding any other law, if the board determines that a practitioner has not complied with this chapter at the time that the practitioner applies for license renewal or after an audit conducted under section 3 of this chapter, the board shall do the following:

(1) Send the practitioner notice of noncompliance by certified mail.

(2) As a condition of license renewal, require the practitioner to comply with subsection (b).
(3) Issue a conditional license to the practitioner that is effective until the practitioner complies with subsection (b).
(b) Upon receipt of a notice of noncompliance under subsection (a), a practitioner shall do either of the following:
(1) If the practitioner believes that the practitioner has complied with this chapter, within twenty-one (21) days of receipt of the notice, send written notice to the board requesting a review so that the practitioner may submit proof of compliance.
(2) If the practitioner does not disagree with the board's determination of noncompliance, do the following:
(A) Except as provided in subsection (d), pay to the board a civil penalty not to exceed one thousand dollars ($1,000) within twenty-one (21) days of receipt of the notice.
(B) Acquire, within six (6) months after receiving the notice, the number of credit hours needed to achieve full compliance.
(C) Comply with all other provisions of this chapter.
(c) If a practitioner fails to comply with subsection (b), the board shall immediately suspend the license of the practitioner and send notice of the suspension to the practitioner by certified mail.
(d) If the board determines that a practitioner has knowingly or intentionally made a false or misleading statement to the board concerning compliance with the continuing education requirements, in addition to the requirements under this section the board may impose a civil penalty of not more than five thousand dollars ($5,000) under subsection (b)(2)(A).
(e) The board shall:
(1) reinstate a practitioner suspended under subsection (c); or
(2) renew the practitioner's license in place of the conditional license issued under subsection (a)(3);
if the practitioner supplies proof of compliance with this chapter under subsection (b)(1).

IC 25-1-4-6

Sec. 6. (a) Notwithstanding any other law, if at the time a practitioner applies for license renewal or after an audit conducted under section 3 of this chapter, the board determines that the practitioner has failed to comply with this chapter and the practitioner has previously received a notice of noncompliance under section 5(a) of this chapter during the preceding license period, the board shall do the following:
(1) Provide the practitioner notice of noncompliance by certified mail.
(2) Deny the practitioner's application for license renewal.
(b) The board shall reinstate a license not renewed under subsection (a) upon occurrence of the following:
(1) Payment by a practitioner to the board of a civil penalty determined by the board, but not to exceed one thousand dollars ($1,000).
(2) Acquisition by the practitioner of the number of credit hours required to be obtained by the practitioner during the relevant license period.
(3) The practitioner otherwise complies with this chapter.

IC 25-1-4-7

Sec. 7. Credit hours acquired by a practitioner under section 5(b)(2) or 6(b)(2) of this chapter may not apply to the practitioner's credit hour requirement for the license period in which the credit hours are acquired.

IC 25-1-4-8 [

Sec. 8. The board may adopt rules under IC 4-22-2 to implement this chapter.

IC 25-1-9
Chapter 9. Health Professions Standards of Practice

IC 25-1-9-1 "Board" defined

Sec. 1. As used in this chapter, "board" means any of the following:
(1) Board of chiropractic examiners (IC 25-10-1).
(2) State board of dentistry (IC 25-14-1).
(3) Indiana state board of health facility administrators (IC 25-19-1).
(4) Medical licensing board of Indiana (IC 25-22.5-2).
(5) Indiana state board of nursing (IC 25-23-1).
(6) Indiana optometry board (IC 25-24).
(7) Indiana board of pharmacy (IC 25-26).
(8) Board of podiatric medicine (IC 25-29-2-1).
(9) Board of environmental health specialists (IC 25-32).
(10) Speech-language pathology and audiology board (IC 25-35.6-2).
(11) State psychology board (IC 25-33).
(12) Indiana board of veterinary medical examiners (IC 15-5-1.1).
(13) Indiana physical therapy committee (IC 25-27-1).
(14) Respiratory care committee (IC 25-34.5).
(15) Occupational therapy committee (IC 25-23.5).
(16) Social worker, marriage and family therapist, and mental health counselor board (IC 25-23.6).
(17) Physician assistant committee (IC 25-27.5).
(18) Indiana athletic trainers board (IC 25-5.1-2-1).
(19) Indiana dietitians certification board (IC 25-14.5-2-1).
(20) Indiana hypnotist committee (IC 25-20.5-1-7).
As added by P.L.152-1988, SEC.1. Amended by P.L.242-1989, SEC.7; P.L.238-1989, SEC.7; P.L.186-1990, SEC.7; P.L.48-1991, SEC.20; P.L.227-1993, SEC.7; P.L.33-1993, SEC.14; P.L.213-1993, SEC.4; P.L.1-1994, SEC.122; P.L.124-1994, SEC.6; P.L.175-1997, SEC.6; P.L.147-1997, SEC.10; P.L.84-1998, SEC.5; P.L.24-1999, SEC.6.

IC 25-1-9-2 "Practitioner" defined

Sec. 2. As used in this chapter, "practitioner" means an individual who holds:
(1) an unlimited license, certificate, or registration;
(2) a limited or probationary license, certificate, or registration;
(3) a temporary license, certificate, registration, or permit;
(4) an intern permit; or
(5) a provisional license;
issued by the board regulating the profession in question, including a certificate of registration issued under IC 25-20.
As added by P.L.152-1988, SEC.1.

IC 25-1-9-3 "License" defined

Sec. 3. As used in this chapter, "license" includes a license, certificate, registration, or permit.
As added by P.L.152-1988, SEC.1.

IC 25-1-9-3.5 "Sexual Contact" defined

Sec. 3.5. As used in this chapter, "sexual contact" means:
(1) sexual intercourse (as defined in IC 35-41-1-26);
(2) deviate sexual conduct (as defined in IC 35-41-1-9); or
(3) any fondling or touching intended to arouse or satisfy the sexual desires of either the individual performing the fondling or touching or the individual being fondled or touched.
As added by P.L.200-2001, SEC.1.

IC 25-1-9-4 Professional standards; types of conduct prohibited; certified copy of record as conclusive evidence

Sec. 4. (a) A practitioner shall conduct the practitioner's practice in accordance with the standards established by the board regulating the profession in question and is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds:
(1) a practitioner has:
(A) engaged in or knowingly cooperated in fraud or material deception in order to obtain a license to practice;
(B) engaged in fraud or material deception in the course of professional services or activities; or
(C) advertised services in a false or misleading manner;
(2) a practitioner has been convicted of a crime that has a direct bearing on the practitioner's ability to continue to practice competently;
(3) a practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question;

(4) a practitioner has continued to practice although the practitioner has become unfit to practice due to:
(A) professional incompetence that:
(i) may include the undertaking of professional activities that the practitioner is not qualified by training or experience to undertake; and
(ii) does not include activities performed under IC 16-21-2-9;
(B) failure to keep abreast of current professional theory or practice;
(C) physical or mental disability; or
(D) addiction to, abuse of, or severe dependency upon alcohol or other drugs that endanger the public by impairing a practitioner's ability to practice safely;
(5) a practitioner has engaged in a course of lewd or immoral conduct in connection with the delivery of services to the public;
(6) a practitioner has allowed the practitioner's name or a license issued under this chapter to be used in connection with an individual who renders services beyond the scope of that individual's training, experience, or competence;
(7) a practitioner has had disciplinary action taken against the practitioner or the practitioner's license to practice in any other state or jurisdiction on grounds similar to those under this chapter;
(8) a practitioner has diverted:
(A) a legend drug (as defined in IC 16-18-2-199); or
(B) any other drug or device issued under a drug order (as defined in IC 16-42-19-3) for another person;
(9) a practitioner, except as otherwise provided by law, has knowingly prescribed, sold, or administered any drug classified as a narcotic, addicting, or dangerous drug to a habitue or addict;
(10) a practitioner has failed to comply with an order imposing a sanction under section 9 of this chapter; ~~or~~
(11) a practitioner has engaged in sexual contact with a patient under the practitioner's care or has used the practitioner-patient relationship to solicit sexual contact with a patient under the practitioner's care; or
(12) a practitioner who is a participating provider of a health maintenance organization has knowingly collected or attempted to collect from a subscriber or enrollee of the health maintenance organization any sums that are owed by the health maintenance organization.
(b) A practitioner who provides health care services to the practitioner's spouse is not subject to disciplinary action under subsection (a)(11).
(c) A certified copy of the record of disciplinary action is conclusive evidence of the other jurisdiction's disciplinary action under subsection (a)(7).
As added by P.L.152-1988, SEC.1. Amended by P.L.2-1993, SEC.136; P.L.149-1997, SEC.7; P.L.22-1999, SEC.4; P.L. 200-2001, SEC.2; P.L.203-2001, SEC.3; P.L.1-2002, SEC.96.

IC 25-1-9-5 Optometrists; sanctions; prohibited employment

Sec. 5. In addition to section 4 of this chapter, a practitioner licensed to practice optometry is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds a practitioner has accepted employment to practice optometry from a person other than:
(1) a corporation formed by an optometrist under IC 23-1.5; or
(2) an individual who is licensed as an optometrist under this article and whose legal residence is in Indiana.
As added by P.L.152-1988, SEC.1.

IC 25-1-9-6 Veterinarians or veterinary technicians; sanctions; cruelty to animals

Sec. 6. In addition to section 4 of this chapter, a practitioner licensed to practice veterinary medicine or registered as a veterinary technician is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds a practitioner has engaged in cruelty to animals.
As added by P.L.152-1988, SEC.1.

IC 25-1-9-6.5 Waiver of deductible or a copayment

Sec. 6.5. (a) In addition to section 4 of this chapter, a practitioner licensed to practice chiropractic is subject to the exercise of the disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the profession finds a practitioner has:
(1) waived a payment of a deductible or a copayment required to be made to the practitioner by a patient under the patient's insurance or health care plan; and
(2) advertised the waiver of a payment described in subdivision (1).
(b) This section does not apply to the waiver of a deductible or a copayment by a practitioner if:
(1) the practitioner determines chiropractic service is necessary for the immediate health and welfare of a patient;
(2) the practitioner determines the payment of a deductible or a copayment would create a substantial financial hardship for the patient; and
(3) the waiver is based on the evaluation of the individual patient and is not a regular business practice of the practitioner.
As added by P.L.151-1989, SEC.9.

IC 25-1-9-6.7 Additional professional standards for licensees under IC 25-23.6

Sec. 6.7. In addition to the actions listed under section 4 of this chapter that subject a practitioner to the exercise of disciplinary sanctions, a practitioner who is licensed under IC 25-23.6 is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board regulating the profession finds that the practitioner has:
(1) performed any therapy that, by the prevailing standards of the mental health professions in the community where the services were provided, would constitute experimentation on human subjects, without first obtaining full, informed, and written consent;
(2) failed to meet the minimum standards of performance in professional activities when measured against generally prevailing peer performance in professional activities, including the undertaking of activities that the practitioner is not qualified by training or experience to undertake;
(3) performed services, including any duties required of the individual under IC 31, in reckless disregard of the best interests of a patient, a client, or the

public;

(4) without the consent of the child's parent, guardian, or custodian, knowingly participated in the child's removal or precipitated others to remove a child from the child's home unless:

(A) the child's physical health was endangered due to injury as a result of the act or omission of the child's parent, guardian, or custodian;

(B) the child had been or was in danger of being a victim of an offense under IC 35-42-4, IC 35-45-4-1, IC 35-45-4-2, IC 35-46-1-3, IC 35-49-2-2, or IC 35-49-3-2; or

(C) the child was in danger of serious bodily harm as a result of the inability, refusal, or neglect of the child's parent, guardian, or custodian to supply the child with necessary food, shelter, or medical care, and a court order was first obtained;

(5) willfully made or filed a false report or record, failed to file a report or record required by law, willfully impeded or obstructed the filing of a report or record, or induced another individual to:

(A) make or file a false report or record; or

(B) impede or obstruct the filing of a report or record; or

(6) performed a diagnosis (as defined in IC 25-22.5-1-1.1(c));

(7) provided evidence in an administrative or judicial proceeding that had insufficient factual basis for the conclusions rendered by the practitioner;

(8) willfully planted in the mind of the patient suggestions that are not based in facts known to the practitioner; or

(9) performed services outside of the scope of practice of the license issued under IC 25-23.6.

As added by P.L.147-1997, SEC.11. Amended by P.L.2-1998, SEC.65.

IC 25-1-9-6.8 Prescribing stimulant medication for a child; guidelines

Sec. 6.8. (a) This section applies to a practitioner who is: (1) licensed to practice medicine or osteopathic medicine under IC 25-22.5; or

(2) an advanced practice nurse granted prescriptive authority under IC 25-23, and whose practice agreement with a collaborating physician reflects the conditions specified in subsection (b).

(b) Before prescribing a stimulant medication for a child for the treatment of attention deficit disorder or attention deficit hyperactivity disorder, a practitioner described in subsection (a) shall follow the most recent guidelines adopted by the American Academy of Pediatrics or the American Academy of Child and Adolescent Psychiatry for the diagnosis and evaluation of a child with attention deficit disorder or attention deficit hyperactivity disorder. As added by P.L. 107-2002, SEC. 27. Amended by P.L. 206-2005, SEC. 14.

IC 25-1-9-6.9 Additional professional standards; failure to provide information; providing false information

Sec. 6.9. In addition to the actions listed under section 4 of this chapter that subject a practitioner to disciplinary sanctions, a practitioner is subject to the exercise of disciplinary sanctions under section 9 of this chapter if, after a hearing, the board finds that the practitioner has:

(1) failed to provide information requested by the Indiana professional licensing agency; or

(2) knowingly provided false information to the Indiana professional licensing agency;

for a provider profile required under IC 25-1-5-10.

As added by P.L.211-2001, SEC.2.

IC 25-1-9-7 Physical or mental examination; power to require

Sec. 7. The board may order a practitioner to submit to a reasonable physical or mental examination, at the practitioner's own expense, if the practitioner's physical or mental capacity to practice safely is at issue in a disciplinary proceeding.

As added by P.L.152-1988, SEC.1. Amended by P.L.158-2003, SEC.2.

IC 25-1-9-8 Failure to submit to examination; summary suspension

Sec. 8. Failure to comply with a board order to submit to a physical or mental examination makes a practitioner liable to summary suspension under section 10 of this chapter. As added by P.L.152-1988, SEC.1.

IC 25-1-9-9 Sanctions; modification or withdrawal of probation

Sec. 9. (a) The board may impose any of the following sanctions, singly or in combination, if it finds that a practitioner is subject to disciplinary sanctions under section 4, 5, 6, 6.7, or 6.9 of this chapter or IC 25-1-5-4:

(1) Permanently revoke a practitioner's license.

(2) Suspend a practitioner's license.

(3) Censure a practitioner.

(4) Issue a letter of reprimand.

(5) Place a practitioner on probation status and require the practitioner to:

(A) report regularly to the board upon the matters that are the basis of probation;

(B) limit practice to those areas prescribed by the board;

(C) continue or renew professional education under a preceptor, or as otherwise directed or approved by the board, until a satisfactory degree of skill has been attained in those areas that are the basis of the probation; or

(D) perform or refrain from performing any acts, including community restitution or service without compensation, that the board considers appropriate to the public interest or to the rehabilitation or treatment of the practitioner.

(6) Assess a fine against the practitioner in an amount not to exceed one thousand dollars ($1,000) for each violation listed in section 4 of this chapter, except for a finding of incompetency due to a physical or mental disability. When imposing a fine, the board shall consider a practitioner's ability to pay the amount assessed. If the practitioner fails to pay the fine within the time specified by the board, the board may suspend the practitioner's license without

additional proceedings. However, a suspension may not be imposed if the sole basis for the suspension is the practitioner's inability to pay a fine.

(b) The board may withdraw or modify the probation under subsection (a)(5) if it finds, after a hearing, that the deficiency that required disciplinary action has been remedied, or that changed circumstances warrant a modification of the order.

As added by P.L.152-1988, SEC.1. Amended by P.L.48-1991, SEC.21; P.L.22-1999, SEC.5; P.L.32-2000, SEC.10; P.L.211-2001, SEC.3.

IC 25-1-9-10 Summary suspension of license; opportunity to be heard

Sec. 10. (a) The board may summarily suspend a practitioner's license for ninety (90) days before a final adjudication or during the appeals process if the board finds that a practitioner represents a clear and immediate danger to the public health and safety if the practitioner is allowed to continue to practice. The summary suspension may be renewed upon a hearing before the board, and each renewal may be for ninety (90) days or less.

(b) Before the board may summarily suspend a license that has been issued under IC 15-5-1.1, IC 25-22.5 or IC 25-14, the consumer protection division of the attorney general's office shall make a reasonable attempt to notify a practitioner of a hearing by the board to suspend a practitioner's license and of information regarding the allegation against the practitioner. The consumer protection division of the attorney general's office shall also notify the practitioner that the practitioner may provide a written or an oral statement to the board on the practitioner's behalf before the board issues an order for summary suspension. A reasonable attempt to reach the practitioner is made if the consumer protection division of the attorney general's office attempts to reach the practitioner by telephone or facsimile at the last telephone number of the practitioner on file with the board.

(c) After a reasonable attempt is made to notify a practitioner under subsection (b):

(1) a court may not stay or vacate a summary suspension of a practitioner's license for the sole reason that the practitioner was not notified; and

(2) the practitioner may not petition the board for a delay of the summary suspension proceedings.

As added by P.L.152-1988, SEC.1. Amended by P.L.43-1995, SEC.2; P.L.71-2000, SEC.18.

IC 25-1-9-10.1 Retention of clinical consultants and experts to advise on suspension

Sec. 10.1. The attorney general may retain the services of a clinical consultant or an expert to provide the attorney general with advice concerning the acts that are the subject of a suspension under this chapter.

As added by P.L.43-1995, SEC.3.

IC 25-1-9-11 Reinstatement of suspended license

Sec. 11. The board may reinstate a license which has been suspended under this chapter if, after a hearing, the board is satisfied that the applicant is able to practice with reasonable skill and safety to the public. As a condition of reinstatement, the board may impose disciplinary or corrective measures authorized under this chapter.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-12 Reinstatement of revoked license

Sec. 12. The board may not reinstate a license that has been revoked under this chapter. An individual whose license has been revoked under this chapter may not apply for a new license until seven (7) years after the date of revocation.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-13 Consistency in application of sanctions

Sec. 13. The board shall seek to achieve consistency in the application of the sanctions authorized in this section. Significant departures from prior decisions involving similar conduct must be explained in the board's findings or orders.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-14 Surrender of license

Sec. 14. A practitioner may petition the board to accept the surrender of the practitioner's license instead of a hearing before the board. The practitioner may not surrender the practitioner's license without the written approval of the board, and the board may impose any conditions appropriate to the surrender or reinstatement of a surrendered license.

As added by P.L.152-1988, SEC.1.

IC 25-1-9-15 Costs in disciplinary proceedings

Sec. 15. Practitioners who have been subjected to disciplinary sanctions may be required by a board to pay for the costs of the proceeding. The practitioner's ability to pay shall be considered when costs are assessed. If the practitioner fails to pay the costs, a suspension may not be imposed solely upon the practitioner's inability to pay the amount assessed. These costs are limited to costs for the following:

(1) Court reporters.

(2) Transcripts.

(3) Certification of documents.

(4) Photoduplication.

(5) Witness attendance and mileage fees.

(6) Postage.

(7) Expert witnesses.

(8) Depositions.

(9) Notarizations.

(10) Administrative law judges.

As added by P.L.152-1988, SEC.1. Amended by P.L.158-2003, SEC.3.

IC 25-1-9-16 Refusal of licensure or grant of probationary license

Sec. 16. (a) The board may refuse to issue a license or may issue a probationary license to an applicant for licensure if:

(1) the applicant has been disciplined by a licensing entity of another state or jurisdiction, or has committed an act that would have subjected the applicant to the disciplinary process had the applicant been licensed in Indiana when the act occurred; and

(2) the violation for which the applicant was, or could have been, disciplined has a direct bearing on the applicant's ability to competently practice in Indiana.

(b) Whenever the board issues a probationary license, the board may impose one (1) or more of the following conditions:

(1) Report regularly to the board upon the matters that are the basis of the discipline of the other state or jurisdiction.

(2) Limit practice to those areas prescribed by the board.

(3) Continue or renew professional education.

(4) Engage in community restitution or service without compensation for a number of hours specified by the board.

(5) Perform or refrain from performing an act that the board considers appropriate to the public interest or to the rehabilitation or treatment of the applicant.

(c) The board shall remove any limitations placed on a probationary license under this section if the board finds after a hearing that the deficiency that required disciplinary action has been remedied.

As added by P.L.33-1993, SEC.15. Amended by P.L.32-2000, SEC.11.

IC 25-1-9-17 Applicant appearance before board or controlled substances advisory committee

Sec. 17. The board and the controlled substances advisory committee (IC 35-48-2-1) may require an applicant for licensure to appear before the board or committee before issuing a license.

As added by P.L.33-1993, SEC.16.

IC 25-1-9-18 Fitness determination of health care provider; filing of complaint

Sec. 18. (a) If the insurance commissioner forwards to the board the name of a practitioner under IC 34-18-9-4(a) (or IC 27-12-9-4(a) before its repeal), the board shall consider whether:

(1) the practitioner has become unfit to practice under section 4 of this chapter; and

(2) a complaint should be filed under IC 25-1-7-4.

(b) If the board determines that a complaint should be filed under subsection (a), the board must report to the consumer protection division whether the board will schedule the matter:

(1) for informal negotiation under IC 25-1-7-6;

(2) on the board's agenda for a vote requesting that the attorney general prosecute the matter before the board under IC 25-1-7-7; or

(3) on the board's agenda for a vote on summary suspension of the practitioner's license pending prosecution of the matter before the board under IC 25-1-7-7.

(c) A board may designate a board member or staff member to act on behalf of the board under this section.

As added by P.L.43-1995, SEC.4. Amended by P.L.1-1998, SEC.131.

IC 25-1-9-19 Third party billing notice

Sec. 19. A practitioner that provides to a patient notice concerning a third party billing for a health care service provided to the patient shall ensure that the notice:

(1) conspicuously states that the notice is not a bill;

(2) does not include a tear-off portion; and

(3) is not accompanied by a return mailing envelope.

As added by P.L.178-2003, SEC.12.

IC 25-1-12 Renewal of Licenses Held by Individuals in Military Service

IC 25-1-12-1 Application of chapter
Sec. 1. This chapter applies to an individual who:
(1) holds a license, certificate, registration, or permit under this title, IC 15, IC 16, or IC 22; and
(2) is called to active duty.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-2 "Active duty" defined
Sec. 2. As used in this chapter, "active duty" means full-time service in the:
(1) armed forces of the United States; or
(2) national guard;
for a period that exceeds thirty (30) consecutive days in a calendar year.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-3 "Armed forces of the United States" defined
Sec. 3. As used in this chapter, "armed forces of the United States" means the active or reserve components of:
(1) the army;
(2) the navy;
(3) the air force;
(4) the coast guard;
(5) the marine corps; or
(6) the merchant marine.

IC 25-1-12-4 "National guard" defined
Sec. 4. As used in this chapter, "national guard" means:
(1) the Indiana army national guard; or
(2) the Indiana air national guard.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-5 "Practitioner" defined
Sec. 5. As used in this chapter, "practitioner" means an individual who holds:
(1) an unlimited license, certificate, or registration;
(2) a limited or probationary license, certificate, or registration;
(3) a temporary license, certificate, registration, or permit;
(4) an intern permit; or
(5) a provisional license;
issued under this title or IC 15, IC 16, or IC 22.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-6 Renewal, extension of time for practitioners on active duty; requirements
Sec. 6. (a) Notwithstanding any other law, a practitioner who is called to active duty out-of-state and meets the requirements of subsection (b) is entitled to an extension of time described in subsection (c) to:
(1) renew; and
(2) complete the continuing education required by;
the practitioner's license, certificate, registration, or permit.
(b) The practitioner must meet the following requirements to receive the extension of time provided under subsection (a):
(1) On the date the practitioner enters active duty, the practitioner's license, certificate, registration, or permit may not be revoked, suspended, lapsed, or be the subject of a complaint under IC 25-1-7.
(2) The practitioner's license, certificate, registration, or permit must expire while the practitioner is out-of-state on active duty, and the practitioner must not have received the notice of expiration before the date the practitioner entered active duty.
(3) The practitioner shall provide proof of out-of-state active duty by providing a copy of the practitioner's:
(A) discharge; or
(B) government movement orders;
to the agency, board, commission, or committee issuing the practitioner's license, certificate, registration, or permit at the time the practitioner renews the practitioner's license, certificate, registration, or permit under this chapter.
(c) The extension of time provided under subsection (a) is equal to one hundred eighty (180) days after the date of the practitioner's discharge or release from active duty.
(d) The agency, board, commission, or committee that issued the practitioner's license, certificate, registration, or permit may extend the period provided in subsection (c) if the agency or board determines that an illness, an injury, or a disability related to the practitioner's active duty prevents the practitioner from renewing or completing the continuing education required for the practitioner's license, certificate, registration, or permit. However, the agency, board,

commission, or committee may not extend the period for longer than three hundred sixty-five (365) days after the date of the practitioner's discharge or release from active duty.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-7 Late fees; waiver
Sec. 7. Any late fees that may be assessed against a practitioner in connection with a renewal under this chapter are waived.
As added by P.L.274-2004, SEC. 2.

IC 25-1-12-8 Construing of chapter
Sec. 8. This chapter may not be construed as a restriction or limitation on any of the rights, benefits, and protections granted to a member of:
(1) the armed forces of the United States; or
(2) the national guard;
under federal law.
As added by P.L.274-2004, SEC. 2.

Non-Code Provision
IC 25-1-12, as added by this act, applies to all individuals who:
(1) hold a license, certificate, registration, or permit under IC 15, IC 16, IC 22, or IC 25; and
(2) have been called to full-time service in the:
(A) armed forces of the United States (as defined in IC 25-1-12-3, as added by this act); or
(B) Indiana army or air national guard;
after September 11, 2001.
As added by P.L.274-2004, SEC. 3.

IC 25-1-13

Chapter 13. Indiana Scheduled Prescription Electronic Collection and Tracking Program [EFFECTIVE JULY 1, 2006]:

Sec. 1. This chapter applies after June 30, 2007.

Sec. 2. As used in this chapter, "agency" refers to the Indiana professional licensing agency established by IC 25-1-5-3.

Sec. 3. As used in this chapter, "INSPECT" refers to the Indiana scheduled prescription electronic collection and tracking program established by section 4 of this chapter.

Sec. 4. The Indiana scheduled prescription electronic collection and tracking program is established within the agency.

Sec. 5. The agency shall perform all administrative functions, duties, and responsibilities for the INSPECT program.

Sec. 6. The INSPECT program shall collect and process information received under IC 35-48-7-8.1 and has duties described in IC 35-48-7-10.1 and IC 35-48-7-11.1.

IC 12-15-35
Chapter 35. Drug Utilization Review

IC 12-15-35-1
Sec. 1. As used in this chapter, "appropriate and medically necessary" means drug prescribing, drug dispensing, and patient medication usage in conformity with the criteria and standards developed under this chapter.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-2
Sec. 2. As used in this chapter, "board" refers to the drug utilization review board created under this chapter.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-3
Sec. 3. As used in this chapter, "compendia" means those resources widely accepted by the medical profession in the efficacious use of drugs, including the following sources:
(1) The American Hospital Formulary Services Drug Information.
(2) The U.S. Pharmacopeia-Drug Information.
(3) The American Medical Association Drug Evaluations.
(4) The peer-reviewed medical literature.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-4
Sec. 4. As used in this chapter, "counseling" means the activities conducted by a pharmacist to inform Medicaid recipients about the proper use of drugs as required by the board under this chapter.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-5
Sec. 5. As used in this chapter, "criteria" means the predetermined and explicitly accepted elements that are used to measure drug use on an ongoing basis to determine if the use is appropriate, medically necessary, and not likely to result in adverse medical outcomes.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-6
Sec. 6. As used in this chapter, "drug-disease contraindication" means an occurrence in which the therapeutic effect of a drug is adversely altered by the presence of another disease condition.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-7
Sec. 7. As used in this chapter, "drug-drug interaction" means an occurrence in which at least two (2) drugs taken by a recipient leads to clinically significant toxicity that:
(1) is characteristic of one (1) or any of the drugs present; or
(2) leads to the interference with the effectiveness of one (1) or any of the drugs.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-8
Sec. 8. As used in this chapter, "drug utilization review" or "DUR" means the program designed to measure and assess on a retrospective and a prospective basis the proper use of outpatient drugs in the Medicaid program.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-9
Sec. 9. As used in this chapter, "intervention" means an action taken by the board with a prescriber or pharmacist to inform about or to influence prescribing or dispensing practices or utilization of drugs.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-10
Sec. 10. As used in this chapter, "overutilization or underutilization" means the use of a drug in such quantities where the desired therapeutic goal is not achieved.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-11
Sec. 11. As used in this chapter, "pharmacist" means an individual who is licensed as a pharmacist in Indiana under IC 25-26.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-12
Sec. 12. As used in this chapter, "physician" means an individual who is licensed to practice medicine in Indiana under IC 25-22.5.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-13
YAMD.1992
Sec. 13. As used in this chapter, "prospective DUR" means the part of the drug utilization review program that:
(1) is to occur before the drug is dispensed;
(2) is designed to screen for potential drug therapy problems based on explicit and predetermined criteria and standards that are developed on an ongoing basis with professional input; and
(3) is to provide for the counseling of recipients about the proper use of drugs.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-14
IC 12-15-35-14 Sec. 14. As used in this chapter, "retrospective DUR" means the part of the drug utilization review program that assesses or measures drug use based on an historical review of drug use data against predetermined and explicit criteria and standards that are developed on an ongoing basis with professional input.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-15
Sec. 15. As used in this chapter, "standards" means the acceptable range of deviation from the criteria that reflects local medical practice and that is tested on the Medicaid recipient database.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-16
Sec. 16. As used in this chapter, "SURS" refers to the surveillance utilization review system of the Medicaid program.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-17
Sec. 17. As used in this chapter, "therapeutic appropriateness" means drug prescribing based on rational drug therapy that is consistent with the criteria and standards developed under this chapter.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-18
Sec. 18. As used in this chapter, "therapeutic duplication" means the prescribing and dispensing of:
(1) the same drug; or
(2) at least two (2) drugs from the same therapeutic class;
where overlapping periods of drug administration are involved and where such prescribing or dispensing is not medically indicated.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-18.5
Sec. 18.5. This chapter applies to any contractor or vendor of the state responsible for providing or managing any part of the Medicaid outpatient drug program.
As added by P.L.76-1994, SEC.2.

IC 12-15-35-18.7
Sec. 18.7. A formulary established by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.
As added by P.L.231-1999, SEC.2.

IC 12-15-35-19
Sec. 19. The drug utilization review board is established.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-20
Sec. 20. The board is composed of the following:
(1) Four (4) individuals licensed and actively engaged in the practice of medicine or osteopathic medicine in Indiana under IC 25-22.5.
(2) Four (4) individuals licensed under IC 25-26 and actively engaged in the practice of pharmacy in Indiana.
(3) One (1) individual with expertise in therapeutic pharmacology who is neither a physician or a pharmacist.
(4) A representative of the office who shall serve as an ex-officio nonvoting member of the board.
(5) One (1) individual who:
(A) is employed by a health maintenance organization that has a pharmacy benefit; and

(B) has expertise in formulary development and pharmacy benefit administration.

The individual appointed under this subdivision may not be employed by a health maintenance organization that is under contract or subcontract with the state to provide services to Medicaid recipients under this article.

(6) One (1) individual who is a health economist.

As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.3.

IC 12-15-35-20.1

Sec. 20.1. (a) Each board member shall fully disclose any potential conflicts of interest, financial or otherwise, relating to an issue that comes before the board for recommendation or other action.

(b) A board member may not vote on a recommendation or other action if the member or the member's employer has a conflict of interest, financial or otherwise, in the outcome of the vote.

(c) A board member who may not vote on a recommendation or other action under subsection (b) may still participate in any discussions regarding the recommendation or other action.

As added by P.L.231-1999, SEC.4.

IC 12-15-35-21

Sec. 21. (a) The members of the board shall be appointed by the governor and serve a term of three (3) years.

(b) The governor shall fill a vacancy on the board by appointing a new member to serve the remainder of the unexpired term.

(c) The governor may remove a member for cause.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-22

Sec. 22. Board members must have expertise in one (1) or more of the following:

(1) Clinically appropriate prescribing of outpatient drugs.

(2) Clinically appropriate dispensing and monitoring of outpatient drugs.

(3) Drug utilization review, evaluation, and intervention.

(4) Medical quality assurance.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-23

Sec. 23. In making the physician appointments, the governor shall provide for geographic balance.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-24

Sec. 24. An individual appointed to the board may be reappointed upon the completion of the individual's term.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-25

Sec. 25. (a) The board shall annually elect a chairman from the members of the board.

(b) The chairman may be re-elected to serve consecutive terms as chairman.

(c) A member of the board who is not a state employee is entitled to the minimum salary per diem as provided by IC 4-10-11-2.1(b). Each member of the board is entitled to reimbursement for traveling expenses and other expenses actually incurred in connection with the member's duties as provided in the state travel policies and procedures established by the Indiana department of administration and the budget agency.

(d) Each member of the board who is a state employee is entitled to reimbursement for traveling expenses actually incurred in connection with the member's duties, as provided in the state travel policies and procedures established by the Indiana department of administration and approved by the budget agency.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-26

Sec. 26. The secretary shall provide additional staff to the board.

As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001, SEC.162.

IC 12-15-35-27

Sec. 27. The board is responsible for the oversight of the retrospective and prospective DUR program.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-28

Sec. 28. The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software

programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.3.

IC 12-15-35-29

Sec. 29. (a) A quorum consists of six (6) voting members of the board.

(b) DUR criteria and standards for appropriate prescribing may only be implemented with the approval of a majority of the quorum of the board. The majority vote must include at least three (3) of the four (4) physician members of the board and may allow the board to accept deviations from the standards on a case-by-case basis.

As added by P.L.75-1992, SEC.19. Amended by P.L.231-1999, SEC.5.

IC 12-15-35-30

Sec. 30. The criteria and standards developed under section 28(3) of this chapter for appropriate prescribing that are implemented must reflect the local practices of physicians to monitor the following:

(1) Therapeutic appropriateness.

(2) Overutilization or underutilization.

(3) Therapeutic duplication.

(4) Drug-disease contraindications.

(5) Drug-drug interactions.

(6) Incorrect drug dosage or duration of drug treatment.

(7) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-31

Sec. 31. (a) An intervention developed under section 28(4) of this chapter that involves a physician must be approved by at least three (3) of the four (4) physician members of the board before implementation.

(b) An intervention that involves a pharmacist must be approved by at least three (3) of the four (4) pharmacist members of the board before implementation.

(c) Interventions include the following:

(1) Information disseminated to physicians and pharmacists to ensure that physicians and pharmacists are aware of the board's duties and powers.

(2) Written, oral, or electronic reminders of recipient-specific or drug-specific information that are designed to ensure recipient, physician, and pharmacist

confidentiality, and suggested changes in the prescribing or dispensing practices designed to improve the quality of care.

(3) Use of face-to-face discussions between experts in drug therapy and the prescriber or pharmacist who has been targeted for educational intervention.

(4) Intensified reviews or monitoring of selected prescribers or pharmacists.

(5) The creation of an educational program using data provided through DUR to provide for active and ongoing educational outreach programs to improve prescribing and dispensing practices.

(6) The timely evaluation of interventions to determine if the interventions have improved the quality of care.

(7) The review of case profiles before the conducting of an intervention.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-32

(*Repealed by P.L.76-1994, SEC.7.)*

IC 12-15-35-32.1

YAMD.1994

Sec. 32.1. The annual report under section 28 of this chapter shall include information on the following:

(1) A description of the nature and scope of the prospective drug review program.

(2) A description of how pharmacies performing prospective DUR without computers are expected to comply with the statutory requirement for written criteria.

(3) Detailed information on the specific criteria and standards in use and any changes in criteria.

(4) A description of the nature and scope of the retrospective DUR program.

(5) A summary of the educational interventions used and an assessment of the effect of these educational interventions on the quality of care.

(6) An estimate of the cost savings generated as a result of the DUR program including savings to the Medicaid drug program attributable to the prospective and retrospective DUR.

(7) An overview of the fiscal impact of the DUR program on other areas of the Medicaid program.

(8) A quantifiable assessment of how DUR has improved quality of care.

(9) A summary of the total number of prescriptions reviewed by drug therapeutic class.

As added by P.L.76-1994, SEC.4.

IC 12-15-35-33

(*Repealed by P.L.1-1993, SEC.132.)*

IC 12-15-35-34

Sec. 34. (a) Information that identifies an individual collected under this chapter is confidential and may not be disclosed by the board.

(b) The board may have access to identifying information for purposes of carrying out intervention activities. The identifying information may not be released to anyone other than a member of the board.

(c) The board may release cumulative non-identifying information for purposes of legitimate research.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-35

Sec. 35. (a) As used in this section, "single source drug" means a covered outpatient drug that is produced or distributed under an original new drug application approved by the federal Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(b) Before the board develops a program to place a single source drug on prior approval, restrict the drug in its use, or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least thirty (30) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least thirty (30) days but not more than sixty (60) days after the notification.

(3). Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must

provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(c) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(d) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

As added by P.L.75-1992, SEC.19. Amended by P.L.76-1994, SEC.5; P.L.231-1999, SEC.6.

IC 12-15-35-36

Sec. 36. The board may establish advisory committees to assist the board in carrying out the board's duties under this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-37

Sec. 37. The board shall, in cooperation with the secretary, include in the Medicaid state plan the creation and implementation of a retrospective and prospective DUR program for Medicaid outpatient drugs to ensure that the prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-38

Sec. 38. The retrospective and prospective DUR program shall be operated under the guidelines and procedures established by the board under section 29 of this chapter.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-39

Sec. 39. Retrospective DUR must:

(1) be based on the guidelines established by the board; and

(2) use the mechanized drug claims processing and information retrieval system to analyze claims data to do the following:

(A) Identify patterns of fraud, abuse, gross overuse, and inappropriate or medically unnecessary care.

(B) Assess data on drug use against explicit predetermined standards that are based on the compendia and other sources to monitor the following:

(i) Therapeutic appropriateness.

(ii) Overutilization or underutilization.

(iii) Therapeutic duplication.

(iv) Drug-disease contraindications.

(v) Drug-drug interactions.

(vi) Incorrect drug dosage or duration of drug treatment.

(vii) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-40

Sec. 40. Prospective DUR must be based on the guidelines established by the board and must provide that prior to the prescription being filled or delivered a review will be conducted by the pharmacist at the point of sale to screen for potential drug therapy problems resulting from the following:

(1) Therapeutic duplication.

(2) Drug-drug interactions.

(3) Incorrect dosage and duration of treatment.

(4) Drug-allergy interactions.

(5) Clinical abuse and misuse.

As added by P.L.75-1992, SEC.19.

IC 12-15-35-41

Sec. 41. The activities of the board in carrying out this chapter are covered under IC 34-30-15.

As added by P.L.75-1992, SEC.19. Amended by P.L.1-1998, SEC.103.

IC 12-15-35-42

Sec. 42. (a) The board may meet in an executive session for purposes of reviewing DUR data or to conduct or to discuss activity as provided for in IC 5-14-1.5-6.1.

(b) The board shall also conduct regular public meetings to gather input from the public on the operation of the DUR program.

(c) The board shall meet monthly to implement its duties under this chapter.
As added by P.L.75-1992, SEC.19. Amended by P.L.291-2001, SEC.163.

IC 12-15-35-43
Sec. 43. Confidential data or information obtained by pharmacists as part of prospective DUR are confidential but may be released to prescribers or others according to procedures established by the board.
As added by P.L.75-1992, SEC.19.

IC 12-15-35-44
Sec. 44. A person who does not comply with the confidentiality provisions under section 34 of this chapter commits a Class A misdemeanor.
As added by P.L.75-1992, SEC.19. Amended by P.L.1-1993, SEC.133.

IC 12-15-35-45
Sec. 45. (a) The chairman of the board, subject to the approval of the board members, may appoint an advisory committee to make recommendations to the board on the development of a Medicaid outpatient drug formulary.
(b) If the office decides to establish a Medicaid outpatient drug formulary, the formulary shall be developed by the board.
(c) A formulary used by a Medicaid managed care organization is subject to sections 46 and 47 of this chapter.
As added by P.L.76-1994, SEC.6. Amended by P.L.231-1999, SEC.7.

IC 12-15-35-46
Sec. 46. (a) This section applies to a managed care organization that enters into an initial contract with the office to be a Medicaid managed care organization after May 13, 1999.
(b) Before a Medicaid managed care organization described in subsection (a) implements a formulary, the managed care organization shall submit the formulary to the office at least thirty-five (35) days before the date that the managed care organization implements the formulary for Medicaid recipients.
(c) The office shall forward the formulary to the board for the board's review and recommendation.
(d) The office shall provide at least thirty (30) days notification to the public that the board will review a Medicaid managed care organization's proposed formulary at a particular board meeting. The notification shall contain the following information:
(1) A statement of the date, time, and place at which the board meeting will be convened.
(2) A general description of the subject matter of the board meeting.
(3) An explanation of how a copy of the formulary to be discussed may be obtained.
The board shall meet to review the formulary at least thirty (30) days but not more than sixty (60) days after the notification.
(e) In reviewing the formulary, the board shall do the following:
(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that the use of the formulary will not:
(A) impede the quality of patient care in the Medicaid program; or
(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.
(2) Make a determination that:
(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary;
(B) a process is in place through which a Medicaid member has access to medically necessary drugs; and
(C) the managed care organization otherwise meets the requirements of IC 27-13-38.
(f) The board shall consider:
(1) health economic data;
(2) cost data; and
(3) the use of formularies in the non-Medicaid markets;
in developing its recommendation to the office.
(g) Within thirty (30) days after the board meeting, the board shall make a recommendation to the office regarding whether the proposed formulary should be approved, disapproved, or modified.
(h) The office shall rely significantly on the clinical expertise of the board. If the office does not agree with the recommendations of the board, the office shall, at a public meeting, discuss the disagreement with the board and present any additional information to the board for the board's consideration. The board's consideration of additional information must be conducted at a public meeting.
(i) Based on the final recommendations of the board, the office shall approve, disapprove, or require modifications to the Medicaid managed care organization's proposed formulary. The office shall notify the managed care organization of the office's decision within fifteen (15) days of receiving the board's final recommendation.
(j) The managed care organization must comply with the office's decision within sixty (60) days after receiving notice of the office's decision. (k) Notwithstanding the other provisions of this section, the office may temporarily approve a Medicaid managed care organization's proposed formulary pending a final recommendation from the board.
As added by P.L.231-1999, SEC.8.

IC 12-15-35-47
Sec. 47. (a) This section applies to the following changes to a formulary used by a Medicaid managed care organization for Medicaid recipients:
(1) Removing one (1) or more drugs from the formulary.

(2) Placing new restrictions on one (1) or more drugs on the formulary.

(b) Before a Medicaid managed care organization makes a change described in subsection (a), the managed care organization shall submit the proposed change to the office.

(c) The office shall forward the proposed change to the board for the board's review and recommendation.

(d) The office shall provide at least thirty (30) days notification to the public that the board will:

(1) review the proposed change; and

(2) consider evidence and credible information provided to the board;

at the board's regular board meeting before making a recommendation to the office regarding whether the proposed change should be approved or disapproved.

(e) Based on the final recommendation of the board, the office may approve or disapprove the proposed change. If a proposed change is not disapproved within ninety (90) days after the date the managed care organization submits the proposed change to the office, the managed care organization may implement the change to the formulary.

(f) A Medicaid managed care organization:

(1) may add a drug to the managed care organization's formulary without the approval of the office; and

(2) shall notify the office of any addition to the managed care organization's formulary within thirty (30) days after making the addition.

As added by P.L.231-1999, SEC.9.

IC 12-15-35-48

Sec. 48. (a) The board shall review the prescription drug program of a managed care organization that participates in the state's risk-based managed care program at least one (1) time per year. The board's review of a prescription drug program must include the following:

(1) An analysis of the single source drugs requiring prior authorization, including the number of drugs requiring prior authorization in comparison to other managed care organizations' prescription drug programs that participate in the state's Medicaid program.

(2) A determination and analysis of the number and the type of drugs subject to a restriction.

(3) A review of the rationale for:

(A) the prior authorization of a drug described in subdivision (1); and

(B) a restriction on a drug.

(4) A review of the number of requests a managed care organization received for prior authorization, including the number of times prior authorization was approved and the number of times prior authorization was disapproved.

(5) A review of:

(A) patient and provider satisfaction survey reports; and

(B) pharmacy-related grievance data for a twelve (12) month period.

(b) A managed care organization described in subsection (a) shall provide the board with the information necessary for the board to conduct its review under subsection (a).

(c) The board shall report to the select joint commission on Medicaid oversight established by IC 2-5-26-3 at least one (1) time per year on the board's review under subsection (a).

As added by P.L.107-2002, SEC.22.

IC 12-15-35-49

Sec. 49. (a) The office shall provide the board with information necessary for the board to carry out its duties under this chapter.

(b) The office shall provide the information required under subsection (a):

(1) when requested by the board; and

(2) in a timely manner.

As added by P.L.291-2001, SEC.164.

End of section.

IC 16-42-3

Chapter 3. Uniform Food, Drug, and Cosmetic Act: Adulteration and Misbranding of Drugs or Devices

IC 16-42-3-1

Sec. 1. As used in this chapter, "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance that is produced by microorganisms and that has the capacity to inhibit or destroy microorganisms in dilute solution, including the chemically synthesized equivalent of the substance.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-2

Sec. 2. As used in this chapter, "established name", with respect to a drug or ingredient of a drug, means:

(1) the applicable official name designated under Section 508 of the Federal Act;

(2) if there is no official name and the drug or the ingredient is an article recognized in an official compendium, the official title of the drug or ingredient in the compendium; or

(3) if neither subdivision (1) nor (2) applies, the common or usual name, if any, of the drug or the ingredient.

However, when subdivision (2) applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia applies unless the article is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia applies.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-2.5

Sec. 2.5. (a) The state veterinarian shall act in place of the state health commissioner under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

(b) The Indiana state board of animal health shall act in place of the state department of health under this chapter when impounding or disposing of adulterated or misbranded products under IC 15-2.1-23 or IC 15-2.1-24.

As added by P.L.137-1996, SEC.70.

IC 16-42-3-3

Sec. 3. A drug or device is considered to be adulterated under the following conditions:

(1) If the drug or device consists in whole or in part of any filthy, putrid, or decomposed substance.

(2) If the drug or device has been produced, prepared, packed, or held under unsanitary conditions under which the drug or device may have been contaminated with filth or made injurious to health.

(3) If the methods used in or the facilities or controls used for a drug's manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that:

(A) the drug meets the requirements of this article as to safety; and

(B) the drug:

(i) has the identity and strength; and

(ii) meets the quality and purity characteristics;

that the drug purports or is represented to possess.

(4) If a drug's container is composed in whole or in part of any poisonous or deleterious substance that may make the contents injurious to health.

(5) If:

(A) a drug bears or contains, for purposes of coloring only, a color additive that is unsafe within the meaning of IC 16-42-2-5; or

(B) a color additive, the intended use of which in or on drugs is for purposes of coloring only, is unsafe under IC 16-42-2-5.

(6) If:

(A) the drug or device purports to be or is represented as a drug, the name of which is recognized in an official compendium; and

(B) the strength of the drug differs from or the drug's quality or purity falls below the standard set forth in that compendium;

the determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence or inadequacy of such tests or methods of assay, those tests or methods prescribed by the federal security administrator in regulations promulgated under the Federal Act. A drug defined in an official compendium is not considered to be adulterated under this subdivision because the drug differs from the standard of strength, quality, or purity set forth in the compendium if the drug's difference in strength, quality, or purity from the standard is plainly stated on the drug's label. If a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia unless the drug is labeled and offered for sale as a homeopathic drug. In the latter case, the drug is subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(7) If:

(A) the drug or device is not subject to the provisions of subdivision (6); and

(B) the drug's or device's strength differs from or the drug's or device's purity or quality falls below that which the drug or device purports or is represented to possess.

(8) If the drug or device is a drug and any substance has been:

(A) mixed or packed with the drug or device so as to reduce the drug's or device's quality or strength; or

(B) substituted wholly or in part for the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-4

Sec. 4. A drug or device is considered to be misbranded under any of the following conditions:

(1) If the labeling of the drug or device is false or misleading in any way.

(2) If the drug or device is in package form unless the drug or device bears a label containing:

(A) the name and place of business of the manufacturer, packer, or distributor; and

(B) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

However, under clause (B) reasonable variations shall be permitted and exemptions as to small packages shall be established by rules adopted by the state department.

(3) If any word, statement, or other information required to appear on the label or labeling, under this chapter or a rule adopted under IC 16-42-1-2 is not prominently placed on the drug or device with conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms that make the label likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(4) If the drug or device:

(A) is for use by humans; and

(B) contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, methamphetamine, or sulphonmethane, or any chemical derivative of such substance, which derivative after investigation has been found to be and is designated as habit forming, by rules adopted by the state department under IC 16-42-1 through IC 16-42-4 or by regulations issued under 21 U.S.C. 352(d);

unless the label on the drug or device bears the name and quantity or proportion of that substance or derivative and the statement "Warning . May Be Habit Forming".

(5) If a drug, unless the following conditions are met:

(A) The label on the drug bears, to the exclusion of any other nonproprietary name except the applicable systematic chemical name or the chemical formula, the following:

(i) The established name of the drug, if any.

(ii) If the drug is fabricated from at least two (2) ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of those substances contained in the drug. However, the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subdivision, applies only to prescription drugs.

(B) If a prescription drug, the established name of the drug or ingredient on the label (and on any labeling on which a name for the drug or ingredient is used) is printed prominently and in type at least half as large as that used for any proprietary name or designation for the drug or ingredient.

However, to the extent that compliance with the requirements of clause (A)(ii) or clause (B) is impracticable, exemptions shall be allowed under rules adopted by the state department or by regulations promulgated under the Federal Act.

(6) Unless the drug's or device's labeling bears:

(A) adequate directions for use; and

(B) adequate warnings against use in those pathological conditions or by children where the drug's or device's use may be dangerous to health or against unsafe dosage or methods or duration of administration or application in the manner and form that is necessary for the protection of users.

However, if any requirement of clause (A) as applied to any drug or device is not necessary for the protection of the public health, the state department shall adopt rules exempting the drug or device from that requirement.

(7) If a drug purports to be a drug the name of which is recognized in an official compendium, unless the drug is packaged and labeled as prescribed in the compendium. However, the method of packing may be modified with the consent of the state department in accordance with regulations promulgated by the federal security administrator under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, the drug is subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless the drug is labeled and offered for sale as a homeopathic drug. In that case the drug is subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia.

(8) If a drug or device has been found by the federal security administrator or the state department to be a drug liable to deterioration, unless the drug or device is packaged in a form and manner and the drug's or device's label bears a statement of such precautions as the federal security administrator or the state department requires by rule or regulation as necessary for the protection of the public health. A rule or regulation may not be established for any drug recognized in an official compendium until the federal security administrator or the state department informs the appropriate body charged with the revision of the compendium of the need for the packaging or labeling requirements and that body fails within a reasonable time to prescribe requirements.

(9) If a drug's container is made, formed, or filled as to be misleading.

(10) If a drug is an imitation of another drug.

(11) If a drug is offered for sale under the name of another drug.

(12) If a drug is or purports to be or is represented to be a drug composed wholly or partly of insulin, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 506 of the Federal Act; and

(B) the certificate or release is in effect with respect to the drug.

(13) If a drug is or purports to be or is represented to be a drug composed wholly or partly of any kind of penicillin, streptomycin, chloretetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative of those drugs, unless:

(A) the drug is from a batch with respect to which a certificate or release has been issued under Section 507 of the Federal Act; and

(B) the certificate or release is in effect with respect to that drug.

However, this subdivision does not apply to any drug or class of drugs exempted by regulations promulgated under Section 507(c) or 507(d) of the

Federal Act.

(14) If a drug or device is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug or device.

(15) Under the conditions described in section 6 of this chapter.

As added by P.L.2-1993, SEC.25. Amended by P.L.17-2001, SEC.3.

IC 16-42-3-5

Sec. 5. A drug or device that, in accordance with the practice of the trade, is to be processed, labeled, or repacked in substantial quantities at an establishment other than the establishment where the drug or device was originally processed or packed, is exempt from the labeling and packaging requirements of IC 16-42-1 through IC 16-42-4 while the drug or device is in transit in intrastate commerce from one (1) establishment to the other if the transit is made in good faith for completion purposes only. However, the drug or device is otherwise subject to the applicable provisions of IC 16-42-1 through IC 16-42-4.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-6

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 or pharmacist intern (as defined in IC 25-26-13-2); or

(3) by refilling a 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 or is entered into an electronic format and filed by the pharmacist or pharmacist intern (as defined in IC 25-26-13-2).

(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 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) 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.

As added by P.L.2-1993, SEC.25. Amended by P.L.144-1996, SEC.12. Amended by P.L. 204-2005, SEC.4.

IC 16-42-3-7

Sec. 7. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) A person may not sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce any new drug unless:

(1) an application to sell, deliver, offer for sale, hold for sale, give away, or introduce into intrastate commerce a new drug has been approved and the approval has not been withdrawn under Section 505 of the Federal Act; or

(2) if not subject to the Federal Act the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed,

recommended, or suggested in the labeling of the drug.

(c) Before selling or offering for sale the new drug, there must be filed with the state department an application setting forth the following:

(1) Full reports of investigations that have been made to show whether or not the drug is safe for use and whether the drug is effective in use.

(2) A full list of the articles used as components of the drug.

(3) A full statement of the composition of the drug.

(4) A full description of the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drug.

(5) Such samples of the drug and of the articles used as components of the drug that the state department requires.

(6) Specimens of the labeling proposed to be used for the drug.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-8

Sec. 8. (a) This section does not apply under the circumstances described in section 9 of this chapter.

(b) An application provided for under section 7 of this chapter becomes effective on the one hundred eightieth day after the filing of the application. However, if the state department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing that:

(1) the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling of the drug;

(2) the methods used in and the facilities and controls used for the manufacture, processing, and packing of the drugs are inadequate to preserve the drug's identity, strength, quality, and purity; or

(3) based on a fair evaluation of all material facts, that the labeling is false or misleading in any particular;

the state department shall, before the effective date of the application, issue an order refusing to permit the application to become effective.

As added by P.L.2-1993, SEC.25.

IC 16-42-3-9

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.

As added by P.L.2-1993, SEC.25; Amended by P.L. 204-2005, SEC.5.

IC 16-42-3-10

Sec. 10. (a) An order refusing to permit an application under section 7 or 8 of this chapter to become effective may be revoked by the state department.

(b) The state department may, after affording an opportunity for public hearing and judicial appeal, revoke an application approved under section 7 or 8 of this chapter if the state department finds any of the following:

(1) That the drug, based on evidence acquired after approval, may not be safe or effective for the intended use.

(2) That the facilities or controls used in the manufacture, processing, or labeling of the drug may present a hazard to the public health.
As added by P.L.2-1993, SEC.25.

IC 16-42-3-11

Sec. 11. The representation of a drug in the labeling or advertisement as an antiseptic is considered to be a representation that the drug is a germicide, except if a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or other use involves prolonged contact with the body.
As added by P.L.2-1993, SEC.25.

IC 16-42-3-12

Sec. 12. (a) Except as otherwise provided, a person who recklessly violates or fails to comply with this chapter commits a Class B misdemeanor.
(b) Each day a violation continues constitutes a separate offense.
As added by P.L.2-1993, SEC.25.

IC 16-42-19

Chapter 19. Drugs: Indiana Legend Drug Act

IC 16-42-19-1

Sec. 1. This chapter is intended to supplement IC 16-42-1 through IC 16-42-4.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-2

Sec. 2. As used in this chapter, "drug" means the following:

(1) Articles or substances recognized in United States Pharmacopeial Convention, Inc.; The United States Pharmacopeia, Twenty-Second Edition (1990) or United States Pharmacopeial Convention, Inc.; The National Formulary, Seventeenth Edition (1990) as revised by United States Pharmacopeial Convention, Inc.; Supplement 1 to The United States Pharmacopeia, Twenty-Second Edition and The National Formulary, Seventeenth Edition (1990); and any supplements printed after 1990.

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

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

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

(5) Devices.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.1.

IC 16-42-19-3

Sec. 3. As used in this chapter, "drug order" means an order that meets the following conditions:

(1) Is:

(A) a written order in a hospital or other health care institution for an ultimate user for a drug or device, issued and signed by a practitioner; or

(B) an order transmitted by other means of communication from a practitioner that is immediately reduced to writing by the pharmacist, registered nurse, or other licensed health care practitioner authorized by the hospital or institution.

(2) Contains the following:

(A) The name and bed number of the patient.

(B) The name and strength or size of the drug or device.

(C) Unless specified by individual institutional policy or guidelines, the amount to be dispensed either in quantity or days.

(D) Adequate directions for the proper use of the drug or device when administered to the patient.

(E) The name of the prescriber.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-4

Sec. 4. As used in this chapter, "investigational or new drug" means a drug that is limited by state law to use under professional supervision of a practitioner authorized by law to prescribe or administer the drug.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-5

Sec. 5. As used in this chapter, "practitioner" means any of the following:

(1) A licensed physician.

(2) A veterinarian licensed to practice veterinary medicine in Indiana.

(3) A dentist licensed to practice dentistry in Indiana.

(4) A podiatrist licensed to practice podiatric medicine in Indiana.

(5) An optometrist who is:

(A) licensed to practice optometry in Indiana; and

(B) certified under IC 25-26-3. [Effective July 1, 2006]

(6) An advanced practice nurse who meets the requirements of IC 25-23-1-19.5.

As added by P.L.2-1993, SEC.25. Amended by P.L.185-1993, SEC.1.

IC 16-42-19-6

Sec. 6. As used in this chapter, "precursor" means a substance, other than a legend drug, that:

(1) is an immediate chemical intermediate that can be processed or synthesized into a legend drug; and

(2) is used or produced primarily for use in the manufacture of a legend drug by persons other than persons:

(A) licensed to manufacture the legend drug by the Indiana board of pharmacy;

(B) registered by the state department; or

(C) licensed to practice pharmacy by the Indiana board of pharmacy.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-7

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 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.

As added by P.L.2-1993, SEC.25; Amended by P.L. 204-2005, SEC.6.

IC 16-42-19-8

Sec. 8. As used in this chapter, "sale" means every sale and includes the following:

(1) Manufacturing, processing, transporting, handling, packing, 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.

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

As added by P.L.2-1993, SEC.25.

IC 16-42-19-9

Sec. 9. As used in this chapter, "warehouseman" means a person who stores legend drugs for others and who has no control over the disposition of legend drugs except for the purpose of storage.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-10

Sec. 10. As used in this chapter, "wholesaler" means a person engaged in the business of distributing legend drugs that the person has not produced or prepared to persons included in any of the classes named in section 21 of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-19-11

Sec. 11. (a) Except as provided in section 21 of this chapter, a person may not sell a legend drug unless either of the following conditions exist:

(1) Except as provided in subsection (b), the legend drug is dispensed by a pharmacist upon an original prescription or drug order with the drug product specified on the prescription or drug order or by the authorization of the practitioner and there is affixed to the immediate container in which the drug is delivered a label bearing the following:

(A) The name, address, and phone number of the establishment from which the drug was dispensed.

(B) The date on which the prescription for the drug was filled.

(C) The number of the prescription as filed in the prescription files of the pharmacist who filled the prescription.

(D) The name of the practitioner who prescribed the drug.

(E) The name of the patient, or if the drug was prescribed for an animal, a statement of the species of the animal.

(F) The directions for the use of the drug as contained in the prescription.

(2) The legend drug is delivered by the practitioner in good faith in the course of practice and the immediate container in which the drug is delivered bears a label on which appears the following:

(A) The directions for use of the drug.

(B) The name and address of the practitioner.

(C) The name of the patient.

(D) If the drug is prescribed for an animal, a statement of the species of the animal.

This section does not prohibit a practitioner from delivering professional samples of legend drugs in their original containers in the course of the practitioner's practice when oral directions for use are given at the time of delivery.

(b) Notwithstanding subsection (a)(1), the following apply:

(1) A pharmacist at a hospital licensed under IC 16-21 may fill a drug order for a legend drug with a drug product allowed under the hospital's policies and procedures for the use, selection, and procurement of drugs.

(2) A pharmacist who fills a prescription for a legend drug must comply with IC 16-42-22 and IC 25-26-16.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.2.

IC 16-42-19-12

Sec. 12. Except as authorized under 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

As added by P.L.2-1993, SEC.25. Amended by P.L.270-2001, SEC.1; Amended by P.L. 204-2005, SEC.7.

IC 16-42-19-13

Sec. 13. A person may not possess or use a legend drug or a precursor unless the person obtains the drug:

(1) on the prescription or drug order of a practitioner; or
(2) in accordance with section 11(2) or 21 of this chapter.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-14
Sec. 14. A person may not fail to keep records as required by section 22 of this chapter.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-15
Sec. 15. A person may not refuse to make available and to accord full opportunity to check a record, as required by section 22 of this chapter.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-16
Sec. 16. A person may not do any of the following:
(1) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by any of the following:
(A) Fraud, deceit, misrepresentation, or subterfuge.
(B) The forgery or alteration of a prescription, drug order, or written order.
(C) The concealment of a material fact.
(D) The use of a false name or the giving of a false address.
(2) Communicate information to a physician in an effort unlawfully to procure a legend drug or unlawfully to procure the administration of a legend drug. Such a communication is not considered a privileged communication.
(3) Intentionally make a false statement in a prescription, drug order, order, report, or record required by this chapter.
(4) For the purpose of obtaining a legend drug, falsely assume the title of or represent oneself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or other person.
(5) Make or utter a false or forged prescription or false drug order or forged written order.
(6) Affix a false or forged label to a package or receptacle containing legend drugs. This subdivision does not apply to law enforcement agencies or their representatives while engaged in enforcing this chapter.
(7) Dispense a legend drug except as provided in this chapter.
As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.3.

IC 16-42-19-17
Sec. 17. A person may not possess or have under the person's control with intent to violate this chapter an instrument or contrivance designed or generally used in smoking a legend drug.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-18
Sec. 18. A person may not possess or have under control with intent to violate this chapter a hypodermic syringe or needle or an instrument adapted for the use of a legend drug by injection in a human being.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-19
Sec. 19. Except as provided in section 21 of this chapter, a person may not possess or use an anabolic steroid without a valid prescription or drug order issued by a practitioner acting in the usual course of the practitioner's professional practice.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-20
Sec. 20. (a) A prescription or drug order for a legend drug is not valid unless the prescription or drug order is issued for a legitimate medical purpose by a practitioner acting in the usual course of the practitioner's business.
(b) A practitioner may not knowingly issue an invalid prescription or drug order for a legend drug.
(c) A pharmacist may not knowingly fill an invalid prescription or drug order for a legend drug.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-21
Sec. 21. Sections 11, 13, 19, and 25(b) of this chapter are not applicable to the following:
(1) The sale of legend drugs to persons included in any of the classes named in subdivision (2), or to the agents or employees of such persons for use in the usual course of their business or practice or in the performance of their official duties.
(2) Possession of legend drugs by the following persons or their agents or employees for such use:
(A) Pharmacists.
(B) Practitioners.
(C) Persons who procure legend drugs for handling by or under the supervision of pharmacists or practitioners employed by them or for the purpose of lawful research, teaching, or testing and not for resale.

(D) Hospitals and other institutions that procure legend drugs for lawful administration by practitioners.
(E) Manufacturers and wholesalers.
(F) Carriers and warehousemen.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-22
Sec. 22. (a) Manufacturers and wholesalers shall maintain records of the movement in commerce of legend drugs for two (2) years immediately following the date of the last entry on those records and shall make those records available, at reasonable times, to law enforcement agencies and their representatives in the enforcement of this chapter.
(b) Evidence obtained under this section may not be used in a criminal prosecution of the person from whom obtained.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-23
Sec. 23. (a) As used in this section, "mechanical device" means a machine for storage and dispensing of drugs. The term does not include devices or instruments used by practitioners in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or other animals.
(b) A person may not maintain, operate, or use any type of mechanical device in which any legend drug or narcotic drug is stored or held for the purpose of dispensing the drug from the mechanical device. However, the mechanical device may be used for the storage and dispensing of legend drugs if:
(1) the mechanical device used in a:
(A) pharmacy that holds a permit issued by the Indiana board of pharmacy;
(B) remote location under the jurisdiction of the board of pharmacy; or
(C) health care facility that is licensed under IC 16-28 or IC 16-21-2; and
(2) the mechanical device is operated under the direct supervision and control of a:
(A) registered pharmacist; or
(B) practitioner;
who is directly responsible for dispensing the drug from the mechanical device.
(c) Inspectors of the Indiana board of pharmacy may inspect the premises of any person suspected of violating this section.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-24
Sec. 24. (a) A store, shop, warehouse, dwelling house, apartment, building, vehicle, boat, aircraft, or any other place that is used:
(1) by a person for the purpose of unlawfully using a legend drug; or
(2) for the unlawful keeping or selling of the legend drug;
is a common nuisance.
(b) A person may not:
(1) keep or maintain a common nuisance; or
(2) frequent or visit a place knowing the place to be used for a purpose;
as described in subsection (a).
As added by P.L.2-1993, SEC.25.

IC 16-42-19-25
Sec. 25. (a) A practitioner may not prescribe, order, distribute, supply, or sell an anabolic steroid for any of the following:
(1) Enhancing performance in an exercise, sport, or game.
(2) Hormonal manipulation intended to increase muscle mass, strength, or weight without a medical necessity.
(b) Except as provided in section 21 of this chapter, a person who is not a practitioner or lawful manufacturer of anabolic steroids may not do any of the following:
(1) Knowingly or intentionally manufacture or deliver an anabolic steroid, pure or adulterated.
(2) Possess, with intent to manufacture or deliver, an anabolic steroid.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-26
Sec. 26. In:
(1) any complaint, information, affidavit, or indictment; and
(2) any action or proceeding brought for the enforcement of any provision of this chapter;
it is not necessary to negate an exception, excuse, proviso, or exemption contained in this chapter. The burden of proof of such an exception, excuse, proviso, or exemption is upon the defendant.
As added by P.L.2-1993, SEC.25.

IC 16-42-19-27
Sec. 27. (a) A person who knowingly violates this chapter, except sections 24 and 25(b) of this chapter, commits a Class D felony. However, the offense is a Class C felony if the person has a prior conviction under this subsection or IC 16-6-8-10(a) before its repeal.
(b) A person who violates section 24 of this chapter commits a Class B misdemeanor.

(c) A person who violates section 25(b) of this chapter commits dealing in an anabolic steroid, a Class C felony. However, the offense is a Class B felony if the person delivered the anabolic steroid to a person who is:

(1) less than eighteen (18) years of age; and

(2) at least three (3) years younger than the delivering person.

As added by P.L.2-2005, SEC.58.

IC 16-42-19-28

Sec. 28. Law enforcement officers in the performance of their official duties are exempt from prosecution for and may not be convicted of violations of this chapter.

As added by P.L.2-1993, SEC.25.

IC 16-42-20
Chapter 20. Drugs: Enforcement of Pharmacy Laws and Rules

IC 16-42-20-1
Sec. 1. (a) Each member of the Indiana board of pharmacy, designated employees of the Indiana board of pharmacy, and all law enforcement officers of Indiana are primarily responsible for the enforcement of all statutes and rules of Indiana relating to controlled substances. However, the Indiana board of pharmacy is primarily responsible for making accountability audits of the supply and inventory of controlled substances.
(b) An officer or employee of the Indiana board of pharmacy designated by the board may do any of the following:
(1) Carry firearms in the performance of the officer's or employee's official duties.
(2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state.
(3) Make arrests without warrant for any offense relating to controlled substances committed in the officer's or employee's presence or if the officer or employee has probable cause to believe that the person to be arrested has committed or is committing a felony relating to controlled substances.
(4) Make seizures of property under this chapter.
(5) Perform other law enforcement duties that the Indiana board of pharmacy designates.
As added by P.L.2-1993, SEC.25.

IC 16-42-20-2
Sec. 2. (a) As used in this section, "controlled premises" means the following:
(1) Places where persons registered or exempted from registration requirements under IC 35-48-3 are required to keep records.
(2) Places, including factories, warehouses, establishments, and conveyances, in which persons registered or exempted from registration requirements under IC 35-48-3 are permitted to possess, manufacture, compound, process, sell, deliver, or otherwise dispose of a controlled substance.
(b) Issuance and execution of administrative inspection warrants must be as follows:
(1) A judge of a court of record within the judge's jurisdiction may, upon proper oath or affirmation showing probable cause, issue warrants for the purpose of conducting administrative inspections authorized by this chapter and seizures of property appropriate to the inspections.
(2) For purposes of the issuance of administrative inspection
warrants, probable cause exists upon showing a valid public interest in the effective enforcement of this chapter sufficient to justify administrative inspection of the area, premises, building, or conveyance in the circumstances specified in the application for the warrant.
(3) A warrant shall be issued only upon an affidavit of a designated officer or employee having knowledge of the facts alleged, sworn to before the judge, and establishing the grounds for issuing the warrant. If the judge is satisfied that grounds for the application exist or that there is probable cause to believe the grounds exist, the judge shall issue a warrant identifying the area, premises, building, or conveyance to be inspected, the purpose of the inspection, and, if appropriate, the type of property to be inspected.
(4) The warrant must do the following:
(A) State the grounds for the warrant's issuance and the name of each person whose affidavit has been taken in support of the warrant.
(B) Be directed to a person authorized by section 1 of this chapter to execute the warrant.
(C) Command the person to whom the warrant is directed to inspect the area, premises, building, or conveyance identified for the purpose specified and, if appropriate, direct the seizure of the property specified.
(D) Identify the item or types of property to be seized, if any.
(E) Direct that the warrant may be served during normal business hours and designate the judge to whom the warrant shall be returned.
(5) A warrant issued under this section must be executed and returned within ten (10) days of the warrant's date unless, upon a showing of a need for additional time, the court orders otherwise.
(6) If property is seized under a warrant, a copy shall be given to the person from whom or from whose premises the property is taken, together with a receipt for the property taken. The return of the warrant shall be made promptly, accompanied by a written inventory of any property taken. The inventory shall be made in the presence of the person executing the warrant and of the person from whose possession or premises the property was taken, if present, or in the presence of at least one (1) credible person other than the person executing the warrant. A copy of the inventory shall be delivered to the person from whom or from whose premises the property was taken and to the applicant for the warrant.
(7) The judge who issues a warrant shall attach to the warrant a copy of the return and all papers returnable in connection with the issuance of the warrant and file them with the clerk of the circuit or superior court for the judicial circuit in which the inspection was made.
(c) The Indiana board of pharmacy may make administrative inspections of controlled premises in accordance with the following provisions:
(1) When authorized by an administrative inspection warrant issued under subsection (b), an officer or employee designated by the Indiana board of pharmacy, upon presenting the warrant and appropriate credentials to the owner, operator, or agent in charge, may enter controlled premises for the purpose of conducting an administrative inspection.
(2) When authorized by an administrative inspection warrant, an officer or employee designated by the Indiana board of pharmacy may do the following:
(A) Inspect and copy records required by IC 35-48-3 to be kept.
(B) Inspect, within reasonable limits and in a reasonable manner, controlled premises and all pertinent equipment, finished and unfinished material, containers, and labeling found on the premises, and, except as provided in subdivision (4), all other things on the premises, including records, files, papers, processes, controls, and facilities bearing on violation of laws relating to controlled substances.
(C) Inventory any stock of any controlled substance on the premises and obtain samples of the controlled substance.
(3) This section does not prevent an inspection without a warrant of books and records under an administrative subpoena issued in accordance with IC 4-21.5-3 or prevent entries and administrative inspections, including seizures of property, without a warrant if any of the following conditions exist:

(A) The owner, operator, or agent in charge of the controlled premises consents.
(B) A situation presents imminent danger to health or safety.
(C) A situation involves the inspection of conveyances if there is reasonable cause to believe that the mobility of the conveyance makes it impracticable to obtain a warrant.
(D) An exceptional or emergency circumstance where time or opportunity to apply for a warrant is lacking.
(E) A situation in which a warrant is not constitutionally required.
(4) An inspection authorized by this section may not extend to financial data, sales data (other than shipment data), or pricing data unless the owner, operator, or agent in charge of the controlled premises consents in writing.
As added by P.L.2-1993, SEC.25.

IC 16-42-20-3
Sec. 3. Any court of record has jurisdiction to restrain or enjoin violations of laws relating to controlled substances.
As added by P.L.2-1993, SEC.25.

IC 16-42-20-4
Sec. 4. (a) The Indiana board of pharmacy shall cooperate with federal and other state agencies in discharging the board's responsibilities concerning traffic in controlled substances and in suppressing the abuse of controlled substances. To this end, the board may do the following:
(1) Arrange for the exchange of information among governmental officials concerning the use and abuse of controlled substances.
(2) Coordinate and cooperate in training programs concerning controlled substance law enforcement at local, state, and federal levels.
(3) Cooperate with the Drug Enforcement Administration by establishing a centralized unit to accept, catalog, file, and collect statistics, including records of drug dependent persons and other controlled substance law offenders within Indiana, and make the information available for federal, state, and local law enforcement purposes. The board may not furnish the name or identity of a patient or research subject whose identity cannot be obtained under subsection (c).
(4) Conduct programs of eradication aimed at destroying wild or illicit growth of plant species from which controlled substances may be extracted.
(b) Results, information, and evidence received from the Drug Enforcement Administration relating to the regulatory functions of this chapter, including the results of inspections conducted by the Drug Enforcement Administration, may be relied on and acted upon by the Indiana board of pharmacy in the exercise of the board's regulatory functions.
(c) A practitioner engaged in medical practice or research is not required or compelled to furnish the name or identity of a patient or research subject to the Indiana board of pharmacy. A practitioner may not be compelled in any state or local civil, criminal, administrative, legislative, or other proceedings to furnish the name or identity of an individual that the practitioner is obligated to keep confidential.
As added by P.L.2-1993, SEC.25.

IC 16-42-20-5
Sec. 5. (a) The following are subject to forfeiture:
(1) All controlled substances that are or have been unlawfully manufactured, distributed, dispensed, acquired, or possessed, or with respect to which there has been an act by a person in violation of laws relating to controlled substances.
(2) All raw materials, instruments, devices, and other objects that are used or intended for use by the person in possession of them in unlawfully planting, growing, manufacturing, compounding, processing, delivering, importing, or exporting a controlled substance.
(3) All property that is used or intended for use by the person in possession of the property as a container for property described in subdivision (1) or (2).
(4) All books, records, and research products and materials, including formulas, microfilm, tapes, and data that are used or intended for use by the person in possession in violation of a law
relating to controlled substances.
(b) Property subject to forfeiture under this chapter may be seized by an enforcement officer upon process issued by any state court of record having jurisdiction over the property. Seizure without process may be made if any of the following conditions exist:
(1) The seizure is incident to an arrest, a search under a search warrant, or an inspection under an administrative inspection warrant.
(2) The property subject to seizure has been the subject of a prior judgment in favor of the state in a criminal injunction or forfeiture proceeding.
(3) The Indiana board of pharmacy has probable cause to believe that the property is directly or indirectly dangerous to health or safety.
(4) The Indiana board of pharmacy has probable cause to believe that the property was used by the person in possession of the property or is intended to be used in violation of a law relating to controlled substances.
(c) In a seizure under subsection (b), proceedings under subsection (d) shall be instituted promptly.
(d) Property taken or detained under this section is not subject to replevin, but is considered to be in the custody of the Indiana board of pharmacy subject only to the orders and decrees of the court having jurisdiction over the forfeiture proceedings. When property is seized under this chapter, the Indiana board of pharmacy may do any of the following:
(1) Place the property under seal.
(2) Remove the property to a place designated by the board.
(3) Take custody of the property and remove the property to an appropriate location for disposition in accordance with law.
All property seized under this chapter shall be retained by the Indiana board of pharmacy until all proceedings in which the property may be involved have concluded.
(e) When property is forfeited under this chapter, the Indiana board of pharmacy shall do the following:
(1) Sell property that by law is not required to be transferred or destroyed, that has a monetary value, and that is not harmful to the public. The proceeds shall be used for payment of all proper expenses of the proceedings for forfeiture and sale, including expenses of seizure, maintenance of custody,

advertising, and court costs. All proceeds in excess of expenses shall be paid into the common school fund of the state.

(2) Take custody of property that has no monetary value or cannot lawfully be sold and remove the property for disposition in accordance with administrative rule or forward the property to the Drug Enforcement Administration for disposition.

(f) Controlled substances listed in schedule I that are unlawfully possessed, transferred, sold, or offered for sale are contraband and shall be seized and summarily forfeited to the state. Controlled substances listed in schedule I that are seized or come into the possession of the state, the owners of which are unknown, are contraband and shall be
summarily forfeited to the state.

(g) Species of plants from which controlled substances in schedules I and II may be derived that:

(1) have been unlawfully planted or cultivated and the owners or cultivators are unknown; or

(2) are wild growths;

may be seized and summarily forfeited to the state.

(h) The failure, upon demand by the Indiana board of pharmacy or the board's authorized agent, of the person in occupancy or in control of land or premises upon which the species of plants are growing or being stored to produce an appropriate registration or proof that the person is the holder of the plants constitutes authority for the seizure and forfeiture of the plants.

As added by P.L.2-1993, SEC.25.

IC 16-42-20-6

Sec. 6. (a) It is not necessary for the state to negate any exemption or exception in this chapter or in IC 35-48 in a complaint, an information, an indictment, or other pleading or in a trial, hearing, or other proceeding under this chapter or under IC 35-48. The burden of proof of an exemption or exception is on the person claiming the exemption or exception.

(b) In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under IC 35-48-3, a person is presumed not to be the holder of the registration or form.

As added by P.L.2-1993, SEC.25.

IC 16-42-20-7

Sec. 7. All final determinations, findings, and conclusions of the Indiana board of pharmacy under this chapter are conclusive decisions of the matters involved. A person aggrieved by the decision may obtain review of the decision in accordance with IC 4-21.5-5. Findings of fact by the Indiana board of pharmacy, if supported by substantial evidence, are conclusive.

As added by P.L.2-1993, SEC.25.

IC 16-42-20-8

Sec. 8. The addiction services bureau of the division of mental health and addiction shall carry out educational programs designed to prevent and deter misuse and abuse of controlled substances. In connection with these programs, the bureau may do the following:

(1) Promote better recognition of the problems of misuse and abuse of controlled substances within the regulated industry and among interested groups and organizations.

(2) Assist the regulated industry and interested groups and organizations in contributing to the reduction of misuse and abuse of controlled substances.

(3) Consult with interested groups and organizations to aid the groups and organizations in solving administrative and organizational problems.

(4) Evaluate procedures, projects, techniques, and controls conducted or proposed as part of educational programs on misuse and abuse of controlled substances.

(5) Disseminate the results of research on misuse and abuse of controlled substances to promote a better public understanding of what problems exist and what can be done to combat the problems.

(6) Assist in the education and training of state and local law enforcement officials in efforts to control misuse and abuse of controlled substances.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.86.

IC 16-42-20-9

Sec. 9. The addiction services bureau of the division of mental health and addiction shall encourage research on misuse and abuse of controlled substances. In connection with the research and in furtherance of the enforcement of laws relating to controlled substances, the bureau may do the following:

(1) Establish methods to assess accurately the effects of controlled substances and identify and characterize those with potential for abuse.

(2) Make studies and undertake programs of research to do the following:

(A) Develop new or improved approaches, techniques, systems, equipment, and devices to strengthen the enforcement of laws relating to controlled substances.

(B) Determine patterns of misuse and abuse of controlled substances and the social effects of such behavior.

(C) Improve methods for preventing, predicting, understanding, and dealing with the misuse and abuse of controlled substances.

(3) Enter into contracts with public agencies, institutions of higher education, and private organizations or individuals for the purpose of conducting research, demonstrations, or special projects that bear directly on misuse and abuse of controlled substances.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.87.

IC 16-42-20-10

Sec. 10. The addiction services bureau of the division of mental health and addiction may enter into contracts for educational and research activities without performance bonds.

As added by P.L.2-1993, SEC.25. Amended by P.L.215-2001, SEC.88.

IC 16-42-20-11

Sec. 11. The Indiana board of pharmacy may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization may not be compelled in any civil, criminal, administrative, legislative, or other proceeding to identify the individuals who are the subjects of research for which the authorization was obtained.

As added by P.L.2-1993, SEC.25.

IC 16-42-20-12

Sec. 12. The Indiana board of pharmacy may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.

As added by P.L.2-1993, SEC.25.

(End of Section)

IC 16-42-21
Chapter 21. Drugs: Drug Samples

IC 16-42-21-1
Sec. 1. As used in this chapter, "controlled substance" has the meaning set forth in IC 35-48-1.
As added by P.L.2-1993, SEC.25.

IC 16-42-21-2
Sec. 2. As used in this chapter, "drug sample" means a legend drug or a controlled substance that is manufactured, packaged, labeled, or otherwise marketed to be distributed and dispensed without consideration.
As added by P.L.2-1993, SEC.25.

IC 16-42-21-3
Sec. 3. As used in this chapter, "practitioner" means any of the following:
(1) A licensed physician.
(2) A dentist licensed to practice dentistry in Indiana.
(3) A podiatrist licensed to practice podiatry in Indiana.
(4) A veterinarian licensed to practice veterinary medicine in Indiana.
(5) An optometrist who is:
(A) licensed to practice optometry in Indiana; and
(B) certified under IC 25-26-3.
As added by P.L.2-1993, SEC.25.

IC 16-42-21-4
Sec. 4. A person who:
(1) is a manufacturer, wholesaler, practitioner, or pharmacist, or is an employee or agent of a manufacturer, wholesaler, practitioner, or pharmacist; and
(2) either:
(A) knowingly or intentionally removes a drug sample from its original packaging, repackages the drug sample, and delivers the drug sample to an ultimate user in exchange for money or other property; or
(B) knowingly or intentionally delivers a drug sample to an ultimate user when the expiration date listed by the manufacturer on the drug sample has passed;
commits a Class B misdemeanor.
As added by P.L.2-1993, SEC.25.

IC 16-42-22
Chapter 22. Drugs: Generic Drugs

IC 16-42-22-1
"Brand name" defined
Sec. 1. As used in this chapter, "brand name" means the proprietary or trade name selected by the drug manufacturer and placed upon a drug or the drug's container, label, or wrappings at the time of packaging.
As added by P.L.2-1993, SEC.25.

IC 16-42-22-2
(*Repealed by P.L.239-1999, SEC.9.)*

IC 16-42-22-3
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.
As added by P.L.2-1993, SEC.25. Amended by P.L. 204-2005, SEC. 8.

IC 16-42-22-4
Sec. 4. (a) As used in this chapter, "generically equivalent drug product" means a multiple source drug product:
(1) that contains an identical quantity of identical active ingredients in the identical dosage forms (but not necessarily containing the same inactive ingredients) that meet the identical physical and chemical standards in The United States Pharmacopeia (USP) described in IC 16-42-19-2, or its supplements, as the prescribed brand name drug; and
(2) if applicable, for which the manufacturer or distributor holds either an approved new drug application or an approved abbreviated new drug application unless other approval by law or of the federal Food and Drug Administration is required.
(b) A drug does not constitute a generically equivalent drug product if it is listed by the federal Food and Drug Administration on or after July 1, 1987, as having actual or potential bioequivalence problems.
As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.4.

IC 16-42-22-4.5
Sec. 4.5. As used in this chapter, "practitioner" means any of the following:
(1) A licensed physician.
(2) A dentist licensed to practice dentistry in Indiana.
(3) A podiatrist licensed to practice podiatric medicine in Indiana.
(4) An optometrist who is:
(A) licensed to practice optometry in Indiana; and
(B) certified under IC 25-26-3.
(5) An advanced practice nurse licensed and granted the authority to prescribe legend drugs under IC 25-23.
As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.5.

IC 16-42-22-5
Sec. 5. As used in this chapter, "substitute" means to dispense a generically equivalent drug product in place of the brand name drug product prescribed by the practitioner.
As added by P.L.2-1993, SEC.25.

IC 16-42-22-5.5
Sec. 5.5. Nothing in this chapter authorizes any substitution other than substitution of a generically equivalent drug product.
As added by P.L.239-1999, SEC.6.

IC 16-42-22-6
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.".
As added by P.L.2-1993, SEC.25. Amended by P.L. 204-2005, SEC.9.

IC 16-42-22-7
(*Repealed by P.L.239-1999, SEC.9.)*

IC 16-42-22-8

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.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.7; P.L.291-2001, SEC.233. Amended by P.L. 204-2005, SEC.10.

IC 16-42-22-9

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.

As added by P.L.2-1993, SEC.25. Amended by P.L. 204-2005, SEC. 11.

IC 16-42-22-10

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 or electronically transmitted 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.

As added by P.L.2-1993, SEC.25. Amended by P.L.239-1999, SEC.8; P.L.291-2001, SEC.234. Amended by P.L. 204-2005, SEC.12.

IC 16-42-22-11

Sec. 11. If under this section a pharmacist substitutes a generically equivalent drug product for a brand name drug product prescribed by a practitioner, the prescription container label must identify the brand name drug for which the substitution is made and the generic drug. The identification required under this subsection must take the form of the following statement on the drug container label, with the generic name and the brand name inserted on the blank lines:

"_____ Generic for _____".

As added by P.L.2-1993, SEC.25. Amended by P.L.186-1993, SEC.1.

IC 16-42-22-12

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.

As added by P.L.2-1993, SEC.25. Amended by P.L. 204-2005, SEC.13.

IC 35-43-10

Chapter 10. Legend Drug Deception

IC 35-43-10-1

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

As added by P.L.212-2005, SEC.76.

IC 35-43-10-2

Sec. 2. Except as provided by federal law or regulation, this chapter does not apply to a pharmaceutical manufacturer that is approved by the federal Food and Drug Administration.

As added by P.L.212-2005, SEC.76.

IC 35-43-10-3

Sec. 3. A person who knowingly or intentionally:

(1) possesses a contraband legend drug;

(2) sells, delivers, or possesses with intent to sell or deliver a contraband legend drug;

(3) forges, counterfeits, or falsely creates a label for a legend drug or falsely represents a factual matter contained on a label of a legend drug; or

(4) manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug;

commits legend drug deception, a Class D felony.

As added by P.L.212-2005, SEC.76.

IC 35-43-10-4

Sec. 4. A person:

(1) who knowingly or intentionally manufactures, purchases, sells, delivers, brings into Indiana, or possesses a contraband legend drug; and

(2) whose act under subdivision (1) results in the death of an individual;

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

As added by P.L.212-2005, SEC.76.

IC 25-26-14

Chapter 14. Wholesale Legend Drug Distributors

IC 25-26-14-1

Sec. 1. (a) This chapter applies to any individual, partnership, limited liability company, corporation, or business firm:

(1) located in or outside Indiana; and

(2) engaging in the wholesale distribution of legend drugs in Indiana.

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

(c) The requirements of this chapter do not apply to a medical gas manufacturer or a distributor that only manufactures or distributes medical gases.

As amended by P.L.212-2005, SEC.23.

IC 25-26-14-1.5

Sec. 1.5. As used in this chapter, "adulterated" refers to a legend drug that:

(1) consists in whole or in part of a filthy, putrid, or decomposed substance;

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

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

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

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

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

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

IC 25-26-14-1.7

Sec. 1.7. As used in this chapter, "authenticate" means to affirmatively verify before distribution occurs that each transaction that is listed on:

(1) the pedigree of a legend drug; and

(2) other accompanying documentation for a legend drug;

has occurred.

IC 25-26-14-1.8

Sec. 1.8. As used in this chapter, "authorized distributor" means a wholesale drug distributor with which a manufacturer has established an ongoing relationship to distribute the manufacturer's products. For purposes of this section, an ongoing relationship exists between a wholesale drug distributor, including any affiliated group (as defined in
Section 1504 of the Internal Revenue Code) of which the wholesale distributor is a member, and a manufacturer if the wholesale drug distributor:

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

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

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

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

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

IC 25-26-14-2

Sec. 2. As used in this chapter, "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3

Sec. 3. As used in this chapter, "blood component" means that part of blood separated by physical or mechanical means.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-3.7

Sec. 3.7. As used in this chapter, "chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:

(1) is licensed as a wholesale distributor;

(2) acts as a central warehouse; and

(3) primarily performs intracompany sales and transfers of legend drugs or devices to members of the same affiliated group that is under common ownership and control.

IC 25-26-14-4

Sec. 4. As used in this chapter, "board" refers to the Indiana board of pharmacy established under IC 25-26-13-3.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-4.1

Sec. 4.1. As used in this chapter, "co-licensed products" means pharmaceutical products:
(1) that have been approved by the federal Food and Drug Administration; and
(2) concerning which two (2) or more parties have the right to engage in a business activity or occupation concerning the pharmaceutical products.

IC 25-26-14-4.2
Sec. 4.2. As used in this chapter, "compendium" refers to:
(1) the United States Pharmacopoeia;
(2) the Homeopathic Pharmacopoeia of the United States;
(3) the National Formulary;
(4) a drug approved by the federal Food and Drug Administration; or
(5) a supplement to a document specified in subdivision (1), (2), or (3).

IC 25-26-14-4.3
Sec. 4.3. As used in this chapter, "contraband" refers to a legend drug:
(1) that is counterfeit;
(2) that is stolen;
(3) that is misbranded;
(4) that is obtained by fraud;
(5) that is purchased by a nonprofit institution for the nonprofit institution's own use and placed in commerce in violation of the own use agreement for the legend drug;
(6) for which a required pedigree does not exist; or
(7) for which a pedigree in existence:
(A) has been forged, counterfeited, or falsely created; or
(B) contains any altered, false, or misrepresented information.

IC 25-26-14-4.4
Sec. 4.4. As used in this chapter, "counterfeit" refers to a legend drug, or the container, seal, or labeling of a legend drug, that, without authorization, bears the trademark, trade name, or other identifying mark or imprint of a manufacturer, processor, packer, or distributor other than the person that manufactured, processed, packed, or distributed the legend drug.

IC 25-26-14-4.5
Sec. 4.5. As used in this chapter, "deliver" means the actual, constructive, or attempted transfer of a legend drug from one (1) person to another.

IC 25-26-14-4.6
Sec. 4.6. As used in this chapter, "designated representative" means an individual who:
(1) is designated by a wholesale drug distributor;
(2) serves as the wholesale drug distributor's responsible individual with the board; and
(3) is actively involved in and aware of the actual daily operation of the wholesale drug distributor.

IC 25-26-14-4.7
Sec. 4.7. As used in this chapter, "distribute" means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a legend drug, whether by passage of title or physical movement, or both. The term does not include the following:
(1) Dispensing or administering a legend drug.
(2) Delivering or offering to deliver a legend drug by a common carrier in the usual course of business as a common carrier.
(3) The provision of a legend drug sample to a patient by a:
(A) practitioner;
(B) health care professional acting at the direction and under the supervision of a practitioner; or
(C) hospital's or other health care entity's pharmacy that received the drug sample in accordance with this chapter and other applicable law to administer or dispense and that is acting at the direction of a practitioner;
licensed to prescribe the legend drug.

IC 25-26-14-5
Sec. 5. As used in this chapter, "drug sample" means a unit of a legend drug that is not intended to be sold and is intended to promote the sale of the drug.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-6
Sec. 6. As used in this chapter, "health care entity" means any organization or business that provides diagnostic, medical, surgical, dental treatment, or rehabilitative care. The term does not include a pharmacy or wholesale drug distributor.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-6.5

Sec. 6.5. As used in this chapter, "label" means a display of written, printed, or graphic matter on the immediate container of a legend drug.

IC 25-26-14-6.6

Sec. 6.6. As used in this chapter, "labeling" means labels and other written, printed, or graphic matter:

(1) on a legend drug or a legend drug's container or wrapper; or

(2) accompanying a legend drug.

IC 25-26-14-7

Sec. 7. As used in this chapter, "legend drug" has the meaning set forth in IC 16-18-2-199. The term includes any human drug required by federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to 21 U.S.C. 811 through 812. The term does not include a device or a device component, part, or accessory.

As added by P.L.182-1991, SEC.3. Amended by P.L.2-1993, SEC.147.

IC 25-26-14-8

Sec. 8. As used in this chapter, "manufacturer" means a person who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a legend drug.

IC 25-26-14-8.3

Sec. 8.3. As used in this chapter, "misbranded" means that a legend drug's label:

(1) is false or misleading;

(2) does not bear the name and address of the manufacturer, packer, or distributor or does not contain an accurate statement of the quantities of active ingredients of the legend drug;

(3) does not show an accurate monograph for the legend drug; or

(4) does not comply with any other requirements of the federal Food, Drug, and Cosmetic Act.

IC 25-26-14-8.5

Sec. 8.5. As used in this chapter, "normal distribution chain of custody" means the route that a legend drug travels:

(1) from a manufacturer to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(2) from a manufacturer to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(3) from a manufacturer to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(4) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a pharmacy, and to a patient or a patient's agent;

(5) from a manufacturer to a third party logistics provider, to a wholesale drug distributor, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent;

(6) from a manufacturer to a third party logistics provider, to a chain drug warehouse, to a pharmacy affiliated with the chain drug warehouse, and to a patient or a patient's agent; or

(7) as prescribed by rules adopted by the board.

IC 25-26-14-8.7

Sec. 8.7. As used in this chapter, "pedigree" means a statement or record in a written or an electronic form that is approved by the board, that:

(1) records each wholesale distribution of a legend drug from the sale by the manufacturer that leaves the normal distribution chain of custody and that includes information designated by the board through rules for each transaction; or

(2) complies with a legend drug pedigree law or regulation in another state or United States territory that meets the pedigree requirements under this chapter.

As added by P.L.212-2005, SEC.40.

IC 25-26-14-9

Sec. 9. As used in this chapter, "person" means an individual, a partnership, a business firm, a limited liability company, a corporation, or another entity, including a governmental entity.

As added by P.L.182-1991, SEC.3. Amended by P.L.8-1993, SEC.395.

IC 25-26-14-9.2

Sec. 9.2. As used in this chapter, "practitioner" has the meaning set forth in IC 16-42-19-5.

IC 25-26-14-9.3

Sec. 9.3. As used in this chapter, "repackage" means changing the container, wrapper, quantity, or labeling of a legend drug to further the distribution of the legend drug.

IC 25-26-14-10

Sec. 10. As used in this chapter, "sale" includes purchase, trade, or offer to sell, purchase, or trade.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-10.5

Sec. 10.5. As used in this chapter, "third party logistics provider" means an entity that:

(1) provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the legend drug or have general responsibility to direct the legend drug's sale or disposition; and

(2) is licensed under this chapter.

IC 25-26-14-11

Sec. 11. As used in this chapter, "wholesale distribution" means to distribute legend drugs to persons other than a consumer or patient. The term does not include:

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

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

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

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

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

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

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

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

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

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

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

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

(13) the distribution of prescription drugs by the original manufacturer of the finished form of the prescription drug or the distribution of the co-licensed products by a partner of the original manufacturer of the finished form of the prescription drug; or

(14) drug returns that meet criteria established by rules adopted by the board.

IC 25-26-14-12

Sec. 12. As used in this chapter, "wholesale drug distributor" means a person engaged in wholesale distribution of legend drugs, including:

(1) manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

(7) warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses;

(8) independent wholesale drug traders;

(9) retail and hospital pharmacies that conduct wholesale distributions; and

(10) reverse distributors.

The term does not include a common carrier or person hired solely to transport prescription drugs.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-13

Sec. 13. The board shall adopt rules under IC 4-22-2 that conform with wholesale drug distributor licensing guidelines adopted by the United States Food and Drug Administration (21 CFR 205), including rules:

(1) necessary to carry out the purposes of this chapter;

(2) that incorporate and set detailed standards for meeting each of the license prerequisites set forth in this chapter; and

(3) establishing reasonable fees to carry out this chapter.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-14

Sec. 14 (a) A person may not engage in wholesale distributions of legend drugs without:

1) after December 31, 2005, obtaining and maintaining accreditation or certification from the National Association of Boards of Pharmacy's Verified

Accredited Wholesale Distributor or an accreditation body approved by the board under subsection (g);
(2) obtaining and maintaining a license issued by the board; and
(3) paying any reasonable fee required by the board.
(b) The board may not issue or renew the license of a wholesale drug distributor that does not comply with this chapter.
(c) The board shall require a separate license for each facility or location where wholesale distribution operations are conducted.
(d) An agent or employee of any licensed wholesale drug distributor does not need a license and may lawfully possess pharmaceutical drugs when acting in the usual course of business or employment.
(e) The issuance of a license under this chapter does not affect tax liability imposed by the department of state revenue or the state board of tax commissioners on any wholesale drug distributor.
(f) The board may adopt rules that permit out-of-state wholesale drug distributors to obtain a license on the basis of reciprocity if:
(1) an out-of-state wholesale drug distributor possesses a valid license granted by another state and the legal standards for licensure in the other state are comparable to the standards under this chapter; and
(2) the other state extends reciprocity to wholesale drug distributors licensed in Indiana.
However, if the requirements for licensure under this chapter are more restrictive than the standards of the other state, the out-of-state wholesale drug distributor must comply with the additional requirements of this chapter to obtain a license under this chapter.
(g) The board may adopt rules under IC 4-22-2 to approve an accreditation body to:
(1) evaluate a wholesale drug distributor's operations to determine compliance with:
(A) professional standards;
(B) this chapter; and
(C) any other applicable law; and
(2) perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.

IC 25-26-14-14.5
Sec. 14.5. After June 30, 2006, a wholesale drug distributor may not accept or deliver a legend drug without a current, accompanying pedigree as required under section 17 of this chapter.
As added by P.L.212-2005,SEC.47.

IC 25-26-14-15
Sec. 15. (a) The board shall require the following minimum information from each wholesale drug distributor as part of the license described in section 14 of this chapter and as part of any renewal of such license:
(1) The name, full business address, and telephone number of the licensee.
(2) All trade or business names used by the licensee.
(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of legend drugs.
(4) The type of ownership of operation.
(5) The name of each owner and operator of the licensee, including:
(A) if an individual, the name, address, Social Security number, and date of birth of the individual;
(B) if a partnership, the name, address, Social Security number, and date of birth of each partner, and the name of the partnership and federal employer identification number;
(C) if a corporation:
(i) the name, address, Social Security number, date of birth, and title of each corporate officer and director;
(ii) the corporate names, the name of the state of incorporation, the federal employer identification number, and the name of the parent company, if any; and
(iii) the name, address, and Social Security number of each shareholder owning ten percent (10%) or more of the voting stock of the corporation, unless the stock is traded on a major stock exchange and not traded over the counter;
(D) if a limited liability company, the name of each manager and member, the name and federal employer identification number of the limited liability company, and the name of the state where organized; and
(E) if a sole proprietorship, the full name, address, Social Security number, and date of birth of the sole proprietor and the name and federal employer identification number of the business entity.
(6) The name, address, and telephone number of the designated representative of each facility.
(7) Additional information concerning record keeping required under this chapter.
(b) The board shall require a wholesale drug distributor to post a surety bond of at least one hundred thousand dollars ($100,000), or an equivalent means of security acceptable to the board, including insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties that may be imposed by the board and any fees and costs that may be incurred by the board and that:
(1) are related to a license held by the wholesale drug distributor;
(2) are authorized under Indiana law; and
(3) the wholesale drug distributor fails to pay less than thirty (30) days after the penalties, fees, or costs become final.
However, a separate surety bond or an equivalent means of security is not required for a separate location or a company of the wholesale drug distributor.
(c) The board may make a claim against a bond or security posted under subsection (b) within one (1) year after the wholesale drug distributor's license is no longer valid or sixty (60) days after the conclusion of:
(1) an administrative or legal proceeding before or on behalf of the board that involves the wholesale drug distributor and results in penalties, fees, or

costs described in subsection (b); or
(2) an appeal of a proceeding described in subdivision (1);
whichever occurs later.
(d) The board or the board's designee shall inspect each facility where wholesale distribution operations are conducted before initial licensure and periodically thereafter in accordance with a schedule determined by the board, but at least one (1) time in each three (3) year period.
(e) A wholesale drug distributor must publicly display or have readily available all licenses and the most recent inspection report administered by the board or the board's designee.
(f) A material change in any information in this section must be submitted to the board at the time of license renewal or within thirty (30) days from the date of the change, whichever occurs first.

IC 25-26-14-15.5
Repealed

IC 25-26-14-16
Sec. 16. (a) In reviewing, for purposes of licensure or renewal of a license under this chapter, the qualifications of persons who engage in wholesale distribution of legend drugs in Indiana, the board shall consider the following factors:
(1) A finding by the board that the applicant has:
(A) violated a law; or
(B) been disciplined by a regulatory agency for violating a law;
related to drug distribution in any state.
(2) A criminal conviction of the applicant.
(3) The applicant's past experience in the manufacture or distribution of legend drugs, including controlled substances.
(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution.
(5) Suspension or revocation of any license held by the applicant or the applicant's owner or the imposition of sanctions against the applicant or the applicant's owner by the federal or a state or local government for the manufacture or distribution of any drugs, including controlled substances.
(6) Compliance with licensing requirements under previously granted licenses.
(7) Compliance with requirements to maintain and make available to the board or to federal, state, or local law enforcement officials those records required under this chapter.
(8) Any other factors or qualifications the board considers relevant to the public health and safety, including whether the granting of the license would not be in the public interest.
(b) In reviewing an application for licensure or renewal of a license under this chapter, the board shall consider the results of criminal history and financial background checks for:
(1) the designated representative or the most senior individual responsible for facility operations, purchasing, and inventory control;
(2) the supervisor or the designated representative or the most senior individual under subdivision (1); and
(3) principals and owners with more than a ten percent (10%) interest in the wholesale drug distributor, if the wholesale drug distributor is a nonpublicly held company.
(c) The criminal history and financial background checks conducted under subsection (b) must:
(1) be conducted at the applicant's expense;
(2) include a criminal history for all current and previous states of residence of the applicant;
(3) include the criminal history in the federal district where the applicant currently resides;
(4) include information from the previous seven (7) years; and
(5) be approved by the board.
(d) An applicant shall provide and attest to:
(1) an affirmation that the applicant has not been involved in or convicted of any criminal or prohibited acts; or
(2) a statement providing a complete disclosure of the applicant's past criminal convictions and violations of state and federal laws;
regarding drugs.
As added by P.L.182-1991, SEC.3. As amended by P.L. 212-2005, SEC.50.

IC 25-26-14-16.5
Sec. 16.5. (a) A wholesale drug distributor shall designate in writing on a form prescribed by the board a designated representative for each of the wholesale drug distributor's facilities licensed under this chapter.
(b) A designated representative shall submit to the board an application prescribed by the board and provide to the board the following:
(1) The date and place of birth of the designated representative.
(2) A list of the occupations, positions of employment, and offices held by the designated representative during the immediately preceding seven (7) years, including the principal business and address of the organization with which the occupation, position, or office was associated.
(3) A statement concerning whether the designated representative, during the immediately preceding seven (7) years, has been temporarily or permanently enjoined by a court from violating a state or federal law regulating the possession, control, or distribution of legend drugs, including details of related events.
(4) A description of any involvement by the designated representative with a business that:
(A) manufactured, administered, prescribed,

distributed, or stored legend drugs; and

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

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

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

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

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

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

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

(8) Any other information required by the board.

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

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

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

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

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

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

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

(g) A third party logistics provider must comply with this subsection until the third party logistics provider has obtained accreditation. A third party logistics provider must identify to the board a designated representative who is responsible for the facility's compliance with applicable state and federal law. The designated representative:

(1) may be a corporate employee or officer, outside counsel, or an outside consulting specialist with authority to help ensure compliance;

(2) may be responsible for multiple facilities; and

(3) is not required to be physically present at the facility.

As added by P.L. 212-2005, SEC.51.

IC 25-26-14-16.6

Sec. 16.6. (a) A wholesale drug distributor that:

(1) is licensed under this chapter;

(2) is located outside Indiana; and

(3) distributes legend drugs in Indiana;

shall designate an agent in Indiana for service of process.

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

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

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

IC 25-26-14-17

Sec. 17. As a condition for receiving and retaining a wholesale drug distributor license issued under this chapter, an applicant must satisfy the board that the applicant has and will continuously maintain the following:

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

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

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

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

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

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

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

(G) freedom of the facility from infestation.

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

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

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

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

(ii) restricted premises access;

(iii) adequate outside perimeter lighting;

(iv) safeguards against theft and diversion, including employee theft and theft or diversion facilitated or hidden by tampering with computers or electronic records; and

(v) a means of protecting the integrity and confidentiality of data and documents and of making the data and documents readily available to the board and other state and federal law enforcement officials.

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

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

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

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

(i) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is an authorized distributor, a pedigree for each distributed legend drug that leaves the normal distribution chain of custody, as determined by rules adopted by the board.

(ii) For legend drugs manufactured by a manufacturer for which the wholesale drug distributor is not an authorized distributor, a pedigree for each distributed legend drug that leaves the normal chain of custody.

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

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

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

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

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

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

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

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

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

(B) Correction of inventory inaccuracies.

(C) Product shipping and receiving problems.

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

(E) Appropriate disposition of returned goods.

(F) Product recalls.

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

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

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

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

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

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

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

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

(L) Conducting for cause authentication as required under sections 17.2 and 17.8 of this chapter.

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

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

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

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

(ii) wholesale drug distributors involved.

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

(i) examination and a determination that the legend drug is not outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution; or

(ii) the legend drug is destroyed or returned to the manufacturer or wholesale drug distributor from which the legend drug was acquired.

(D) Written policies and procedures to ensure that if the wholesale drug distributor determines that a legend drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale drug distributor provides notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the board, the federal Food and Drug Administration, and the manufacturer or wholesale drug distributor from which the legend drug was acquired within three (3) business days.

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

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

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

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

(G) Written policies and procedures to ensure that:

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

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

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

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

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

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

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

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

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

(9) Appropriate inventory management and control systems to:

(A) prevent; and

(B) allow detection and documentation of;

theft, counterfeiting, or diversion of legend drugs.

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

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

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

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

(14) Packaging operations in accordance with an official compendium allowing the identification of a compromise in the integrity of the legend drugs due

to tampering or adverse storage conditions.
As added by P.L.182-1991, SEC.3. As amended by P.L.212-2005, SEC.53.

IC 25-26-14-17.2

Sec. 17.2. (a) A wholesale drug distributor that purchases legend drugs from another wholesale drug distributor and has reason to believe that a legend drug purchased from the other wholesale drug distributor is counterfeit, suspected counterfeit, misbranded, or adulterated shall conduct a for cause authentication of each distribution of the legend drug back to the manufacturer.

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

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

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

(4) contact information, including name, address, telephone number, and electronic mail address of the wholesale drug distributor that sold the legend drug.

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

(d) If a wholesale drug distributor authenticates the distribution of a legend drug back to the manufacturer under subsection (a), the wholesale drug distributor shall maintain records of the authentication for three (3) years and shall produce the records for the board and the federal Food and Drug Administration upon request.
As added by P.L.212-2005, SEC.54.

IC 25-26-14-17.3
Repealed.

IC 25-26-14-17.8

Sec. 17.8. (a) A wholesale drug distributor licensed under this chapter that purchases legend drugs from a wholesale drug distributor that is not licensed under this chapter shall act with due diligence as required under this section and rules adopted by the board. However, the due diligence requirements of this section do not apply to purchases from an unlicensed wholesale drug distributor that has obtained accreditation through the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors program.

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

(1) A list of states in which the unlicensed wholesale drug distributor is licensed.

(2) A list of states into which the unlicensed wholesale drug distributor ships legend drugs.

(3) Copies of all state and federal regulatory licenses and registrations held by the unlicensed wholesale drug distributor.

(4) The unlicensed wholesale drug distributor's most recent facility inspection reports.

(5) Information regarding general and product liability insurance maintained by the unlicensed wholesale drug distributor, including copies of relevant policies.

(6) A list of other names under which the unlicensed wholesale drug distributor does business or has been previously known.

(7) A list of corporate officers and managerial employees of the unlicensed wholesale drug distributor.

(8) A list of all owners of the unlicensed wholesale drug distributor that own more than ten percent (10%) of the unlicensed wholesale drug distributor, unless the unlicensed wholesale drug distributor is publicly traded.

(9) A list of all disciplinary actions taken against the unlicensed wholesale drug distributor by state and federal agencies.

(10) A description, including the address, dimensions, and other relevant information, of each facility used by the unlicensed wholesale drug distributor for legend drug storage and distribution.

(11) A description of legend drug import and export activities of the unlicensed wholesale drug distributor.

(12) A description of the unlicensed wholesale drug distributor's procedures to ensure compliance with this chapter.

(13) A statement:

(A) as to whether; and

(B) of the identity of each manufacturer for which;

the unlicensed wholesale drug distributor is an authorized distributor.

(c) Before the initial purchase of legend drugs from an unlicensed wholesale drug distributor, the licensed wholesale drug distributor shall:

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

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

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

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

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

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

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

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

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

(1) date of purchase of the legend drug;

(2) lot number of the legend drug;

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

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

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

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

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

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

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

As added by P.L.212-2005, SEC.56.

IC 25-26-14-17.9

Sec. 17.9. A wholesale drug distributor licensed under this chapter may not use a trade name or business name identical to a trade name or business name used by an unrelated wholesale drug distributor licensed under this chapter.

As added by P.L.212-2005, SEC.57.

IC 25-26-14-18

Sec. 18. (a) Any applicant denied a license or renewal under this chapter has the right of review of the board's action under IC 4-21.5.

(b) An applicant that is denied the accreditation under section 14 of this chapter from an accreditation body that has entered into an agreement with the board has the right of review of the accreditation body's decision by the board.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-19

Sec. 19. (a) A person authorized by the board may enter and inspect, during normal business hours, all open premises that appear to be used by a wholesale drug distributor.

(b) Wholesale drug distributors may keep records regarding purchase and sales transactions at a central location apart from the principal office of the wholesale drug distributor or the location where the drugs were stored and from which the drugs were shipped, if the records are made available for inspection within two (2) working days of a request by the board. The records may be kept in any form permissible under federal law applicable to legend recordkeeping.

As added by P.L.182-1991, SEC.3.

IC 25-26-14-20

Sec. 20. A person employed in wholesale distribution must have appropriate education or experience to assume responsibility for positions related to compliance with licensing requirements.

As added by P.L.182-1991, SEC.3. As amended by P.L.212-2005, SEC.58.

IC 25-26-14-21

Sec. 21. (a) A wholesale drug distributor license expires at midnight of the renewal date specified by the health professions bureau under IC 25-1-5-4 in each even-numbered year.

(b) The board shall mail renewal application forms to each licensed wholesale drug distributor before the first day of the month before the month in which the license expires. If an application for renewal has not been filed and the required fee paid before the license expiration date, the wholesale drug distributor

license shall lapse and become void.
(c) A lapsed license may be reinstated only by meeting the requirements under IC 25-1-8-6.
(d) A wholesale drug distributor may not be open for business after the license has lapsed, until the renewal is completed.
As added by P.L.182-1991, SEC.3. Amended by P.L.269-2001, SEC.26.

IC 25-26-14-21.5
Sec. 21.5. (a) A person may not perform, cause the performance of, or aid the performance of the following:
(1) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a legend drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution.
(2) The adulteration, misbranding, or counterfeiting
of a legend drug.
(3) The receipt of a legend drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the legend drug for pay or otherwise.
(4) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a legend drug or the commission of another act with respect to a legend drug that results in the legend drug being misbranded.
(5) Forging, counterfeiting, simulating, or falsely representing a legend drug using a mark, stamp, tag, label, or other identification device without the authorization of the manufacturer.
(6) The purchase or receipt of a legend drug from a person that is not licensed to distribute legend drugs to the purchaser or recipient.
(7) The sale or transfer of a legend drug to a person that is not authorized under the law of the jurisdiction in which the person receives the legend drug to purchase or receive legend drugs from the person selling or transferring the legend drug.
(8) Failure to maintain or provide records as required under this chapter.
(9) Providing the board, a representative of the board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to this chapter.
(10) The wholesale distribution of a legend drug that was:
(A) purchased by a public or private hospital or other health care entity;
(B) donated or supplied at a reduced price to a charitable organization; or
(C) stolen or obtained by fraud or deceit.
(11) Obtaining or attempting to obtain a legend drug
by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a legend drug.
(12) Failure to obtain, authenticate, or provide a required pedigree.
(13) The receipt of a legend drug through wholesale distribution without first receiving a required pedigree attested to as accurate and complete by the wholesale drug distributor.
(14) Distributing a legend drug that was previously dispensed by a retail pharmacy or distributed by a practitioner.
(15) Failure to report an act prohibited by this section.
(b) The board may impose the following sanctions if, after a hearing under IC 4-21.5-3, the board finds that a person has violated subsection (a):
(1) Revoke the wholesale drug distributor's license issued under this chapter if the person is a wholesale drug distributor.
(2) Assess a civil penalty against the person. A civil penalty assessed under this subdivision may not be more than ten thousand dollars ($10,000) per violation.

IC 25-26-14-22
Sec. 22. (a) The board, upon a showing of a violation of this chapter, may revoke, suspend, or limit a license issued under this chapter after a proceeding under IC 4-21.5.
(b) After a proceeding under IC 4-21.5, the board may assess a civil penalty against a licensed wholesale drug distributor of not more than one thousand dollars ($1,000) for each occurrence. If the licensed wholesale drug distributor fails to pay the civil penalty within the time specified by the board, the board may suspend the license without additional proceedings.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-23
Sec. 23. A person that knowingly purchases or receives a legend drug from any source other than a person licensed under this chapter, including a wholesale distributor, manufacturer, pharmacy distributor, or pharmacy commits a Class A misdemeanor. A subsequent unrelated violation of this section is a Class D felony.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-24
Sec. 24. (a) Upon application by the board, a circuit or superior court may grant an injunction, a restraining order, or other order to enjoin a person from offering to engage or engaging in the performance of any practices for which a permit or license is required by any applicable federal or state law including this chapter, upon a showing that the practices were or are likely to be performed or offered to be performed without a permit or license.
(b) An action brought under this section must be commenced either in the county where the conduct occurred or is likely to occur or in the county where the defendant resides.
(c) An action brought under this section is in addition to any other penalty provided by law and may be brought concurrently with other actions to enforce

this chapter.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-25

Sec. 25. A wholesale drug distributor that fails to allow an authorized person to enter and inspect a facility as provided in section 19 of this chapter commits a Class A misdemeanor. However, the offense is a Class D felony if the person has a prior unrelated conviction for an offense under this section.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-26

Sec. 26. (a) A person who knowingly or intentionally engages in the wholesale distribution of a legend drug without a license issued under this chapter commits a Class D felony.

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

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

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

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

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

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

(2) who knowingly or intentionally:

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

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

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

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

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

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

(3) who:

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

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

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

commits a Class D felony.
As added by P.L.182-1991, SEC.3.

IC 25-26-14-27

Sec. 27. A wholesale drug distributor that fails to comply with the conditions and requirements described in section 17, 17.2, 17.8, 17.9, or 20 of this chapter commits a Class D felony.
As added by P.L.182-1991, SEC.3. As amended by P.L.212-2005,SEC.61.

NON-CODE PROVISIONS:

(a) IC 25-26-14, as amended by this act, applies:

(1) after December 31, 2005, for an initial license issued under IC 25-26-14, as amended by this act; and

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

(b) The Indiana board of pharmacy established by IC 25-26-13-3 may establish an electronic pedigree pilot program to authenticate, track, and trace legend drugs.

The pilot program must include participation of drug manufacturers, wholesale drug distributors, and pharmacies that are licensed in Indiana. The board may establish the requirements and guidelines for the pilot program.

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

(1) the board has completed the study under this subsection; and

(2) the board has consulted with the federal Food and Drug Administration concerning the implementation of a mandatory electronic pedigree program.

(d) The Indiana board of pharmacy established by IC 25-26-13-3 shall adopt rules under IC 25-26-14-8.5(7), as added by this act, prescribing the route that a legend drug travels that is in the normal distribution chain of custody.

(e) IC 25-26-14-26(b), as added by this act, applies only to offenses committed after December 31, 2005.

(f) This SECTION expires December 31, 2007.

ARTICLE 3. WHOLESALE LEGEND DRUGS

Rule 1. Definitions

856 IAC 3-1-1 Definitions
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. All terms which are defined in IC 25-26-14 shall have the same meanings as they are so defined when used in this article. *(Indiana Board of Pharmacy; 856 IAC 3-1-1; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2460; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

856 IAC 3-1-2 "Chain drug warehouse" defined
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 2. As used in IC 25-26-14 and in this article, "chain drug warehouse" means a permanent physical location for drugs or devices, or both, that:
(1) is licensed as a wholesale distributor;
(2) acts as a central warehouse; and
(3) primarily performs intracompany sales and transfers of legend drugs or devices to chain pharmacies that are members of the same affiliated group under common ownership and control.
(Indiana Board of Pharmacy; 856 IAC 3-1-2)

856 IAC 3-1-3 "Statement" defined
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 3. "Statement" means the specific unit of the specific legend drug that was purchased directly from the manufacturer. *(Indiana Board of Pharmacy; 856 IAC 3-1-3)*

Rule 2. Licensing and Operational Requirements

856 IAC 3-2-1 Persons required to register (Repealed)
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. (Repealed by Indiana Board of Pharmacy)

856 IAC 3-2-2 Fees
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 2. (a) The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for in-state applicants. The fee for original licensure and biennial renewal shall be one hundred dollars ($100) for out-of-state applicants.

(b) Licensure fees shall be paid at the time when the application for licensure or renewal of a license is filed. *(Indiana Board of Pharmacy; 856 IAC 3-2-2; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; filed Jun 6, 1996, 9:00 a.m.: 19 IR 3107; readopted filed Oct 17, 2001, 3:30 p.m.: 25 IR 941)*

856 IAC 3-2-3 Application forms; renewal forms
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. (a) Applications for licensure may be obtained by writing to the Indiana Board of Pharmacy, Indiana Professional Licensing Agency, 402 West Washington Street, Room W072, Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September 30 of each even-numbered year. Applications for renewal shall be mailed to the licensee. *(Indiana Board of Pharmacy; 856 IAC 3-2-3; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; errata filed Aug 24, 1992, 9:00 a.m.: 16 IR 66; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

856 IAC 3-2-4 Inspection and review of application
Authority: IC 25-26-14-13
Affected: IC 25-26-14-17; IC 25-26-14-19

Sec. 4. The board may inspect, or cause to be inspected, the establishment of an applicant or licensee pursuant to IC 25-26-14-19. The board shall review the application for licensure and other information regarding an applicant to determine whether the applicable standards of IC 25-26-14-17 have been met by the applicant. *(Indiana Board of Pharmacy; 856 IAC 3-2-4; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

856 IAC 3-2-5 Wholesale drug distributor license
Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 5. (a) The board shall issue a wholesale drug distributor license to applicants that qualify under IC 25-26-14.
(b) The wholesale drug distributor license shall contain the name, address, and license number of the licensee, the amount of fee paid, and the expiration date of the license. The licensee shall maintain the wholesale drug distributor license in a readily retrievable manner and shall permit inspection of the license by any official, agent, or employee of the board. *(Indiana Board of Pharmacy; 856 IAC 3-2-5; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

856 IAC 3-2-6 Termination of licensure; transfer of license
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14; IC 25-26-14-15

Sec. 6. (a) The license of any person shall terminate if and when such person dies or ceases legal existence. Any licensee who ceases legal existence or discontinues business shall notify the board within ten (10) days of such fact in writing.
(b) No license or any authority conferred thereby shall be assigned or otherwise transferred except to the extent allowed by IC 25-26-14-15, and then only pursuant to the written consent of the board. *(Indiana Board of Pharmacy; 856 IAC 3-2-6; filed Jun 26, 1992, 5:00 p.m.: 15 IR 2461; readopted filed Jun 12, 2001, 2:17 p.m.: 24 IR 3823)*

856 IAC 3-2-7 Reciprocity (Repealed)
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 7. (Repealed by Indiana Board of Pharmacy)

856 IAC 3-2-8 Minimum conditions for licensure, renewal, and operations (Repealed)
Authority: IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 8. (Repealed by Indiana Board of Pharmacy)

Rule 3. Accreditation

856 IAC 3-3-1 Board-approved accreditation body
Authority: IC 25-26-14-13; IC 25-26-14-14
Affected: IC 25-26-14-14

Sec. 1. The National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program shall do the following:
(1) Evaluate a wholesale drug distributor's operations to determine compliance with the following:
(A) Industry standards.
(B) IC 25-26-14.
(C) This title.
(D) Any other applicable law.
(2) Perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesale drug distributor.
(3) Ensure that the information obtained during accreditation remains confidential and privileged.
(4) Adhere to other requirements set by the board or the Indiana professional licensing agency.
(Indiana Board of Pharmacy; 856 IAC 3-3-1)

856 IAC 3-3-2 Accreditation for new applicants
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 2. For licenses issued after December 31, 2005, applicants for licensure as wholesale drug distributors shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before issuance of licensure. *(Indiana Board of Pharmacy; 856 IAC 3-3-2)*

856 IAC 3-3-3 Accreditation for existing license holders
Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 3. For licenses issued before January 1, 2006, license holders shall obtain the accreditation from the National Association of Boards of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program before renewal of licensure on September 30, 2006. *(Indiana Board of Pharmacy; 856 IAC 3-3-3)*

Rule 4. Pedigrees

856 IAC 3-4-1 Pedigrees; contents
Authority: IC 25-26-14-8.7; IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. A pedigree for each legend drug shall contain the following information:
(1) The legend drug proprietary and established name.
(2) The container size of the legend drug.
(3) The number of containers.
(4) The dosage form.
(5) The dosage strength.
(6) Lot/control numbers with expiration dates.
(7) The name of the manufacturer and repackager, if applicable, of the finished legend drug product.
(8) The name, address, and telephone number of each entity involved in the chain of the legend drug's custody.
(9) The name and address of each person certifying delivery or receipt of the legend drug.
(10) The sales invoice number.
(11) The dates of each transaction, including manufacturer, delivery, and receipt.
(12) A certification that each recipient has authenticated the pedigree, back to the manufacturer.
(13) A certification from the licensed entity that the information contained on the pedigree is true.
(Indiana Board of Pharmacy; 856 IAC 3-4-1)

856 IAC 3-4-2 Pedigrees; approved formats
Authority: IC 25-26-14-8.7; IC 25-26-14-13
Affected: IC 25-26-14

Sec. 2. The pedigree format:
(1) shall include the contents described in section 1 of this rule; and
(2) may be subject to the approval of the board.
(Indiana Board of Pharmacy; 856 IAC 3-4-2)

Rule 5. Normal Distribution Chain of Custody

856 IAC 3-5-1 Authorized distributor to authorized distributor transaction; pedigree requirement
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 1. For purposes of IC 25-26-14 and this article, within the normal distribution chain of custody, an authorized distributor that receives a legend drug directly from the manufacturer, or from the manufacturer's third party logistics provider, may sell the legend drug to a pharmacy, chain drug warehouse, or practitioner or one (1) other authorized distributor of the manufacturer that sells the legend drug directly to a pharmacy, chain drug warehouse, or practitioner without passing a pedigree if the invoice or accompanying document for the transaction includes a statement that the product was purchased directly from:
(1) the manufacturer; or
(2) an authorized distributor of the manufacturer who purchased the product directly from the manufacturer.
(Indiana Board of Pharmacy; 856 IAC 3-5-1)

856 IAC 3-5-2 Chain drug warehouses in the normal distribution chain of custody
Authority: IC 25-26-14-8.5; IC 25-26-14-13
Affected: IC 25-26-14-1.8; IC 25-26-14-17

Sec. 2. As used in IC 25-26-14 and in this article, chain drug warehouses that are distributing to their affiliated pharmacies or warehouses are not required to:

(1) be recognized as an authorized distributor, as defined in IC 25-26-14-1.8, for the normal distribution chain of custody to apply; or

(2) within the normal distribution chain of custody, pass a pedigree to or between their affiliated pharmacies or warehouses.

(Indiana Board of Pharmacy; 856 IAC 3-5-2)

856 IAC 3-5-3 Entities within the normal distribution chain custody

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 3. All entities, other than manufacturers approved by the Food and Drug Administration, within the normal distribution chain of custody shall be located and licensed within the United States or its territories. *(Indiana Board of Pharmacy; 856 IAC 3-5-3)*

856 IAC 3-5-4 Applicability of normal distribution chain of custody

Authority: IC 25-26-14-8.5; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 4. Normal distribution chain of custody applies to the following:

(1) Physical movement of the legend drug.

(2) Its passage of title.

(Indiana Board of Pharmacy; 856 IAC 3-5-4)

Rule 6. Drug Returns

856 IAC 3-6-1 Drug returns; pedigree requirement

Authority: IC 25-26-14-11; IC 25-26-14-13

Affected: IC 25-26-14-17

Sec. 1. The returns or exchanges of saleable legend drugs, received by the wholesale distributor as provided by this article, are not subject to the pedigree requirements under IC 25-26-14 and 856 IAC 3-4. Wholesale distributors are responsible for the following:

(1) Policing the returns process.

(2) Maintaining operations that are designed against the entry of an adulterated or counterfeit product into distribution.

(Indiana Board of Pharmacy; 856 IAC 3-6-1)

Rule 7. Authentications

856 IAC 3-7-1 Authentication

Authority: IC 25-26-14-13

Affected: IC 25-26-14

Sec. 1. Manufacturers shall cooperate in the process of authentication, as defined in IC 25-26-14. *(Indiana Board of Pharmacy; 856 IAC 3-7-1)*

IC 25-26-16

Chapter 16. Drug Regimens

IC 25-26-16-1

"Protocol" defined

Sec. 1. As used in this chapter, "protocol" means the policies, procedures, and protocols of a hospital listed in IC 16-18-2-161(1) concerning the adjustment of a patient's drug regimen by a pharmacist.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-2

Adjustment

Sec. 2. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug; or

(4) adds a drug to the treatment regimen.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-3

Protocol upon hospital admission

Sec. 3. (a) At the time of admission to a hospital that has adopted a protocol under this chapter, the following apply:

(1) The admitting practitioner shall signify in writing in the form and manner prescribed by the hospital whether the protocol applies in the care and treatment of the patient.

(2) A pharmacist may adjust the drug therapy regimen of the patient pursuant to the:

(A) written authorization of the admitting practitioner under subdivision (1); and

(B) protocols of the hospital.

The pharmacist shall review the appropriate medical records of the patient to determine whether the admitting practitioner has authorized the use of a specific protocol before adjusting the patient's drug therapy regimen. The admitting practitioner may at any time modify or cancel a protocol by entering the modification or cancellation in the patient's medical record.

(b) Notwithstanding subsection (a)(2), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the admitting practitioner to receive approval to begin the protocol. The authorization of the admitting practitioner to use the protocol shall be entered immediately in the patient's medical record, if required by the protocol.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-4

Minimum protocol requirements

Sec. 4. (a) This section applies to a pharmacist practicing in a

hospital listed in IC 16-18-2-161(1), in which the pharmacist is supervised by a physician as required under the protocols of the facility that are developed by health care professionals, including physicians, pharmacists, and registered nurses.

(b) The protocols developed under this chapter must at a minimum require that the medical records of the patient are available to both the patient's practitioner and the pharmacist and that the procedures performed by the pharmacist relate to a condition for which the patient has first seen a physician or other licensed practitioner.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-5

Implementation, revision, or renewal of protocol

Sec. 5. If a hospital or private mental health institution elects to implement, revise, or renew a protocol under this chapter, the governing board of the hospital or private mental health institution shall consult with that facility's medical staff, pharmacists, and other health care providers selected by the governing board. However, the governing board is the ultimate authority regarding the terms, implementation, revision, and renewal of the protocol.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-6

Modification of written protocol

Sec. 6. Except for the addition or deletion of authorized practitioners and pharmacists, a modification to written protocols requires the initiation of a new protocol.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-7

Annual review

Sec. 7. A protocol of a health care facility developed under this chapter must be reviewed at least annually.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-8

Documentation

Sec. 8. Documentation of protocols must be maintained in a current, consistent, and readily retrievable manner. A pharmacist is required to document decisions made under this chapter in a manner that shows adequate, consistent, and regular communication with an authorizing practitioner. After making an adjustment or a change to the drug regimen of a patient, the pharmacist shall immediately enter the change in the patient's medical record.

As added by P.L.114-1996, SEC.2.

IC 25-26-16-9

Confidentiality; liability

Sec. 9. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.

(b) This chapter does not make any other licensed health care provider liable for the actions of a pharmacist carried out under this section.

As added by P.L.114-1996, SEC.2.

IC 25-26-16.5
Chapter 16.5. Drug Regimens in Health Facilities

IC 25-26-16.5-1
Sec. 1. This chapter applies to a health facility licensed under IC 16-28.

IC 25-26-16.5-2
Sec. 2. (a) As used in this chapter, "attending physician" means a physician licensed under IC 25-22.5 who is responsible for the ongoing health care of an individual who resides in a health facility.
(b) The medical director of a health facility to which the individual is admitted may not serve as the individual's attending physician unless the medical director meets the requirements set forth in subsection (a).

IC 25-26-16.5-3
Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning the adjustment of a patient's drug regimen as allowed under this chapter by a pharmacist licensed under this article.

IC 25-26-16.5-4
Sec. 4. As used in this chapter, "therapeutic alternative" means a drug product that:
(1) has a different chemical structure from;
(2) is of the same pharmacological or therapeutic class as; and
(3) usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses as;
another drug.

IC 25-26-16.5-5
Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:
(1) changes the duration of treatment for a current drug therapy;
(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;
(3) discontinues the use of a drug; or
(4) adds a drug to the treatment regimen.

IC 25-26-16.5-6
Sec. 6. At the time an individual is admitted to a health facility that has adopted a protocol under this chapter, the individual's attending physician shall signify in writing in the form and manner prescribed by the health facility whether the protocol applies in the care and treatment of the individual.

IC 25-26-16.5-7
Sec. 7. (a) A pharmacist may adjust the drug therapy regimen of the individual under:
(1) the written authorization of the individual's attending physician under section 6 of this chapter;
(2) the health facility's protocols; and
(3) this chapter.
(b) The pharmacist shall review the appropriate medical records of the individual to determine whether the attending physician has authorized the use of a specific protocol before the pharmacist adjusts the individual's drug therapy regimen.
(c) Notwithstanding subsection (a), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the attending physician to receive approval to begin the protocol. The pharmacist shall document the authorization of the attending physician to use the protocol immediately in the individual's medical record.

IC 25-26-16.5-8
Sec. 8. If a health facility elects to implement, revise, or renew a protocol under this chapter, the health facility shall establish a drug regimen review committee consisting of:
(1) the health facility's medical director;
(2) the health facility's director of nursing; and
(3) a consulting pharmacist licensed under this article;
for the implementation, revision, or renewal of a protocol.

IC 25-26-16.5-9
Sec. 9. Except for the addition or deletion of authorized physicians and pharmacists, a modification to a written protocol requires the initiation of a new protocol.

IC 25-26-16.5-10
Sec. 10. (a) A protocol of a health facility developed under this chapter must be:
(1) based on clinical considerations; and

(2) reviewed by the health facility's drug regimen committee at least quarterly.
(b) A protocol of a health facility developed under this chapter may not:
(1) prohibit the attending physician from approving only specific parts of a protocol; or
(2) provide for an adjustment to an individual's drug regimen for the sole purpose of achieving a higher reimbursement for the substituted drug therapy than what would have been received for the original drug therapy ordered by the attending physician.

IC 25-26-16.5-11
Sec. 11. A protocol developed under this chapter must include the following:
(1) The identification of:
(A) the individual whose drug regimen may be adjusted;
(B) the attending physician who is delegating the authority to adjust an individual's drug regimen; and
(C) the pharmacist who is authorized to adjust the individual's drug regimen.
(2) The attending physician's diagnosis of the individual's:
(A) condition; or
(B) disease state;
whose drug regimen may be adjusted.
(3) A statement regarding:
(A) the types and:
(i) categories; or
(ii) therapeutic classifications;
of medication, including the specific therapeutic alternatives that may be substituted for a drug prescribed by a physician;
(B) the minimum and maximum dosage levels within the types and:
(i) categories; or
(ii) therapeutic classifications;
of medications described in clause (A);
(C) the dosage forms;
(D) the frequency of administration;
(E) the route of administration;
(F) the duration of the administration of the drug regimen and any adjustment to the drug regimen; and
(G) exceptions to the application of the drug regimen or the adjustment to the drug regimen;
for which the pharmacist may adjust the individual's drug regimen.
(4) A requirement that:
(A) the individual's medical records be available to both the individual's attending physician and the pharmacist; and
(B) the procedures performed by the pharmacist relate to a disease or condition for which the patient has been under the attending physician's medical care.

IC 25-26-16.5-12
Sec. 12. A protocol developed under this chapter that is implemented for a Medicaid recipient must comply with any statutes, regulations, and procedures under the state Medicaid program relating to the preferred drug list established under IC 12-15-35-28.

IC 25-26-16.5-13
Sec. 13. If a protocol developed under this chapter allows a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order.

IC 25-26-16.5-14
Sec. 14. This chapter does not allow a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol under this chapter.

IC 25-26-16.5-15
Sec. 15. The individual's attending physician:
(1) shall review a protocol approved and implemented for a patient of the physician at the physician's next visit to the health facility, and at each subsequent visit of the physician to the health facility; and
(2) may at any time modify or cancel a protocol by entering the modification or cancellation in the individual's medical record.

IC 25-26-16.5-16
Sec. 16. (a) Documentation of protocols must be maintained in a current, consistent, and readily retrievable manner.
(b) After making an adjustment to an individual's drug regimen, the pharmacist shall immediately document the adjustment in the patient's medical record.
(c) The pharmacist shall notify the individual's attending physician of an adjustment at least one (1) business day before the adjustment is made.

IC 25-26-16.5-17
Sec. 17. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.
(b) This chapter does not make any other licensed health care provider or pharmaceutical manufacturer liable for the actions of a pharmacist carried out

under this section.

(c) A physician who approves the use of a protocol under this chapter and a pharmacist who adjusts a drug regimen of a patient pursuant to a protocol under this chapter do not violate IC 25-22.5-1-2(d).

IC 25-26-16.5-18

Sec. 18. A pharmacist who violates this chapter is subject to discipline under IC 25-1-9.

IC 25-26-17

Chapter 17. Nonresident Pharmacies

IC 25-26-17-1

"Board" defined

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

As added by P.L.183-1997, SEC.1.

IC 25-26-17-2

"Nonresident pharmacy" defined

Sec. 2. For purposes of this chapter, "nonresident pharmacy" means a pharmacy located outside Indiana that dispenses drugs or devices through the United States Postal Service or other delivery services to patients in Indiana.

As added by P.L.183-1997, SEC.1.

IC 25-26-17-3

Registration; required information; fee

Sec. 3. A nonresident pharmacy must register with the board. To register with the board, a nonresident pharmacy must submit the following to the board:

(1) A verified statement that the nonresident pharmacy is licensed, certified, or registered to operate in the state in which the pharmacy is located.

(2) The location, names, and titles of all principal corporate officers and pharmacists who are dispensing drugs to residents of Indiana. This disclosure must be made on an annual basis. The nonresident pharmacy must notify the board within thirty (30) days after any change of office location, corporate officer, or pharmacist in charge.

(3) A verified statement that the nonresident pharmacy complies with all lawful requests for information from the regulatory or licensing agency of all states in which it is licensed.

(4) Information requested and deemed necessary by the board to carry out this chapter.

(5) The fee required by IC 25-1-8 which shall be reasonable and not exceed the costs to the board.

As added by P.L.183-1997, SEC.1.

IC 25-26-17-4

Duties of nonresident pharmacies

Sec. 4. A nonresident pharmacy must:

(1) comply with all requests for information made by the board;

(2) respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of drugs to the residents of Indiana;

(3) maintain records of drugs dispensed to patients in Indiana in a manner making those records readily retrievable and identifiable from the other business records of the pharmacy;and

(4) provide a toll-free telephone service that:

(A) facilitates communications between a patient in Indiana and a pharmacist with access to the patient's records;

(B) is attended by a pharmacist with access to a patient's records during the nonresident pharmacy's regular business hours, but not less than six (6) days per week and not less than forty (40) hours per week; and

(C) has the toll-free telephone number displayed on a label affixed to each container of dispensed drugs.

As added by P.L.183-1997, SEC.1.

IC 25-26-17-5

Grounds for denial, suspension, or revocation of registration

Sec. 5. The board may deny, revoke, or suspend the registration of a nonresident pharmacy for:

(1) failing to comply with sections 3, 4, and 6 of this chapter; or

(2) conduct that causes serious bodily or psychological harm to a customer who lives in Indiana or purchased drugs from the nonresident pharmacy while in Indiana, if the board reports the matter to the pharmacy regulatory or licensing agency in the state in which the nonresident pharmacy is located.

As added by P.L.183-1997, SEC.1.

IC 25-26-17-6

Compliance with laws and rules of domicile state required

Sec. 6. A nonresident pharmacy registered under this chapter must comply with the laws and rules of the state in which it is domiciled.

As added by P.L.183-1997, SEC.1.

IC 25-26-17-7

Waiver of registration requirements

Sec. 7. The board may waive the registration requirements of this chapter for a nonresident pharmacy that only dispenses drugs to Indiana in limited transactions.

As added by P.L.183-1997, SEC.1.

IC 25-26-18

Chapter 18. Mail Order and Internet Based Pharmacies

IC 25-26-18-1

"Mail order or Internet based pharmacy" defined

Sec. 1. As used in this chapter, "mail order or Internet based pharmacy" means a pharmacy that is located in Indiana or is a nonresident pharmacy (as defined in IC 25-26-17-2) that dispenses prescription drugs:

(1) through the United States Postal Service or other delivery services; or

(2) after receiving a request for prescription drugs through the Internet;

to patients in Indiana.

As added by P.L.231-1999, SEC.17.

IC 25-26-18-2

Compliance with laws required

Sec. 2. A mail order or Internet based pharmacy shall comply with the following:

(1) The licensure laws of the state in which the mail order or Internet based pharmacy is domiciled.

(2) The drug substitution laws of Indiana.

As added by P.L.231-1999, SEC.17.

IC 25-26-19
Chapter 19. Regulation of Pharmacy Technicians

IC 25-26-19-1
"Board"
Sec. 1. As used in this chapter, "board" refers to the Indiana board of pharmacy established by IC 25-26-13-3.
As added by P.L.251-2003, SEC.3
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IC 25-26-19-2
"Pharmacy technician"
Sec. 2. As used in this chapter, "pharmacy technician" means an individual who:
(1) works under the direct supervision of a pharmacist licensed under this article; and
(2) performs duties to assist a pharmacist in activities that do not require the professional judgment of a pharmacist.
As added by P.L.251-2003, SEC.3.

IC 25-26-19-3
"Pharmacy technician in training"
Sec. 3. As used in this chapter, "pharmacy technician in training" means a person who is enrolled in a training program for pharmacy technicians prescribed by the board.
As added by P.L.251-2003, SEC.3.

IC 25-26-19-4
Adoption of rules
Sec. 4. (a) The board may adopt rules under IC 4-22-2 to:
(1) implement and enforce this chapter;
(2) set fees under IC 25-1-8; and
(3) establish education and training requirements for certification to practice as a pharmacy technician.
(b) The board shall:
(1) establish standards for the competent practice of pharmacy technicians; and
(2) subject to IC 4-21.5, IC 25-1-7, and IC 25-1-9, conduct proceedings on any matter under the jurisdiction of the board.
As added by P.L.251-2003, SEC.3.

IC 25-26-19-5
Qualification for pharmacy technician certificate
Sec. 5. (a) The board shall issue a pharmacy technician certificate to an individual who:
(1) applies to the board in the form and manner prescribed by the board;
(2) is at least eighteen (18) years of age;
(3) has not been convicted of a crime that has a direct bearing upon the individual's ability to practice competently;
(4) is not in violation of this chapter or rules adopted by the board under section 4 of this chapter;
(5) has paid the fee set by the board under section 4 of this chapter; and
(6) has completed a program of education and training approved by the board or has passed a certification examination offered by a nationally recognized certification body approved by the board.
(b) For good cause, the board may waive the age requirement under subsection (a)(2).
As added by P.L.251-2003, SEC.3.

IC 25-26-19-6
Qualification for pharmacy technician in training permit
Sec. 6. (a) The board shall issue a pharmacy technician in training permit to an individual who:
(1) applies to the board in the form and manner prescribed by the board;
(2) is at least eighteen (18) years of age;
(3) has not been convicted of a crime that has a direct bearing upon the individual's ability to practice competently;
(4) is not in violation of this chapter or rules adopted by the board under section 4 of this chapter; and
(5) has applied for certification under section 5 of this chapter.
(b) An applicant:
(1) may work as a pharmacy technician in training without a permit for not more than thirty (30) consecutive days after the applicant files an application under this section;
(2) shall provide the applicant's employer with a receipt issued by the board that:
(A) provides the date an application under this section was filed; and
(B) indicates that the fee has been paid;
before the applicant may begin work as a pharmacy technician in training; and

(3) may request an additional thirty (30) day period to practice as a pharmacy technician in training without a permit. The board may approve a request under this subdivision if the board determines that the extension is for good cause.

(c) A pharmacy technician in training permit expires on the earliest of the following:

(1) The date the permit holder is issued a pharmacy technician certificate under this chapter.

(2) The date the board disapproves the permit holder's application for a pharmacy technician certificate under this chapter.

(3) The date the permit holder ceases to be enrolled in good standing in a pharmacy technician training program approved by the board. The graduation of a permit holder from a pharmacy technician program does not cause the permit to expire under this subdivision.

(4) Sixty (60) days after the date that the permit holder successfully completes a program approved by the board.

(5) Twelve (12) months after the date of issuance.

(d) For good cause, the board may waive the age requirement in subsection (a)(2).

As added by P.L.251-2003, SEC.3.

IC 25-26-19-7

Expiration of pharmacy technician certificate; renewal fee; reinstatement of pharmacy technician certificate

Sec. 7. (a) A pharmacy technician certificate expires on a date set by the health professions bureau in each even-numbered year.

(b) An application for renewal of a pharmacy technician certificate must be accompanied by the appropriate fee.

(c) If a person fails to renew a pharmacy technician certificate, the certificate may be reinstated by meeting the requirements under IC 25-1-8-6.

(d) The board may require a person who applies for a certificate under subsection (c) to appear before the board and explain the reason why the person failed to renew a pharmacy technician certificate.

As added by P.L.251-2003, SEC.3.

IC 25-26-19-8

Prohibited activities of a certified pharmacy technician

Sec. 8. A certified pharmacy technician may not perform the following activities:

(1) Providing advice or consultation with the prescribing practitioner or other licensed health care provider regarding the patient or the interpretation and application of information contained in the prescription or drug order, medical record, or patient profile.

(2) Providing advice or consultation with the patient regarding the interpretation of the prescription or the application of information contained in the patient profile or medical record.

(3) Dispensing prescription drug information to the patient.

(4) Final check on all aspects of the completed prescription and assumption of the responsibility for the filled prescription, including the appropriateness of the drug for the patient and the accuracy of the:

(A) drug dispensed;

(B) strength of the drug dispensed; and

(C) labeling of the prescription.

(5) Receiving a new prescription drug order over the telephone or electronically unless the original information is recorded so a pharmacist may review the prescription drug order as transmitted.

(6) Any activity required by law to be performed only by a pharmacist.

(7) Any activity that requires the clinical judgment of a pharmacist and is prohibited by a rule adopted by the board.

As added by P.L.251-2003, SEC.3.

IC 25-26-19-9

Specific violations

Sec. 9. (a) An individual may not practice as a pharmacy technician unless the individual is certified under this chapter.

(b) An individual may not act as a pharmacy technician in training unless the individual has obtained a permit under this chapter or the individual is acting as a pharmacy technician in training during the period permitted under section 6(b) of this chapter.

(c) An individual who knowingly violates this section commits a Class D felony.

As added by P.L.251-2003, SEC.3.

IC 25-26-19-10

Injunctions

Sec. 10. (a) If an individual violates this chapter, the attorney general, the board, or the prosecuting attorney of the county in which the individual violates this chapter may maintain an action in the name of the state to enjoin the individual from continued violation of this chapter.

(b) An injunction issued under this section does not relieve an individual person from criminal prosecution but is in addition to any remedy provided under criminal law.

As added by P.L.251-2003, SEC.3.

IC-25-26-20
Chapter 20. Regional Drug Repository Program

IC 25-26-20-1
Sec. 1. The definitions in IC 25-26-13-2 apply throughout this chapter.

IC 25-26-20-2
Sec. 2. As used in this chapter, "nonprofit health clinic" means any of the following:
(1) A federally qualified health center (as defined in 42 U.S.C. 1396d(l)(2)(B)).
(2) A rural health clinic (as defined in 42 U.S.C. 1396d(l)(1)).
(3) A nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured.

IC 25-26-20-3
Sec. 3. (a) The board may organize a voluntary regional drug repository program to collect and redistribute drugs to nonprofit health clinics.
(b) The board may enter into a voluntary agreement with any of the following to serve as a regional drug repository:
(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 nonprofit health clinic.
(c) A regional drug repository may not receive compensation for participation in the program.

IC 25-26-20-4
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(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.
Amended by PL.204-2005, SEC. 19.

IC 25-26-20-5
Sec. 5. (a) A drug that is given by a regional drug repository to a nonprofit health clinic may not be:
(1) sold; or
(2) given to a patient, except upon a practitioner's prescription or drug order.
(b) An individual who is eligible to participate in:
(1) the state Medicaid program under IC 12-15; or
(2) a program that:
(A) provides a prescription drug benefit; and
(B) is funded in whole or in part by state funds;
is not eligible to receive a drug donated under the voluntary regional drug repository program organized under section 3 of this chapter.

IC 25-26-20-6
Sec. 6. (a) The following are not subject to liability under IC 34-20-2-1:
(1) A person or entity who donates a drug to a regional drug repository program under this chapter in accordance with rules adopted by the board under section 7 of this chapter.
(2) A non-profit health clinic or practitioner who accepts or dispenses a drug under the regional drug repository program in accordance with rules adopted by the board under section 7 of this chapter.
(3) A regional drug repository that distributes a drug under the program in accordance with rules adopted by the board under section 7 of this chapter.
(b) Except in cases of negligence or willful misconduct by the manufacturer, a drug manufacturer is not subject to liability under IC 34-20-2-1 for a claim arising from a drug that is donated, accepted, or dispensed under this chapter to the user or the consumer.

IC 25-26-20-7

Sec. 7. The board may adopt rules under IC 4-22-2 to:

(1) establish standards and procedures for accepting, storing, and dispensing drugs donated under this chapter;

(2) establish the types of drugs that may be donated; and

(3) administer this chapter.

IC 25-26-21
Chapter 21. Home Medical Equipment Services Providers

IC 25-26-21-1
Sec. 1. As used in this chapter, "board" refers to the Indiana board of pharmacy established by IC 25-26-13-3.

IC 25-26-21-2
Sec. 2. As used in this chapter, "home medical equipment" means technologically sophisticated medical devices that may be used in a residence, including the following:
(1) Oxygen and oxygen delivery systems.
(2) Ventilators.
(3) Respiratory disease management devices.
(4) Continuous positive airway pressure (CPAP) devices.
(5) Electronic and computerized wheelchairs and seating systems.
(6) Apnea monitors.
(7) Transcutaneous electrical nerve stimulator (TENS) units.
(8) Low air loss cutaneous pressure management devices.
(9) Sequential compression devices.
(10) Feeding pumps.
(11) Home phototherapy devices.
(12) Infusion delivery devices.
(13) Distribution of medical gases to end users for human consumption.
(14) Hospital beds.
(15) Nebulizers.
(16) Other similar equipment determined by the board in rules adopted under section 7 of this chapter.

IC 25-26-21-3
Sec. 3. As used in this chapter, "home medical equipment services" means the:
(1) sale;
(2) rental;
(3) delivery;
(4) installation;
(5) maintenance or replacement; or
(6) instruction in the use;
of medical equipment used by an individual that allows the individual to reside in a noninstitutional environment.

IC 25-26-21-4
Sec. 4. As used in this chapter, "provider" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence.

IC 25-26-21-5
Sec. 5. (a) This chapter does not apply to the following:
(1) A home health agency (as defined in IC 16-27-1-2) that does not sell, lease, or rent home medical equipment.
(2) A hospital licensed under IC 16-21-2 that:
(A) provides home medical equipment services only as an integral part of patient care; and
(B) does not provide home medical equipment services through a separate business entity.
(3) A manufacturer or wholesale distributor that does not sell, lease, or rent home medical equipment directly to a consumer.
(4) Except as provided under subsection (b), a practitioner (as defined in IC 25-1-9-2) who does not sell, lease, or rent home medical equipment.
(5) A veterinarian licensed under IC 15-5-1.1.
(6) A hospice program (as defined in IC 16-25-1.1-4) that does not sell, lease, or rent home medical equipment.
(7) A health facility licensed under IC 16-28 that does not sell, lease, or rent home medical equipment.
(8) A provider that:
(A) provides home medical equipment services within the scope of the licensed provider's professional practice;
(B) is otherwise licensed by the state; and
(C) receives annual continuing education that is documented by the provider or the licensing entity.
(9) An employee of a person licensed under this chapter.
(b) A pharmacist licensed in Indiana or a pharmacy that holds a permit issued under IC 25-26 that sells, leases, or rents home medical equipment:
(1) is not required to obtain a license under this chapter; and
(2) is otherwise subject to the:
(A) requirements of this chapter; and
(B) requirements established by the board by rule under this chapter.

IC 25-26-21-6

Sec. 6. (a) A person seeking to provide home medical equipment services in Indiana shall apply to the board for a license in the manner prescribed by the board.

(b) A provider shall do the following:

(1) Comply with:

(A) federal and state law; and

(B) regulatory requirements;

for home medical equipment services.

(2) Maintain a physical facility and medical equipment inventory in Indiana.

(3) Purchase and maintain in an amount determined by the board:

(A) product liability insurance; and

(B) professional liability insurance;

and maintain proof of the insurance coverage.

(4) Establish procedures to ensure that an employee or a contractor of the provider who is engaged in the following home medical equipment activities receives annual training:

(A) Delivery.

(B) Orientation of a patient in the use of home medical equipment.

(C) Reimbursement assistance.

(D) Maintenance.

(E) Repair.

(F) Cleaning and inventory control.

(G) Administration of home medical equipment services.

The provider shall maintain documentation of the annual training received by each employee or contractor.

(5) Maintain clinical records on a customer receiving home medical equipment services.

(6) Establish home medical equipment maintenance and personnel policies.

(7) Provide home medical equipment emergency maintenance services available twenty-four (24) hours a day.

(8) Comply with the rules adopted by the board under this chapter.

IC 25-26-21-7

Sec. 7. (a) The board may adopt rules under IC 4-22-2 to do the following:

(1) Specify home medical equipment in addition to the home medical equipment set forth in section 2 of this chapter that is to be regulated under this chapter.

(2) Set standards for the licensure of providers.

(3) Govern the safety and quality of home medical equipment services that are provided to customers.

(4) Specify the amount of insurance coverage required under section 6(b)(3) of this chapter.

(5) Set reasonable fees for the application, issuance, and renewal of a license under this chapter and set other fees permitted under IC 25-1-8.

(b) The board may consult with individuals engaged in the home medical equipment services business to advise the board on the formulation of rules under subsection (a). The individuals may not be compensated or reimbursed for mileage by the board.

IC 25-26-21-8

Sec. 8. (a) After June 30, 2006, a provider must be licensed by the board before the provider may provide home medical equipment services. If a provider provides home medical equipment services from more than one (1) location in Indiana, the provider must obtain a license under this chapter for each location.

(b) An applicant shall submit the application to the board on a form adopted by the board. The nonrefundable application fee set by the board must be submitted with the application. The fee must be deposited in the state general fund.

(c) If the board determines that the applicant:

(1) meets the standards set forth by the board; and

(2) has satisfied the requirements under this chapter and the requirements established by the board by rule;

the board shall notify the applicant in writing that the license is being issued to the applicant. The license is effective on the applicant's receipt of the written notification.

(d) A license issued under this chapter is effective for not more than two (2) years, beginning on a date determined by the board. An entity that is licensed under this chapter shall display the license or a copy of the license on the licensed premises.

(e) The board may renew a license every two (2) years.

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

(1) the out-of-state provider possesses a valid license granted by another state;

(2) the legal standards for licensure in the other state are comparable to the standards under this chapter; and

(3) the other state extends reciprocity to providers licensed in Indiana.

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

As added by P.L.122-2005, SEC.1.

IC 25-26-21-9

Sec. 9. (a) The board may inspect the operations and facilities of an applicant for a license under this chapter to determine whether to issue the applicant a license.

(b) The board may conduct random inspections at any time for the following reasons:

(1) To ensure the integrity and effectiveness of the licensing process.

(2) To investigate a consumer complaint or a complaint by a qualified source as identified by the board.

(3) To ensure continuing compliance with the licensing requirements under this chapter.

(c) The board shall provide the provider a report of the board's findings after the board completes an investigation under this section.

(d) A provider that disputes the report in subsection (c) may file an appeal under IC 4-21.5 with the board not later than thirty (30) days after receipt of the report. The board shall review the inspection report and, upon the provider's request, conduct a new inspection.

(e) The board shall employ qualified inspectors to investigate complaints and conduct inspections. Investigators may review and audit records under an investigation or inspection during the inspected facility's normal business hours at the place of business of the provider being investigated.

(f) The board and the board's employees may not disclose confidential information obtained during an investigation except:

(1) during a disciplinary hearing held under section 10 of this chapter; or

(2) under a court order.

IC 25-26-21-10

Sec. 10. The board may discipline the holder of a license under IC 25-1-9 after a hearing or for any of the following reasons:

(1) Violation of this chapter or violation of a rule established by the board.

(2) Violation of a board order.

(3) Failure to meet the standards set forth in section 6(b) of this chapter.

(4) The conviction or plea of guilty for a felony or misdemeanor that:

(A) involves fraud or deceit; or

(B) is directly related to providing home medical equipment services.

(5) Negligence or gross misconduct in providing home medical equipment services.

(6) The aid, assistance, or willful allowance of another person in violating a provision under this chapter or a rule adopted by the board.

(7) Failure to provide information within sixty (60) days in response to a written request from the board.

(8) The engagement in conduct that is likely to deceive, defraud, or harm the public.

(9) Denial, revocation, suspension, or restriction of a license in another state or jurisdiction to provide home medical equipment services for a reason other than the failure to renew the license.

(10) The receipt of a fee, commission, rebate, or other form of compensation for services not rendered.

(11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state or federal agencies or departments.

(12) Failure to comply with federal rules issued under the federal Medicare program (42 U.S.C. 1395 et seq.) relating to operations, financial transactions, and general business practices of home medical equipment services providers.

IC 25-26-21-11

Sec. 11. (a) A person who engages in the business of home medical equipment services and who:

(1) is required to be licensed under this chapter; and

(2) knowingly provides home medical equipment services without a license issued under this chapter;

commits a Class A misdemeanor.

(b) Each day a violation of this section continues constitutes a separate offense.

(c) The board may, in the name of the state and through the attorney general, apply in a court to enjoin a person from providing home medical equipment services in violation of this chapter.

As Added by P.L. 122-2005, SEC.1.