

Document: Readopted Rules

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TITLE 856 INDIANA BOARD OF PHARMACY

LSA Document #01-150

DIGEST

Readopts rules in anticipation of IC 4-22-2.5-2, providing that all rules of the Indiana administrative agencies in force on December 31, 1995, expire on January 1, 2002. Effective 30 days after filing with the secretary of state.

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SECTION 1. UNDER IC 4-22-2.5-3, THE FOLLOWING ARE READOPTED:

- 856 IAC 1-1 Definitions
- 856 IAC 1-2-4 Service by mail sufficient notice
- 856 IAC 1-3.1-1 Licensure by examination
- 856 IAC 1-3.1-2 Information for licensure
- 856 IAC 1-3.1-5 Pharmacist intern/extern; experience requirement
- 856 IAC 1-3.1-9 Pharmacist intern/extern; practical experience affidavits
- 856 IAC 1-3.1-11 Out of state externship and other practical experience programs
- 856 IAC 1-3.1-13 Fraud or misrepresentation in applying for or taking examination
- 856 IAC 1-7-1 Change of pharmacy ownership
- 856 IAC 1-7-2 Application for permit to conduct pharmacy
- 856 IAC 1-7-3 Relocation of pharmacy
- 856 IAC 1-7-4 Licensed pharmacist required for each pharmacy
- 856 IAC 1-13-3 "Prescription department closed" closing hours; electronic monitoring; applicability
- 856 IAC 1-13-4 Record of hours open without a pharmacist on duty
- 856 IAC 1-29-2 Online retrieval and printout capabilities; data requirements; discontinuance of system
- 856 IAC 1-29-3 Hard-copy of daily dispensing; verification and retention; back-up capability
- 856 IAC 1-29-4 Auxiliary system
- 856 IAC 1-29-5 Safeguards
- 856 IAC 1-29-6 Data entry; supervision
- 856 IAC 1-29-9 Applicability of rule
- 856 IAC 1-30-1 Sterile pharmaceuticals; preparation and dispensing
- 856 IAC 1-30-2 "Biological safety cabinet" defined
- 856 IAC 1-30-3 "Class 100 environment" defined
- 856 IAC 1-30-4 "Cytotoxic" defined
- 856 IAC 1-30-6 "Sterile pharmaceutical" defined
- 856 IAC 1-30-7 Policy and procedure manual
- 856 IAC 1-30-8 Physical requirements
- 856 IAC 1-30-10 Support personnel
- 856 IAC 1-30-11 Staffing
- 856 IAC 1-30-12 Profile or medication record system
- 856 IAC 1-30-16 Emergency kit
- 856 IAC 1-30-17 Cytotoxic drugs
- 856 IAC 1-31 Facsimile Machines
- 856 IAC 1-33 Counseling
- 856 IAC 1-34-1 Patient counseling requirements
- 856 IAC 1-34-3 Preprinted controlled substance prohibition
- 856 IAC 1-34-4 Exemption
- 856 IAC 1-34-5 Approval
- 856 IAC 1-35 Pharmacy Technicians
- 856 IAC 1-36-1 Temporary variances
- 856 IAC 1-36-2 Submission of a request for temporary variance
- 856 IAC 1-36-3 Positive impact on delivery of pharmaceutical care
- 856 IAC 1-36-4 Period of time
- 856 IAC 1-36-6 Revocation
- 856 IAC 1-36-7 Public notice

856 IAC 1-36-8 Justification of denial
856 IAC 1-36-9 Copies of requests

SECTION 2. UNDER IC 4-22-2.5-3, 856 IAC 1-2-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~registration~~ **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 ~~regulation rule~~ shall be deemed sufficient cause for suspension or revocation of the ~~certificate~~ **license**. (*Indiana Board of Pharmacy; Reg 2, Sec 1; filed Jun 18, 1962, 10:00 a.m.: Rules and Regs. 1963, p. 119*)

SECTION 3. UNDER IC 4-22-2.5-3, 856 IAC 1-2-2 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~registration~~ **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 ~~certificate~~ **license** is not in bona fide employment, shall be deemed an illegal use of such ~~certificate~~ **license**, and upon satisfactory proof of such illegal use, such ~~certificate~~ **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*)

SECTION 4. UNDER IC 4-22-2.5-3, 856 IAC 1-2-3 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~certificates~~ **a license** as a ~~registered~~ pharmacist or ~~registered~~ assistant pharmacist shall notify the ~~secretary~~ **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*)

SECTION 5. UNDER IC 4-22-2.5-3, 856 IAC 1-3.1-3 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~each~~ **section** of the examination taken after the effective date of this ~~regulation~~ **rule**. (*Indiana Board of Pharmacy; 856 IAC 1-3.1-3; filed Dec 3, 1985, 3:02 p.m.: 9 IR 767*)

SECTION 6. UNDER IC 4-22-2.5-3, 856 IAC 1-3.1-4 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 entire 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*)

SECTION 7. UNDER IC 4-22-2.5-3, 856 IAC 1-3.1-6 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~reapproval~~ **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 ~~of in~~ **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*)

SECTION 8. UNDER IC 4-22-2.5-3, 856 IAC 1-3.1-7 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~registered~~ 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*)

SECTION 9. UNDER IC 4-22-2.5-3, 856 IAC 1-3.1-12 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~Indiana~~ **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 **of pharmacy** of 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*)

SECTION 10. UNDER IC 4-22-2.5-3, 856 IAC 1-4-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-4-1 License transfer

Authority: IC 25-26-13-4

Affected: IC 25-26-13

Sec. 1. All applicants for **reciprocal 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 **reciprocity 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*)

SECTION 11. UNDER IC 4-22-2.5-3, 856 IAC 1-4-2 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 **reciprocity license transfer** in the State of 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*)

SECTION 12. UNDER IC 4-22-2.5-3, 856 IAC 1-4-4 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 **reciprocity 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 ~~the State 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*)

SECTION 13. UNDER IC 4-22-2.5-3, 856 IAC 1-15-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~registered~~ **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 co-partnership 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*)

SECTION 14. UNDER IC 4-22-2.5-3, 856 IAC 1-20-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-20-1 Prohibitions

Authority: IC 25-26-13-4

Affected: IC 16-1-30; IC 16-6-8; 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**:

(~~a~~) **(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 ~~or regulations~~ promulgated by the ~~pharmacy~~ 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 ~~the state of~~ Indiana as defined by IC 25-26-13-2.

(~~b~~) **(2)** Violate the Indiana Legend Drug Act found at IC 16-6-8-1 through 16-6-8-9, as amended up to and including January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in ~~the state of~~ Indiana as defined by ~~the~~ IC 25-26-13-2.

(~~c~~) **(3)** Violate IC 16-1-30-1 through **IC 16-1-30-19**, as amended to and including January 1, 1983, which deal with adulterated and misbranded drugs or devices, or any rules ~~or regulations~~ promulgated by the ~~pharmacy~~ board under the authority of IC 16-1-30-1 through **IC 16-1-30-19**, which were effective as of January 1, 1983, insofar as such violation would pertain to the sale of drugs and devices in ~~the state of~~ Indiana as defined by IC 25-26-13-2.

(~~d~~) **(4)** Violate ~~Title 21 of United States Code, Sections 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 ~~the state of~~ Indiana as defined by IC 25-26-13-2.

(~~e~~) **(5)** Violate the Federal Food, Drug, and Cosmetic Act, which is found at ~~Title 21 of the United States Code, Sections 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 ~~the state of~~ Indiana as defined by IC 25-26-13-2.

(~~f~~) **(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 ~~the state of~~ Indiana as defined by IC 25-26-13-2.

(~~g~~) **(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.

~~(h) Dispense a different drug; biological; medicinal substance; device or brand of any of the foregoing in the place of the drug; biological; medicinal substance; device or brand prescribed in the prescription of a licensed practitioner without the expressed permission of such practitioner except a different brand name of the same drug; biological; medicinal substance; or device containing the identical chemical entities (i.e., the identical salt, ester, ether, isomer, etc., of the basic chemical); in the same dosage form and strength may be substituted for the drug; biological; medicinal substance; or device prescribed only in the case of a prescription which qualifies for reimbursement under 42 U.S.C. §1396a et. seq. commonly referred to as Title XIX of the Federal Social Security Act and any rules and regulations pertaining thereto; provided a maximum allowable cost program for purposes of reimbursement has been established for the prescribed drug; biological; medicinal substance; or device pursuant to the laws and regulations of the United States and provided further the prescriber has not certified the prescription medically necessary or brand necessary. The pharmacist must dispense the brand prescribed if the prescriber has certified medically necessary or brand necessary. Prior to dispensing a different brand on a prescription not certified medically necessary or brand necessary, the pharmacist may consult the prescriber to verify his or her intention to authorize substitution; if the pharmacist deems it necessary.~~

~~(i) (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.~~

~~(j) (9) Aid or abet in the practice of a pharmacy a person not having a license to practice as a pharmacist in this state: Indiana.~~

~~(k) (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 or controlled substance as defined in the Uniform Controlled Substances Act of 1973, under IC 35-48-1-1.~~

~~(l) (11) Violate the act regulating the practice of pharmacy in the state of 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 or regulations promulgated by the pharmacy 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)

SECTION 15. UNDER IC 4-22-2.5-3, 856 IAC 1-21-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~six~~ **(6) months from the date of repackaging or twenty-five percent (25%) of the time one (1) year** until the manufacturer's expiration date, whichever is ~~less~~ **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)*

SECTION 16. UNDER IC 4-22-2.5-3, 856 IAC 1-23-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 **dangerous prescription** drug or narcotic, the pharmacist shall be required to affix to the immediate container in which such **dangerous prescription** drug or narcotic is delivered a label bearing the following information:

- (a) (1) The name, ~~and~~ address, **and telephone number** of the establishment from which such drug was sold.
- (b) (2) The date on which the prescription for such drug was filled.
- (c) (3) The number of such prescription as filed in the prescription files of the pharmacy where the prescription was filled.
- (d) (4) The name of the practitioner who prescribed such drug.
- (e) (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.
- (f) (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)

SECTION 17. UNDER IC 4-22-2.5-3, 856 IAC 1-26-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~the state 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) ~~A~~ "Contact hour" means not less than fifty (50) nor more than sixty (60) minutes of clock time participating in a continuing education program.
- (4) ~~A~~ "Continuing education unit" or "CEU" means ten (10) contact hours of continuing education credit.
- (5) "Approved by ACPE" means pharmacy continuing education providers ~~which 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 ~~here~~, **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 ~~at least ninety (90) days in advance of the program date~~ 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 ~~within sixty (60) days of the receipt of the application~~ 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 ($\frac{1}{5}$) of the total hours may be business, management, or computer courses;
 - (B) at least four-fifths ($\frac{4}{5}$) of the total hours must be pharmacy practice related; **and**
 - (C) at least one-half ($\frac{1}{2}$) 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.]*)

SECTION 18. UNDER IC 4-22-2.5-3, 856 IAC 1-29-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~Indiana board, of pharmacy~~, and such an electronic data processing system does not qualify for approval unless it satisfies at a minimum the requirements found in ~~856 IAC 1-29-1~~ **this rule**. Any such system must be approved by the board of ~~pharmacy~~ before initial installation in Indiana. Any pharmacy installing such a system must make a written request to the board for approval. ~~This shall be the responsibility of the pharmacist manager~~. 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*)

SECTION 19. UNDER IC 4-22-2.5-3, 856 IAC 1-30-5 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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, ~~“pharmacist-in-charge”~~ **“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 ~~the state of~~ 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.]*)

SECTION 20. UNDER IC 4-22-2.5-3, 856 IAC 1-30-9 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-30-9 Personnel

Authority: IC 25-26-13-4

Affected: IC 25-26-13-18

Sec. 9. (a) Each pharmacist 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 ~~pharmacist-in-charge~~ **qualifying pharmacist** shall be responsible for the purchasing, storage, compounding, repackaging, dispensing, and distribution of all sterile pharmaceuticals.

(c) The ~~pharmacist-in-charge~~ **qualifying pharmacist** shall also be responsible for the development and continuing review of all policies and procedures, training manuals, and quality assurance programs. (*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.]*)

SECTION 21. UNDER IC 4-22-2.5-3, 856 IAC 1-30-13 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 a ~~label containing~~ 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)

SECTION 22. UNDER IC 4-22-2.5-3, 856 IAC 1-30-14 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~pharmacist-in-charge~~ **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 cytotoxic 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. *(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.]*

SECTION 23. UNDER IC 4-22-2.5-3, 856 IAC 1-30-15 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-30-15 Disposal of infectious waste

Authority: IC 25-26-13-4

Affected: IC 25-26-13-18

Sec. 15. The ~~pharmacist-in-charge~~ **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.]

SECTION 24. UNDER IC 4-22-2.5-3, 856 IAC 1-30-18 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-30-18 Quality assurance

Authority: IC 25-26-13-4

Affected: IC 25-26-13-18

Sec. 18. (a) The designated ~~pharmacist-in-charge~~ **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 their specifications. 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, ~~which include~~ **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 at least annually. Records documenting certification 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 must be thoroughly cleaned between each use for cytotoxic and noncytotoxic 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 written justification of the chosen expiration dates for compounded parenteral products documented in the policy and procedure manual.

(g) There shall be 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.]*)

SECTION 25. UNDER IC 4-22-2.5-3, 856 IAC 1-32-1 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~prescriptions~~, **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*)

SECTION 26. UNDER IC 4-22-2.5-3, 856 IAC 1-32-2 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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) ~~Prescriptions~~ **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*)

SECTION 27. UNDER IC 4-22-2.5-3, 856 IAC 1-32-3 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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*)

SECTION 28. UNDER IC 4-22-2.5-3, 856 IAC 1-32-4 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

856 IAC 1-32-4 Pharmacists' responsibilities

Authority: IC 25-26-13-4

Affected: IC 25-26-13-25

Sec. 4. Transfer of ~~prescriptions~~ **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)

SECTION 29. UNDER IC 4-22-2.5-3, 856 IAC 1-34-2 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ($\frac{1}{8}$) of an inch from the top of the pad and five-sixteenths ($\frac{5}{16}$) of an inch from the right side of the pad. The symbol must be three-fourths ($\frac{3}{4}$) 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-quarter~~ **one-fourth** ($4\frac{1}{4}$) ~~inch~~ **inches** high and five and one-half ($5\frac{1}{2}$) ~~inch~~ **inches** wide.

(b) Nothing in ~~the~~ **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)*

SECTION 30. UNDER IC 4-22-2.5-3, 856 IAC 1-36-5 IS READOPTED AND AMENDED TO READ AS FOLLOWS:

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 ~~three (3)~~ **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*)

SECTION 31. UNDER IC 4-22-2.5-3, THE FOLLOWING ARE REPEALED: 856 IAC 1-3.1-10; 856 IAC 1-5-1; 856 IAC 1-12; 856 IAC 1-29-7.

Notice of Public Hearing

Under IC 4-22-2-24 and IC 4-22-2.5-3, notice is hereby given that on October 9, 2001 at 10:00 a.m., at the Indiana Government Center-South, 402 West Washington Street, Conference Center Room C, Indianapolis, Indiana the Indiana Board of Pharmacy will hold a public hearing to readopt rules.

Requests for any part of this readoption to be separate from this action must be made in writing within 30 days of this publication. Send written comments to:

*Mark Bina, Director
Health Professions Bureau
402 West Washington Street, Room W041
Indianapolis, Indiana 46204
Mbina@hpb.state.in.us.*

Copies of these rules are now on file at the Indiana Government Center-South, 402 West Washington Street, Room W041 and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Lisa R. Hayes
Executive Director
Health Professions Bureau