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 Application Requirements (Repealed)

(Repealed by Indiana Board of Pharmacy; filed Dec 3, 1985, 3:02 pm: 9 IR 771)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. *(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 atmospheric environment which contains less than one hundred (100) particles five-tenths (0.5) microns in diameter per cubic foot of air. *(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 "Cytotoxic" defined

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 4. As used in this rule, "cytotoxic" means a pharmaceutical that has the capability of killing living human cells. *(Indiana Board of Pharmacy; 856 IAC 1-30-4; 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 1-30-5 "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 dosage form of a drug, free from living micro-organisms. *(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 sterile pharmaceuticals shall maintain a policy and procedure manual relating to sterile products 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 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 clean-up of accidental spills of cytotoxic 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 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 a Class 100 environment in the work space where critical objects are exposed and critical activities are performed. Examples of appropriate devices include laminar airflow hood and zonal laminar flow of high efficiency particulate air (HEPA) filtered air.
(2) A sink with hot and cold running water which is convenient to the compounding area for the purpose of hand scrubs prior to compounding.
(3) Disposal containers for used needles, syringes, gowns, gloves, etc., and, if applicable, cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patients.
(4) Environmental controls including biohazard cabinetry when cytotoxic drug products are prepared.
(5) A refrigerator with a thermometer.

(d) 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 solutions.
(3) Hand washing agent with antibacterial action.
(4) Disposable towels or wipes.
(5) Filters and filtration equipment, if utilized.
(6) A cytotoxic drug spill kit shall be available in the facility, if cytotoxic 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 1-28-7.

(f) A pharmacy preparing 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) other electronic data base for determining mixing and administration guidelines and drug incompatibilities;

in addition to other publications as required in 856 IAC 1-6-2.

(g) If the pharmacy is handling or preparing cytotoxic drugs, the pharmacy shall have a copy of Occupational Safety and Health Administration requirements for handling cytotoxic drugs as published in Occupational Safety and Health Administration Publication 8-1.1, 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 Nov 13, 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 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 purchasing, storage, compounding, repackaging, dispensing, and distribution of all sterile pharmaceuticals.

(c) The 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.]; 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 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.]; 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 Cytotoxic drugs

Authority: IC 25-26-13-4
Affected: IC 25-26-13-18

Sec. 17. The following additional requirements are necessary to ensure the protection of the personnel involved in those licensed pharmacies that prepare cytotoxic drugs:

(1) All cytotoxic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet.

(2) Protective apparel shall be worn by personnel compounding cytotoxic drugs. This shall include disposable gloves and gowns with tight cuffs.

(3) Appropriate safety and special handling techniques for compounding cytotoxic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(4) Procedures for disposal of cytotoxic waste shall be specified within the policy and procedure manual as required by section 7 of this rule.

(5) Written procedures for handling both major and minor spills of cytotoxic agents must be developed and included in the policy and procedure manual.

(6) Cytotoxic agents shall be properly labeled to identify the need for caution in handling, e.g., "Chemotherapy-Dispose of

Properly". If shipped, the outer container must also be properly labeled with the same cautionary statement. *(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 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, 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.]; 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; filed Jun 7, 2004, 4:45 p.m.: 27 IR 3073)

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; filed Jun 7, 2004, 4:45 p.m.: 27 IR 3073)

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; filed Jun 7, 2004, 4:45 p.m.: 27 IR 3073)*

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 25-26-13-4

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; filed Jun 7, 2004, 4:45 p.m.: 27 IR 3074)*

856 IAC 1-33-5 Patient counseling violations
Authority: IC 25-26-13-4
Affected: IC 25-1-9

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; filed Jun 7, 2004, 4:45 p.m.: 27 IR 3074)*

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 (⅛) 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)*

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:
$\triangle^{1}$ cis or trans tetrahydrocannabinol, and their optical isomers.
$\triangle^{6}$ cis or trans tetrahydrocannabinol and their optical isomers.
$\triangle^{3,4}$ 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) Racemethorphan 9732
(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) Δ^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]*.

EXCEPTED PRESCRIPTION DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
A.E.A.	Tablet: Amobarbital, 25 mg.; aminophylline, 120 mg.; ephedrine hydrochloride, 25 mg.	Haack Laboratories, Inc.
Alased	Tablet: Phenobarbital, 16.2 mg.; homatropine methylbromide, 3.6 mg.; aluminum hydroxide gel, dried, 7½ gr.; magnesium trisilicate, 2½ gr.	Norgine Laboratories, Inc.
Alcitex	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/5000 gr.; calcium carbonate, 3½ gr.; magnesium carbonate, 2½ gr.; cerium oxalate, ½ gr.	Paul B. Elder Co., Inc.
Algoson	Tablet: Butabarbital sodium, 7.5 mg.; acetaminophen, 300 mg.	McNeil Laboratories, Inc.
Albydrox	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply.
Alkasans	Tablet: Phenobarbital, 8.0 mg.; atropine sulfate, 0.06 mg.; kaolin-alumina gel, 500 mg.	P. J. Noyes Co.
Alsical	Powder (60 gr.): Phenobarbital, ¼ gr.; belladonna extract, ¼ gr.; calcium carbonate, 24 gr.; magnesium trisilicate, 15 gr.; magnesium oxide, 10 gr.; aluminum hyroxide gel, dried. 10 gr.	Dorsey Laboratories.
Alubelap	Tablet: Phenobarbital, 8 mg.; aluminum hydroxide gel, dried, 2300 mg.; belladonna extract, 4 mg.	Haack Laboratories, Inc.
Aludrox SA suspension	Suspension (5 cc.): Butabarbital, 3 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Aludrox SA tablets	Tablet: Butabarbital, 8 mg.; ambutonium bromide, 2.5 mg.	Wyeth Laboratories.
Alu-Mag	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide gel, dried, 2½ gr.; magnesium trisilicate, 2½ gr.; belladonna leaf extract, ⅛ gr.	Norsal Laboratories, Inc.
Alumazen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; magnesium trisilicate, 500 mg.; aluminum hydroxide gel, dried, 250 mg.; saccharin sodium, 0.12 mg.	The Zemmer Co.
Aluminum hydroxide, magnesium trisilicate, and kaolin with phenobarbital and atropine sulfate	Tablet: Phenobarbital, ⅛ gr.; aluminum hydroxide, 2 gr.; magnesium trisilicate, 4 gr.; kaolin, colloidal, 2 gr.; atropine sulfate, 1/300 gr.	Buffalo Pharmaceutical Supply Corp.
Aminodrox with phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 0.1 gm., aluminum hydroxide gel, dried, 0.12 gm.	The S. E. Massengill Co.
Aminodrox-forte with phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.; aluminum hydroxide gel, dried, 250 mg.	The S. E. Massengill Co.
Aminophylline and amytal	Capsule: Amobarbital, 32 mg.; aminophylline, 0.1 gm.	Eli Lilly Co.
Aminophylline with pentobarbital	Suppository: Pentobarbital sodium, 100 mg.; aminophylline, 500 mg.	G. D. Searle & Co.
Aminophylline and phenobarbital	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	The Zemmer Co.
Do	Tablet: Phenobarbital, ¼ gr.; aminophylline, 100 mg.	The Blue Line Chemical Co.
Aminophylline with phenobarbital	Tablet: Phenobarbital, 16 mg.; aminophylline, 100 mg.	H. E. Dubin Laboratories, Inc.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 100 mg.	G. D. Searle & Co.
Do	Tablet: Phenobarbital, 15 mg.; aminophylline, 200 mg.	Do.
Do	Tablet: Phenobarbital, 30 mg.; aminophylline, 200 mg.	Do.
Amobarbital and PETN	Capsule: Amobarbital, 50 mg.; pentaerythritol tetranitrate, 30 mg.	Meyer Laboratories, Inc.
Ampyrox with butabarbital sodium (AMPYROX)	Tablet: Butabarbital sodium, 15 mg.; scopolamine methylnitrate, 2 mg.	Paul B. Elder Co., Inc.
Ampyrox with butabarbital sodium, elixir	Elixir (5 cc.): Butabarbital sodium, 10 mg.; scopolamine methylnitrate, 1 mg.	Do.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Amsed (NAP-37)	Tablet: Phenobarbital, ¼ gr.; hyocine hydrobromide, 0.0072 mg.; atropine sulfate, 0.024 mg.; hyoscyamine hydrobromide, 0.128 mg.	North American Pharmaceal, Inc.
Amsodyne	Tablet: Phenobarbital, ¼ gr.; extract belladonna leaves, ⅛ gr.; aspirin, 5 gr.; caffeine, ¼ gr.	Paul B. Elder Co., Inc.
Antacia No. 3 with phenobarbital and atropine	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 5 gr.; magnesium hydroxide, 5 gr.	Meyers and Co.
Antispasmodic	Tablet (purple): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1037 mg.; homatropine methylbromide, 0.567 mg.; hyocine hydrobromide, 0.0065 mg.	Hydrex Co., Inc.
Antispasmodic-enzyme	Tablet: Phenobarbital, 8.1 mg.; hyoscyamine sulfate, 0.0519 mg.; homatropine methylbromide, 0.2885 mg.; hyoscine hydrobromide, 0.0033 mg.; pancreatin, 100 mg.; pepsin, 150 mg.	Do.
Antrocol	Tablet or capsule: Phenobarbital, 16 mg.; atropine sulfate, 0.324 mg.; colloidal sulfur, 22 mg.	Wm. P. Poythress & Co., Inc.
Aqualin-plus, children	Suppository: Pentobarbital sodium, ⅜ gr.; theophylline, 1⅜ gr.	The Wm. A. Webster Co.
Aqualin-plus No. 1	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 3¾ gr.	Do.
Aqualin-plus No. 2	Suppository: Pentobarbital sodium, 1½ gr.; theophylline, 7½ gr.	Do.
Aqualin-plus No. 2A	Suppository: Pentobarbital sodium, ¾ gr.; theophylline, 7½ gr.	Do.
Asmabar	Tablet: Butabarbital, 20 mg.; ephedrine sulfate, 25 mg.; theophylline hydroxide, 130 mg.	The Blue Line Chemical Co.
Asmacol	Tablet: Butabarbital, 15 mg.; aminophylline, 180 mg.; phenylpropanolamine hydrochloride, 25 mg.; chlorpheniramine maleate, 2 mg.; aluminum hydroxide gel, dried, 60 mg.; magnesium trisilicate, 60 mg.	The Vale Chemical Co., Inc.
Asperease, modified with phenobarbital	Tablet: Phenobarbital, 0.008 gm.; acetylsalicylic acid, 0.5 gm.	P. J. Noyes Co.
Atropal	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/300 gr.; magnesium trisilicate, 2½ gr.; aluminum hydroxide gel, dried, 2½ gr.	Mallinckrodt Chemical Works.
Atrosilital	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.; magnesium trisilicate, 0.5 gm.; saccharine sodium, 0.12 mg.	The Zemmer Co.
Banthine with phenobarbital	Tablet: Phenobarbital, 15 mg.; methantheline bromide, 50 mg.	G. D. Searle & Co.
Barbatro No. 1	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The S. E. Massengill Co.
Barbatro No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.25 mg.	Do.
Barbeloid	Tablet: Amobarbital sodium, 20 mg.; hyoscyamine sulfate, 0.125 mg.; hyoscine hydrobromide, 0.007 mg.; homatropine methylbromide, 0.5 mg.	The Vale Chemical Co., Inc.
Barbidonna elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Mallinckrodt Chemical Works.
Barbidonna tablets	Tablet: Phenobarbital, 16 mg.; hyoscyamine sulfate, 0.1286 mg.; atropine sulfate, 0.0250 mg.; scopolamine hydrobromide, 0.0074 mg.	Do.
Barboma elixir	Elixir (100 cc.): Phenobarbital, 0.4 gm.; homatropine methylbromide, 33.8 mg.	The Blue Line Chemical Co.
Barboma tablets	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 123 gr.	Do.
Bardase	Tablet or elixir (4 cc.): Phenobarbital, 16.2 mg.; hyoscyamine sulfate, 0.1 mg.; hyoscine hydrobromide, 0.007 mg.; atropine, 0.020 mg.; Taka-Diastase, 162.0 mg.	Parke, Davis & Co.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Bar-Don elixir	Elixir (30 cc.): Phenobarbital, 100 mg.; hyoscyamine hydrobromide, 0.60 mg.; hyoscine hydrobromide, 0.042 mg.; atropine sulfate, 0.12 mg.	Warren-Teed Pharmaceuticals, Inc.
Bar-Don tablets	Tablet: Phenobarbital, 16.670 mg.; hyoscyamine hydrobromide, 0.10 mg.; hyoscine hydrobromide, 0.007 mg.; atropine sulfate 0.020 mg.	Do.
Belap No. 0	Tablet: Phenobarbital, 8 mg.; belladonna extract, 8 mg.	Haack Laboratories, Inc.
Belap No. 1	Tablet: Phenobarbital, 15 mg.; belladonna extract, 8 mg.	Do.
Belap Ty-Med	Tablet: Amobarbital, 50 mg.; homotropine methylbromide, 7.5 mg.	Do.
Belladenal	Tablet: Phenobarbital, 50 mg.; bellafoline, 0.25 mg.	Sandos Pharmaceuticals.
Do	Elixir (15 cc.): Phenobarbital, 15.6 mg.; bellafoline, 0.078 mg.	Do.
Bellatol elixir	Elixir (5 cc.): Butabarbital sodium, 20 mg.; tincture belladonna, 0.33 cc.	The Zemmer Co.
Bellergal	Tablet: Phenobarbital, 20 mg.; ergotamine tartrate, 0.3 mg.; levorotatory alkaloids of belladonna, 0.1 mg.	Sandoz Pharmaceuticals.
Do	Tablet: Phenobarbital, 40 mg.; ergotamine tartrate, 0.6 mg.; levorotatory alkaloids of belladonna, 0.2 mg.	Do.
Beplete with belladonna elixir	Elixir (4 cc): Phenobarbital, 15 mg.; vitamin B_1, 1.5 mg.; vitamin B_2, 1 mg.; vitamin B_6, 0.33 mg.; vitamin B_{12}, 1.66 mg.; niacinamide, 10 mg.; pantothenol, 0.2 mg.; belladonna alkaloids, 0.2 mg.	Wyeth Laboratories.
Bexadonna	Tablet: Phenobarbital, 16 mg.; homatropine methylbromide, 10 mg.; hyoscine hydrobromide, 0.0065 mg.; hyoscyamine sulfate, 0.1 mg.	Bexar Pharmaceuticals.
Bilamide	Tablet: Phenobarbital, ¼ gr.; dried ox bile, 2 gr.; dehydrocholic acid, 2 gr.; homatropine methylbromide, 1/48 gr.	Norgine Laboratories, Inc.
Binitrin	Tablet: Butabarbital sodium, 15.0 mg.; nitroglycerin, 0.3 mg.; pentaerythritol tetranitrate, 10.1 mg.	The Vale Chemical Co., Inc.
Bioxatphen	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.; bismuth subnitrate, 120 mg.; cerium oxalate, 120 mg.	The Zemmer Co.
Bismuth, belladonna, and phenobarbital	Capsule: Phenobarbital, ¼ gr.; bismuth subgallate, 5 gr.; extract belladonna leaf, ⅛ gr.	The Bernard Co.
Buffadyne A-S	Tablet: Amobarbital, 15 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; homatropine methylbromide, 2.5 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Lemmon Pharmacal Co.
Buffadyne with barbiturates	Tablet: Secobarbital sodium, 8 mg.; amobarbital, 8 mg.; aspirin, 300 mg.; phenacetin, 150 mg.; caffeine, 30 mg.; aluminum hydroxide gel, 75 mg.; magnesium hydroxide, 45 mg.	Do.
Bunesia	Tablet: Butabarbital sodium, 10 mg.; homatropine methylbromide, 2.5 mg.; magnesium hydroxide, 300 mg.	McNeil Laboratories, Inc.
Buren	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; scopolamine hydrobromide, 0.0065 mg.; atropine sulfate, 0.0194 mg.; hyoscyamine sulfate, 0.1037 mg.	B. F. Ascher & Co., Inc.
Burrizem	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.1 mg.; rutin, 20 mg.; mannitol hexanitrate, 30 mg.	The Zemmer Co.
Butabarbital and hyoscyamine sulfate	Tablet or elixir (5 cc.): Butabarbital, 15 mg.; hyoscyamine sulfate, 0.125 mg.	McNeil Laboratories, Inc.
Do	Capsule: Butabarbital, 45 mg.; hyoscyamine sulfate, 0.375 mg.	Do.
Butibel	Tablet or elixir (5 cc.): Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (hyoscyamine sulfate, 0.138 mg.; hyoscine hydrobromide, 0.027 mg.; atropine sulfate, 0.067 mg.).	Do.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Butibel R-A	Tablet: Butabarbital sodium, 30 mg.; belladonna extract, 30 mg.	Do.
Butibel-gel suspension	Suspension (15 cc.): Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.187 mg.); activated attapulgite, 1.5 mg.; pectin, 75 mg.	McNeil Laboratories, Inc.
Butibel-gel tablets	Tablet: Butabarbital sodium, 7.5 mg.; belladonna extract, 7.5 mg. (total alkaloids 0.0935 mg.); activated attapulgite, 500 mg.; pectin, 45 mg.	Do.
Butibel-Zyme	Tablet: Butabarbital sodium, 15 mg.; belladonna extract, 15 mg. (total alkaloids 0.187 mg.); proteolytic enzyme standardized, 10 mg.; amylolytic enzyme standardized, 20 mg.; cellulolytic enzyme standardized, 5 mg.; lipolytic enzyme standardized, 100 mg.; iron ox bile (45% cholic acid), 30 mg.	Do.
Butigetic	Tablet: Butabarbital sodium, 15 mg.; acetaminophen, 200 mg.; phenacetin, 150 mg.; caffeine, 30 mg.	Do.
Cafergot P-B	Tablet: Phenobarbital sodium, 30 mg.; ergotamine tartrate, 1 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.125 mg.	Sandoz Pharmaceuticals.
Do	Suppository: Pentobarbital, 60 mg.; ergotamine tartrate, 2 mg.; caffeine, 100 mg.; levorotatory alkaloids of belladonna, 0.25 mg.	Do.
Cal-Ma-Phen	Tablet: Phenobarbital, ¼ gr.; calcium-carbonate, 5 gr.; magnesium hydroxide, 5 gr.; atropine sulfate, 1/300 gr.	Physicians Supply Co.
Cantil with phenobarbital	Tablet: Phenobarbital, 16 mg.; mepenzolate bromide, 25 mg.	Lakeside Laboratories, Inc.
Carbonates No. 3 with phenobarbital and atropine	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.11 mg.; calcium carbonate, 224 mg.; magnesium carbonate, 160 mg.; bismuth subcarbonate, 32 mg.	P. J. Noyes Co.
Cardalin-Phen	Tablet: Phenobarbital, ¾ gr.; aminophylline, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ½ gr.	Mallinckrodt Chemical Works.
Cardilate-P	Tablet: Phenobarbital, 15 mg.; erythrityl tetranitrate, 10 mg.	Burroughs Wellcome & Co. (U.S.A.) Inc.
Cholarace	Tablet: Pentobarbital, 27.5 mg.; oxtriphylline, 200 mg.; racephedrine, 20 mg.	Warner-Chilcott Laboratories.
Co-Elorine 25	Capsule: Amobarbital, 8 mg.; tricyclamol chloride, 25 mg.	Eli Lilly and Co.
Co-Elorine 100	Capsule: Amobarbital, 16 mg.; tricyclamol chloride, 100 mg.	Do.
Cold Preparation, special	Tablet: Phenobarbital, 8.1 mg.; chlorpheniramine maleate, 2 mg; pseudoephedrine hydrochloride, 60 mg.; salicylamide, powder, 300 mg.	Knight Pharmacal Co.
Covadil	Tablet: Butabarbital sodium, 20 mg.; pentaerythritol tetranitrate, 15 mg.	The Blue Line Chemical Co.
Dactil with phenobarbital	Tablet: Phenobarbital, 16 mg.; piperidolate hydrochloride, 50 mg.	Lakeside Laboratories, Inc.
Dainite	Tablet: Pentobarbital sodium, ¼ gr. aminophyline, 3 gr.; ephedrine hydrochloride, ¼ gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Mallinckrodt Chemical Works.
Dainite-K1	Tablet: Phenobarbital, ¼ gr.; aminophylline, 3 gr.; ephedrine hydrochloride, ¼ gr.; potassium iodide, 5 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Dainite Night	Tablet: Phenobarbital, ⅜ gr.; pentobarbital sodium, ½ gr.; aminophylline, 4 gr.; aluminum hydroxide gel, dried, 2½ gr.; benzocaine, ¼ gr.	Do.
Daricon PB	Tablet: Phenobarbital, 15 mg.; oxyphencyclimine hydrochloride, 6 mg.	Pfizer Laboratories.
Diatraegus	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerine, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims.	Buffington's, Inc.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Dis-Tropine	Tablet: Diallylbarbituric acid, ¼ gr.; atropine sulfate, 1/300 gr.; magnesium carbonate, 2½ gr.; calcium carbonate, 3½ gr.; bismuth subcarbonate, 1 gr.	Do.
Dilantin with phenobarbital	Capsule: Phenobarbital, ¼ gr.; diphenylhydantoin sodium, 0.1 gm.	Parke, Davis & Co.
Do	Capsule: Phenobarbital, ½ gr.; diphenylhydantoin sodium, 0.1 gm.	Do.
Dolonil	Tablet: Butabarbital, 15 mg.; phenazopyridine hydrochloride, 150 mg.; hyoscyamine hydrobromide, 0.3 mg.	Warner-Chilcott Laboratories.
Donabarb	Tablet: Phenobarbital, ¼ gr.; powder extract belladonna, ¼ gr.	Paul B. Elder Co., Inc.
Donaphen, new special donaphen	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.024 mg.; scopolamine hydrobromide, 0.0072 mg.; hyoscyamine hydrobromide, 0.128 mg.	Burt Krone Co.
Donna-Sed elixir	Elixir (5 cc.): Phenobarbital, 16.2 mg.; hyoscyamine hydrobromide, 0.1037 mg.; atropine sulfate, 0.0194 mg.; hyscine hydrobromide, 0.0065 mg.	North American Pharmacal, Inc.
Donnasep	Tablet: Phenobarbital, 8.1 mg.; phenazopyridine hydrochloride, 50.0 mg.; methenamine mandelate, 500 mg.; hyoscyamine sulfate, 0.0519 mg.; atropine sulfate, 0.0097 mg.; hyoscine hydrobromide, 0.0033 mg.	A. H. Robins Co., Inc.
Donphen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1 mg.; atropine sulfate, 0.02 mg.; scopolamine hydrobromide, 8 ug.	Lemmon Pharmacal Co.
Dormital-HM	Tablet: Phenobarbital, ¼ gr.; homatropine methylbromide, 1/84 gr.; strontium bromide, 1 gr.	Buffington's Inc.
Dynapin with phenobarbital	Tablet: Phenobarbital, 15 mg.; nitroglycerin, 0.5 mg.; pentaerythritol tetranitrate, 15 mg.	Key Pharmacal Co.
Elmaloin with phenobarbital	Capsule: Phenobarbital, 15 mg.; diphenylhydantoin, 1½ gr.	Paul B. Elder Co., Inc.
Ephedrine and sodium phenobarbital	Tablet: Sodium phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	The Vale Chemical C Inc.
Ephedrine sulfate and phenobarbital	Tablet: Phenobarbital, 15 mg.; ephedrine sulfate, 25 mg.	The Zemmer Co.
Ephedrine with phenobarbital	Tablet: Phenobarbital, ¼ gr.; ephedrine sulfate, ⅜ gr.	P. J. Noyes Co.
Ercafital	Tablet: Phenobarbital, 7.5 mg.; ergotamine tartrate, 0.5 mg.; caffeine, 60 mg.	The Blue Line Chemic Co.
Ethrava-trate	Tablet: Mephobarbital, 10 mg.; pentaerythrityl tetranitrate, 20 mg.; ethaverine, hydrochloride, 30 mg.	North American Pharmacal, Inc.
Eu-Phed-Amin	Tablet: Phenobarbital, 30 mg.; aminophylline, 0.1 gm.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.1 gm.	Warren-Teed Pharmaceticals Inc.
Eu-Phed-Ital	Tablet: Phenobarbital sodium, 30 mg.; ephedrine sulfate, 30 mg.; extract euphorbia, 0.12 gm.	Warren-Teed Pharmaceticals Inc.
Fensobel	Tablet: Phenobarbital, 8.1 mg.; belladona extract, 2.95 mg.; aluminum hydrochloride gel, dried, 63 mg.; magnesium trisilicate, 63 mg.; bismuth subcarbonate, 32.5 mg.; magnesium carbonate, 252 mg.; precipitated calcium carbonate, 203.5 mg.; malt diastase, 12.5 mg.; peppermint oil, 3 mg.	United States Vitamin Pharmaceutical Corp.
Franol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine hydrochloride, 32 mg.	Winthrop Laboratories.
Homechol	Tablet: Pentobarbital sodium, 8.0 mg.; homatropine methylbromide, 2.5 mg.; dehydrocholic acid, 60.0 mg.; ox bile extract, 150.0 mg.	Lemmon Pharmacal Co.
Homopent	Tablet: Pentobarbital sodium, 15 mg.; homatropine methylbromide, 2.5 mg; magnesium trisilicate, 300 mg.	Lemmon Pharmacal Co.
H-P-A (modified)	Tablet: Phenobarbital, ¼ gr.; aspirin, 5 gr.; extract hyoscyamus, ¼ gr.	Paine Drug Co.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Hybephen	Tablet: Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	The S. E. Massengil Co.
Hybephen elixir	Elixir (5 cc.): Phenobarbital, 15 mg.; hyoscyamine sulfate, 0.1277 mg.; atropine sulfate, 0.0233 mg.; hyoscine hydrobromide, 0.0094 mg.	Do.
Hydrochol plus	Tablet: Amobarbital, 15 mg.; dehydrocholic acid, 200 mg.; scopolamine methylnitrate, 0.8 mg.; ox bile desiccated, 50 mg.	Paul B. Elder Co., Inc.
Hytrona antispasmodic elixir	Elixir (5 cc.): Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Pitman-Moore.
Hytrona antispasmodic tablets	Tablet: Phenobarbital, 16 mg.; belladonna alkaloids, 0.2 mg.	Do.
Hocalm	Tablet: Methobarbital, 30 mg.; methscopolamine nitrate, 2.5 mg.; d-calcium pantothenate, 25 mg.	Warren-Teed Pharmaceuticals Inc.
Isordil with phenobarbital	Tablet: Phenobarbital, 15 mg; isosorbide dinitrate, 10 mg.	Ives Laboratories, Inc.
Isufranol	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 10 mg.	Winthrop Laboratories.
Isufranol, mild	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; benzylephedrine, 32 mg.; isoproterenol hydrochloride, 5 mg.	Do.
Isuprel compound elixir	Elixir (15 cc.): Phenobarbital, 6 mg.; isoproterenol hydrochloride, 2.5 mg.; ephedrine sulfate, 12 mg.; theophylline, 45 mg.; potassium iodide, 150 mg.	Do.
Kaphebel	Tablet: Phenobarbital, ⅛ gr.; belladonna root, ¼ gr.; kaolin colloidal, 7½ gr.	Paul B. Elder Co., Inc.
Kanumodic	Tablet: Phenobarbital, 8 mg.; methscopolamine nitrate, 2 mg.; cellulase, 9 mg.; pancrestin, 500 mg.; glutamic acid hydrochloride, 200 mg.; ox bile extract, 100 mg.; pepsin, 150 mg.	Dorsey Laboratories.
Kavatrate	Tablet: Phenobarbital sodium, ⅛ gr.; veratrum veride, ¼ gr.; mistletoe, ½ gr.; hawthorn tincture, 30 minims; sodium nitrite, 1 gr.	Key Pharmacal Co.
Kie with phenobarbital	Tablet: Phenobarbital, 16 mg.; potassium iodide, 400 mg.; ephedrine sulfate, 24 mg.	Laser Inc.
Kiophyllin	Tablet: Phenobarbital, 15 mg.; aminophyllin, 150 mg.; potassium iodide, 125 mg.	G. D. Searle & Co.
Librax	Capsule: Chlordiazepoxide hydrochloride 5 mg. and clidinium bromide, 2.5 mg.	Roche Laboratories.
Luftodill suspension	Suspension (5 cc.): Phenobarbital, 8 mg.; theophylline, 50 mg.; ephedrine hydrochloride, 12 mg.; glyceryl gualacolate, 100 mg.	Mallinckrodt Chemical Works.
Luftodil tablets	Tablet: Phenobarbital, 16 mg.; theophylline, 100 mg.; ephedrine hydrochloride, 24 mg.; glyceryl gualacolate, 200 mg.	Do.
Lufyllin-EP	Tablet: Phenobarbital, 16 mg.; lufyllin (dyphylline), 100 mg.; ephedrine hydrochloride; 16 mg.	Do.
Magnesium hydroxide-phenobarbital compound	Tablet: Phenobarbital sodium, 15 mg.; magnesium hydroxide, 300 mg.; atropine sulfate with aromatics, 0.12 mg.	McNeil Laboratories, Inc.
Malglyn compound	Tablet or suspension (5 cc.): Phenobarbital, 16.2 mg.; belladonna alkaloids, 0.162 mg.; dihydroxy aluminum aminoacetate, 0.5 gm.	Brayten Pharmaceutical Co.
Manniphen	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The Vale Chemical Co., Inc.
Manniphen with rutin	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.; rutin, 20 mg.	Do.
Mannitol hexanitrate with phenobarbital	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	The Blue Line Co.
Maxitol	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 15 mg.; rutin, 15 mg.; ascorbic acid, 15 mg.	Burt Krone Co.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Menrium 5-2	Tablet: Chlordiazepoxide, 5 mg. and water-soluble esterfied estrogens, 0.2 mg.	Do.
Menrium 5-4	Tablet: Chlordiazepoxide, 5 mg. and water-soluble esterfied estrogens, 0.4 mg.	Do.
Menrium 10-4	Tablet: Chlordiazepoxide, 10 mg. and water-soluble esterfied estrogens, 0.4 mg.	Do.
Meprane phenobarbital	Tablet: Phenobarbital, 16 mg.; promethestrol dipropionate, 1 mg.	Reed & Carnrick.
Mesopin-PB	Tablet or elixir (5 cc.): Phenobarbital, 15 mg.; homatropine methylbromide, 5 mg.	Endo Laboratories Inc.
Metamine with butabarbital	Tablet: Butabarbital, 16.2 mg.; trolnitrate phosphate, 2 mg.	Pfizer Laboratories.
Do	Tablet: Butabarbital, 48.6 mg.; trolnitrate phosphate, 10 mg.	Do.
Mexal	Tablet: Phenobarbital, 16 mg.; mannitol hexanitrate, 32 mg.	The S. E. Massengill Co.
Milprem-200	Tablet: Meprobamate, 200 mg. conjugated estrogens—equine, 0.4 mg.	Wallace Pharmaceuticals.
Milprem-100	Tablet: Meprobamate, 400 mg. conjugated estrogens—equine, 0.4 mg.	Do.
Milpath-200	Tablet: Meprobamate, 200 mg.; tridihexethyl chloride, 25 mg.	Do.
Milpath-100	Tablet: Meprobamate, 400 mg.; tridihexethyl chloride, 25 mg.	Wallace Pharmaceuticals.
Miltrate-10	Tablet: Meprobamate, 200 mg.; pentaerythritol tetranitrate, 10 mg.	Do.
Miltrate-20	Tablet: Meprobamate, 200 mg.; pentaerythritol tetranitrate, 20 mg.	Do.
Monomeb	Tablet: Mephobarbital, 32 mg.; penthienate bromide, 5 mg.	Winthrop Laboratories.
Mudrane	Tablet: Phenobarbital, 21 mg.; potassium iodide, 195 mg.; aminophylline, 130 mg.; ephedrine hydrochloride, 16 mg.	Wm. P. Poythress & Co., Inc.
Mudrane GG elixir	Elixir (5 cc.): Phenobarbital, 5.4 mg.; theophylline 20 mg.; ephedrine hydrochloride, 4 mg.; glyceryl guaiacolate, 26 mg.	Do.
Nactisol	Tablet: Butabarbital sodium, 15 mg.; poldine methylsulfate, 4 mg.	McNeil Laboratories, Inc.
Natrona compound	Tablet: Phenobarbital, 15 mg.; extract hawthorn berries, 30 mg.; extract mistletoe, 15 mg.; sodium nitrite, 60 mg.; sodium bicarbonate, 0.2 gm.	The Zemmer Co.
Neocholan	Tablet: Phenobarbital, 8 mg.; dehydrocholic acid, 250 mg.; bile extract, 15 mg.; homatropine methylbromide, 1.2 mg.	Pitman-Moore.
Nergestic	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.10 mg.; magnesium trisilicate, 0.5 gm.	The S. E. Massengill Co.
Nitrased	Tablet: Secobarbital, 15 mg.; nitroglycerin, 0.4 mg.; pentaerythrityl tetranitrate, 15 mg.	Lemmon Pharmacal Co.
Nophesan tablets	Tablet: Phenobarbital, 8 mg.; acetylsalicylic acid, 300 mg.	P. J. Noyes Co.
Novalene	Tablet: Phenobarbital, 16 mg.; ephedrine sulfate, 24 mg.; potassium iodide, 162 mg.; calcium lactate, 162 mg.	Lemmon Pharmacal Co.
Oxsorbil-PB	Capsule: Phenobarbital, 7.5 mg.; belladonna extract, 7.5 mg.; dehydrochloric acid, 32 mg.; desoxycholic acid, 32 mg.; ox bile extract, 65 mg.; sorbitan mono-oleate, 160 mg.; oleic acid, 180 mg.	Ives Laboratories, Inc.
Paminal elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	The Upjohn Co.
Pamine PB elixir	Elixir (5 cc.): Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pamine PB, half strength	Tablet: Phenobarbital, 8 mg.; methscopolamine bromide, 1.25 mg.	Do.
Pediatric piptal antipyretic	Solution (0.6 cc.): Phenobarbital, 3 mg.; pipenzolate bromide, 5 mg.; acetaminophen, 60 mg.	Lakeside Laboratories, Inc.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Pediatric piptal with phenobarbital	Solution (0.5 cc.): Phenobarbital, 8 mg.; pipensolate bromide, 2 mg.	Do.
Pencetylon	Tablet: Phenobarbital, ¼ gr.; acetylsalicylic acid, 5 gr.	Paul B. Elder Co., Inc.
Pentaerythrityl tetranitrate with phenobarbital	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 10 mg.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Pentratrol with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	North American Pharmacal Co.
Pentraline	Tablet: Butabarbital sodium, 10 mg.; reserpine, 0.05 mg.; pentaerythrityl tetranitrate, 10 mg.	McNeil Laboratories, Inc.
Perbuzem	Tablet: Butabarbital sodium, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	The Zemmer Co.
Peribar L-A No. 1	Tablet: Phenobarbital, 48.6 mg.; pentaerythrityl tetranitrate, 30 mg.	Whittier Laboratories, Inc.
Peritrate with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Warner-Chilcott
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Peritrate with phenobarbital SA	Tablet: Phenobarbital, 45 mg.; pentaerythrityl tetranitrate, 80 mg.	Do.
Phedorine	Tablet: Diallybarbituric acid, 16 mg.; extract stramonium, 8 mg. (alkaloids 0.0015 gr.); ephedrine, 8 mg.; theophyline, 100 mg.	Buffington's Inc.
Phenobarbital and atropine	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/500 gr.	The Blue Line Chemical Co.
Do	----do----	Meyers & Co.
Do	----do----	Paine Drug Co.
Do	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/250 gr.	The Vale Chemical Co., Inc.
Phenobarbital with atropine sulfate	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.06 mg.	The Zemmer Co.
Phenobarbital with atropine sulfate No. 2	Tablet: Phenobarbital, 15 mg.; atropine sulfate, 0.12 mg.	The Zemmer Co.
Phenobarbital and atropine sulfate	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Buffington's Inc.
Phenobarbital and atropine No. 1	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 0.13 mg.	Pitman-Moore.
Phenobarbital and atropine No. 2	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.65 mg.	Do.
Phenobarbital and atropine tablets	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 1/1000 gr.	P. J. Noyes Co.
Do	Tablet: Phenobarbital, 16 mg.; atropine sulfate, 1/500 gr.	Do.
Phenobarbital and atropine tablets No. 2	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Phenobarbital and atropine tablets No. 3	Tablet: Phenobarbital, ½ gr.; atropine sulfate, 1/300 gr.	Do.
Phenobarbital and belladonna	Tablet: Phenobarbital, ¼ gr.; belladonna leaves ½ gr. (total alkaloids 0.0015 gr.).	The Vale Chemical Co., Inc.
Do	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ⅓ gr.	Paine Drug Co.
Do	Tablet: Phenobarbital, 16 mg.; belladonna extract, 8 mg.	Eli Lilly and Co.
Phenobarbital and belladonna No. 2	Tablet: Phenobarbital, ¼ gr.; belladonna extract, ⅛ gr. (alkaloids 0.00156 gr.)	The Upjohn Co.
Phenobarbital with mannitol hexanitrate	Tablet: Phenobarbital, 7.5 mg., mannitol hexanitrate, 15 mg.; ascorbic acid powder, 25 mg.; rutin, 25 mg.	Paul B. Elder Co., Inc. (Harold M. Harter, D. V. M.)
Phenobarbital with mannitol hexanitrate	Tablet: Phenobarbital, ¼ gr.; mannitol hexanitrate, ½ gr.	Meyer Drug & Surgical Supply Co.
Phenobarbital sodium atropine No. 1	Tablet: Phenobarbital sodium, 8 mg.; atropine sulfate, 60 ug.	McNeil Laboratories
Phenobarbital sodium atropine No. 2	Tablet: Phenobarbital sodium, 15 mg.; atropine sulfate, 120 ug.	Do.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Phenobarbital sodium atropine No. 3	Tablet: Phenobarbital sodium, 20 mg.; atropine sulfate, 200 ug.	Do.
Phenobarbital and sodium nitrite	Tablet: Phenobarbital, ¼ gr.; sodium nitrite, 1 gr.	P. J. Noyes Co.
Phenobarbital theocalcin	Tablet: Phenobarbital, 15 mg.; theobromine calcium salicylate, 0.5 gm.	Knoll Pharmaceutical Co.
Phenodonna tablets	Tablet: Phenobarbital, ¼ gr.; tincture belladonna, 6 minims.	Flint Medical & Surgical Supply Co.
Phenodrox	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/500 gr.; magnesium trisilicate, 4 gr.; aluminum hydroxide gel, dried, 4 gr.	North American Pharmacal Inc.
Phyldrox	Tablet: Phenobarbital, 15 mg.; neothylline, 100 mg.; ephedrine sulfate, 25 mg.	Lemmon Pharmacal Co.
Piptal PHB elixir	Elixir (5cc.): Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Lakeside Laboratories, Inc.
Piptal PHB tablets	Tablet: Phenobarbital, 16 mg.; pipenzolate bromide, 5 mg.	Do.
Prantal with phenobarbital	Tablet: Phenobarbital, 16 mg.; diphemanil methylsulfate, 100 mg.	Schering Corp.
Premarin with phenobarbital	Tablet: Phenobarbital 32 mg.; conjugated estrogens-equine, 6.626 mg.	Ayerst Laboratories.
Probanthine with phenobarbital	Tablet: Phenobarbital, 15 mg.; probanthine, 15 mg.	G. D. Searle & Co.
Probital	Tablet: Phenobarbital, 15 mg.; probanthine, 7.5 mg.	Do.
Propenite	Tablet: Phenobarbital sodium, 12 mg.; sodium nitrite, 60 mg.; hawthorn berries extract, 120 mg.; mistletoe extract, 60 mg.	The Zemmer Co.
Prydonnal Spansule	Capsule: Phenobarbital, 65 mg.; belladonna alkaloids, 0.4 mg. (hyoscyamine sulfate, 0.305 mg.; atropine sulfate, 0.06 mg.; scopolamine hydrobromide, 0.035 mg.).	Smith Kline & French Laboratories.
Quadrinal	Tablet: Phenobarbital, 24 mg.; ephedrine hydrochloride, 24 mg; theophylline calcium salicylate, 130 mg.; potassium iodide, 300 mg.	Knoll Pharmaceutical Co.
Do	Suspension (5 cc.): Phenobarbital, 12 mg.; ephedrine hydrochloride, 12 mg.; theophylline calcium salicylate, 65 mg.; potassium iodide, 160 mg.	Do.
Quintrate with nitroglycerin and phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.; nitroglycerine, 0.4 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Quintrate with phenobarbital	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 10 mg.	Paul B. Elder Co., Inc. (Glynn A. Beard).
Do	Tablet: Phenobarbital, 15 mg.; pentaerythrityl tetranitrate, 20 mg.	Do.
Robinul-PH	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 1.0 mg.	A. H. Robins Co., Inc.
Robinul-PH forte	Tablet: Phenobarbital, 16.2 mg.; glycopyrrolate, 2.0 mg.	Do.
Ruhexatal	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; ascorbic acid, 10 mg; rutin, 20 mg.	Lemmon Pharmacal Co.
Rutol	Tablet: Phenobarbital, 8.0 mg.; mannitol hexanitrate, 16 mg.; rutin, 10 mg.	Pitman-Moore.
Salisil with phenobarbital	Tablet: Phenobarbital, ½ gr.; acetylsalicylic acid, 5 gr.; magnesium trisilicate, 2 gr.	Paul B. Elder Co., Inc.
Selbella	Tablet: Phenobarbital, ½ gr.; aluminum hydroxide, 5 gr.; belladonna extract, ⅛ gr.	Wyeth Laboratories.
Sed-Tens	Tablet (12 hr.): Amobarbital, 50 mg.; homatropine methylbromide, 7.5 mg.	Lemmon Pharmacal Co.
Sibena	Tablet: Butabarbital sodium, 16 mg.; simethicone, 25 mg.; belladonna extract, 16 mg. (total alkaloids, 0.20 mg.).	Plough Laboratories, Inc.
Sodium nitrite with phenobarbital	Tablet: Phenobarbital sodium, ¼ gr.; sodium nitrite, 1 gr.; sodium bicarbonate, 2 gr.; hawthorn berries, fluid extract, ¼ minim.	Paine Drug Co.
Do	Tablet: Phenobarbital, ½ gr.; sodium nitrite, 1 gr.	Buffalo Pharmaceutical Supply Corp.
Spasticol PB	Tablet: Phenobarbital, 15 mg.; homatropine methylbromide, 2.5 mg.	Key Pharmaceuticals, Inc.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Spastosed	Tablet: Phenobarbital, 8 mg.; atropine sulfate, 0.13 mg.; calcium carbonate, 227 mg.; magnesium hydroxide, 162 mg.	North American Pharmacal, Inc.
Synirin	Tablet: Pentobarbital, 8 mg.; aspirin, 324 mg.	Wm. P. Poythress & Co., Inc.
TCS	Tablet: Phenobarbital, 16 mg.; theobromine salicylate, 0.4 gm.; calcium salicylate, 0.06 gm.	Do.
Tedral-25	Tablet: Butabarbital, 25 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral S.A.	Tablet: Phenobarbital, 25 mg.; theophylline, 150 mg.; ephedrine hydrochloride, 48 mg.	Warner-Chilcott Laboratories.
Tensodin	Tablet: Phenobarbital, 15 mg.; ethaverine hydrochloride, 30 mg.; theophylline calcium salicylate, 200 mg.	Knoll Pharmaceutical Co.
Tensophen	Tablet: Phenobarbital, 16 mg.; nitroglycerin, 0.26 mg.; sodium nitrite, 32 mg.; podophyllin, 1 mg.; extract beef bile, 16 mg.	P. J. Noyes Co.
Thedrizem	Tablet: Phenobarbital, 8 mg.; theophylline, hydrous, 100 mg.; ephedrine hydrocloride, 25 mg.	The Zemmer Co.
Theobarb	Tablet: Phenobarbital, 32 mg.; theobromine, 325 mg.	Mallinckrodt Chemical Works.
Theobarb-R	Tablet: Phenobarbital, 10 mg.; reserpine, 0.1 mg.; theobromine, 324 mg.	Do.
Theobarb special	Tablet: Phenobarbital, 16 mg.; theobromine, 325 mg.	Do.
Theobromine and phenobarbital	Tablet: Phenobarbital, 16 mg.; theobromine, 0.3 gm.	P. J. Noyes Co.
Theobromine-phenobarbital	Tablet: Phenobarbital, 30 mg.; theobromine, 0.3 gm.	The S. E. Massengill Co.
Do	Tablet: Phenobarbital, 32 mg.; theobromine, 324 mg.	The Upjohn Co.
Theobromine-phenobarbital compound	Tablet: Phenobarbital, ¼ gr.; theobromine, 2½ gr.; potassium iodide, 2½ gr.; potassium bicarbonate, 2 gr.	Do.
Theobromine with phenobarbital No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 324 mg.	Buffington's, Inc.
Theobromine and sodium acetate with phenobarbital	Tablet: Phenobarbital, ¼ gr.; theobromine and sodium acetate, 3 gr.	Paul B. Elder Co., Inc.
Theobromine sodium salicylate with phenobarbital	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 300 mg.	The Zemmer Co.
Theocardone No. 1	Tablet: Phenobarbital, 15 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theocardone No. 2	Tablet: Phenobarbital, 30 mg.; theobromine, 300 mg.	Haack Laboratories, Inc.
Theodide	Tablet: Phenobarbital, ¼ gr.; potassium iodide, 2½ gr.; theobromine sodium salicylate, 2½ gr.	The Vale Chemical Co., Inc.
Theoglycinate with phenobarbital	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.	Brayten Pharmaceutical Co.
Theoglycinate with racephedrine and phenobarbital	Tablet: Phenobarbital, 16 mg.; theophylline-sodium glycinate, 324 mg.; racephedrine hydrochloride, 24 mg.	Brayten Pharmaceutical Co.
Theoplaphen	Tablet: Phenobarbital, 15 mg.; theobromine sodium salicylate, 0.2 gm.; calcium lactate, 0.1 mg.	The S. E. Massengill Co.
Theominal	Tablet: Phenobarbital, 32 mg.; theobromine, 320 mg.	Winthrop Laboratories.
Theominal M	Tablet: Phenobarbital, 16 mg.; theobromine, 320 mg.	Do.
Theominal R S	Tablet: Phenobarbital, 10 mg.; theobromine, 320 mg.; alseroxylon, 1.5 mg.	Do.
Theophen	Tablet: Phenobarbital, ¼ gr.; theobromine sodium salicylate, 5 gr.; calcium carbonate, 2½ gr.	The Vale Chemical Co., Inc.
Theorate	Tablet: Phenobarbital, 16.2 mg.; theobromine, 324 mg.	Whittier Laboratories, Inc.
Thymodyne	Tablet: Phenobarbital, 32 mg.; theophylline anhydrous, 130 mg.; ephedrine sulfate, 24 mg.	P. J. Noyes Co.
Trocinate with phenobarbital	Tablet: Phenobarbital, 16 mg.; thiphenamil hydrochloride, 100 mg.	Wm. P. Poythress & Co., Inc.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Tricoloid	Tablet: Phenobarbital, 16 mg.; tricyclamol chloride, 50 mg.	Burroughs Wellcome & Co.
Triophen	Tablet: Phenobarbital, ⅛ gr.; atropine sulfate, 1/500 gr.; magnesium trisilicate, 7 gr.	The Vale Chemical Co., Inc.
Valpin-PB	Tablet or elixir (5 cc.): Phenobarbital, 8 mg.; anisotropine methylbromide, 10 mg.	Endo Laboratories, Inc.
Vasorutin	Tablet: Diallylbarbituric acid, ¼ gr.; nitroglycerine, 1/250 gr.; sodium nitrite, 1 gr.; tincture crataegus, 2 minims; rutin, 20 mg.	Buffington's, Inc.
Veralzem	Tablet: Phenobarbital, 15 mg.; veratrum viride, 50 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Veratrite	Tablet: Phenobarbital, ¼ gr.; cryptenamine, 40 CSR (carotid sinus reflex) units; sodium nitrite, 1 gr.	Neisler Laboratories, Inc.
Veritag	Tablet: Phenobarbital, 16 mg.; veratrum viride, 40 mg.; sodium nitrite, 65 mg.	S. J. Tutag and Co.
Vertegus	Tablet: Phenobarbital, ¼ gr.; veratrum viride, ¾ gr.; sodium nitrite, 1 gr.; mistletoe, ½ gr.; hawthorn berries, ½ gr.	Burt Frone Co.
Veruphen	Tablet: Phenobarbital, 15 mg.; rutin, 20 mg.; veratrum viride, 15 mg.; sodium nitrite, 60 mg.	The Zemmer Co.
Viritin	Tablet: Phenobarbital, 15 mg.; mannitol hexanitrate, 30 mg.; veratrum viride alkaloids, 1.5 mg.; rutin, 20 mg.	Lemmon Pharmacal Co.
W-T	Powder (4 gm.): Phenobarbital, 15 mg.; belladonna extract, 10 mg. (0.12 mg. belladonna alkaloids); benzocaine, 15 mg.; calcium carbonate, 1.55 gm.; magnesium oxide, 0.5 gm.; aluminum hydroxide gel, dried, 60 mg.	Warren-Teed Pharmaceuticals, Inc.
W-T	Tablet: Phenobarbital, 1/16 gr.; belladonna extract, 1/24 gr.; benzocaine, 1/16 gr.; calcium carbonate, 6 gr.; magnesium trisilicate, 3¾ gr.; aluminum hydroxide gel, dried, 2½ gr.; chlorophyll extract, 1⅔.	Do.
Xaniophen	Tablet: Phenobarbital, 16.2 mg.; theobromine, 162 mg.; ethylenediamine dihydriodide, 32.4 mg.	Pitman-Moore.
Zallogen compound	Tablet: Phenobarbital, 8 mg.; tocamphyl, 75 mg.; homatropine methylbromide, 2.5 mg.	The S. E. Massengill Co.
Zantrate	Tablet: Cyclopentenylallybarbituric acid, ½ gr.; ephedrine sulfate, ⅜ gr.; theophylline anhydrous, 2 gr.	The Upjohn Co.
Zem-Dab	Tablet: Butabarbital sodium, 10 mg.; dehydrocholic acid, 60 mg.; ox bile desiccated, 120 mg.; homatropine methylbromide, 2.5 mg.	The Zemmer Co.
No. 23	Tablet: Phenobarbital, ½ gr.; aminophylline, 3 gr.	Stayner Corp.
No. 35	Tablet: Phenobarbital, ⅛ gr.; aminophylline, 1.5 gr.; ephedrine sulfate, ⅜ gr.	Do.
No. 36	Tablet: Pentabarbital sodium, ¾ gr.; ephedrine sulfate, ⅜ gr.; aminophylline, 3 gr.	Do.
No. 65	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 66	Tablet: Phenobarbital, ¼ gr.; extract belladonna, ¼ gr.	Do.
No. 75	Tablet: Phenobarbital, ¼ gr.; belladonna, ⅛ gr.	Bariatric Corp.
No. 88	Tablet: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 89	Tablet: Phenobarbital, ½ gr.; aminophylline, 1.5 gr.	Stayner Corp.
No. 111	Tablet: Phenobarbital, ½ gr.; ephedrine sulfate, ⅜ gr.	Do.
No. 136	Tablet: Phenobarbital, 20 mg.; homatropine methylbromide, 5 mg.	Do.
No. 643	Tablet: Phenobarbital, ¼ gr.; theophylline, 2 gr.; ephedrine hydrochloride, ⅜ gr.	Do.
Rx. No. 4104	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 7½ gr.; magnesium oxide, 4 gr.; atropine sulfate, 1/300 gr.	The Zemmer Co.
Rx. No. 4105	Tablet: Phenobarbital, ¼ gr.; calcium carbonate, 10 gr.; atropine sulfate, 1/300 gr.	Do.

EXCEPTED PRESCRIPTION DRUGS—Continued

Trade name or other designation	Composition	Manufacturer or supplier
Rx. No. 4108	Capsule: Phenobarbital, ¼ gr.; atropine sulfate, 1/300 gr.; calcium carbonate, 6½ gr.; magnesium oxide, heavy, 2 gr.	Do.
Rx. No. 4123	Capsule: Phenobarbital, ¼ gr.; bismuth subgalate, 5 gr.; extract belladonna, ⅛ gr.	Do.
Rx. No. 4126	Capsule: Pentobarbital sodium, 15 mg.; extract belladonna, 10 mg.	Do.
Rx. No. 4143	Capsule: Phenobarbital, ¼ gr.; aminophylline, 1.5 gr.; potassium iodide, 1 gr.	Do.
Rx. No. 4152	Tablet: Phenobarbital, ¼ gr.; atropine sulfate, 1/200 gr.	Do.
Rx. No. 4155	Tablet: Phenobarbital, ⅙ gr.; atropine sulfate, 1/1000 gr.; aluminum hydroxide gel, 3¾ gr.; kaolin, 3¾ gr.	Do.
Rx. No. 4170	Tablet: Phenobarbital, ⅓ gr.; atropine sulfate, 1/200 gr.; calcium carbonate, 10 gr.	Do.
Rx. No. 4184	Capsule: Sodium butabarbital, 15 mg.; belladonna extract, 15 mg.	Do.

(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.

EXCLUDED OVER-THE-COUNTER DRUGS

Trade name or other designation	Composition	Manufacturer or supplier
Amodrine	Tablet: Phenobarbital, 8 mg.; aminophylline, 100 mg.; racephedrine hydrochloride, 25 mg.	G. D. Searle & Co.
Bronkolixir	Elixir (5 cc.): Phenobarbital, 4 mg.; ephedrine sulfate, 12 mg.; glyceryl guaiacolate, 50 mg.; theophylline, 15 mg.	Breon Laboratories, Inc.
Bronkotabs	Tablet: Phenobarbital, 8 mg.; ephedrine sulfate, 24 mg.; glyceryl guaiacolate, 100 mg.; theophylline, 100 mg.	Do.
Primatene	Tablet: Phenobarbital, ⅛ gr.; ephedrine, ⅜ gr.	Whitehall Laboratories.
Rynal	Solution for Spray: dl-Desoxyephedrine HCL 0.22%; antipyrine 0.28%; pyrilamine maleate 0.01%; methyl dodecylbenzyltrimethyl ammonium chloride 0.02%; glycerine dehydrate 1.50%.	Blaine Co.
Tedral	Tablet: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Warner-Chilcott Laboratories.
Tedral Anti-H	Tablet: Phenobarbital, 8 mg.; chlorpheniramine maleate, 2 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Tedral one-half strength	Tablet: Phenobarbital, 4 mg.; theophylline, 65 mg.; ephedrine hydrochloride, 12 mg.	Do.
Tedral Pediatric Suspension	Suspension (5 cc.): Phenobarbital, 4 mg.; ephedrine hydrochloride, 12 mg.; theophylline, 65 mg.	Do.
Tedral suppositories double strength	Suppository: Phenobarbital, 16 mg.; theophylline 260 mg.; ephedrine hydrochloride, 48 mg.	Do.
Tedral suppositories regular strength	Suppository: Phenobarbital, 8 mg.; theophylline, 130 mg.; ephedrine hydrochloride, 24 mg.	Do.
Verequad	Tablet: Phenobarbital, 8 mg.; theophylline calcium salicylate, 130 mg.; ephedrine hydrochloride, 24 mg.; glyceryl guaiacolate, 100 mg.	Knoll Pharmaceutical Co.
Verequad	Suspension (5 cc.): Phenobarbital, 4 mg.; theophylline calcium salicylate, 65 mg.; ephedrine hydrochloride, 12 mg.; glyceryl guaiacolate, 50 mg.	Do.

(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.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Abbott Laboratories	CEP Agarose Plates, NDC 0074-9023-12, NDC 0074-9023-35.	Foil Pouch: 4½ by 4 inches, 6½ by 5¼ inches.	Mar. 24, 1975
	Barbital-Acetate Buffer Powder with 1 g Sodium Azide, NDC 0074-7591-12.	Plastic Bag: 16.24 g per bag.	Do.
Do	Digoxin I 125 Imusay • diagnostic kit No. 7649.	Kit: 100 units	June 6, 1974
Do	HTSH RIA diagnostic kit No. 7504	Kit: 50 units	Sept. 25, 1974
Do	Tetrasorb-125 T-4 diagnostic kit No. 7775.	Vial: 11 ml	Aug. 21, 1972
Do	Irosorb-59 diagnostic kit No. 6764	Vial: 10 ml	Do.
Do	Quantisorb T-4N diagnostic kit No. 6719.	Vial: 11 ml	Do.
Airwick Industries	Airkem Solidaire Green	Tube: 7 oz. and 14 oz.	Dec. 5, 1973
Do	Airkem Solidaire Gold	Do	Do.
Do	Airwick Solidaire Citrus	Do	Do.
Do	Airkem Musketeer, Jr.	Can: 5 oz.	Do.
Do	Airwick Solid Natural	Do	Do.
Do	Airwick Solid Floral	Do	Do.
Do	Airwick Solid Lemon	Do	Do.
Do	Airwick Solid Rose	Do	Do.
American Hospital Supply Corp. (Dade Division).	Buffered Thrombin (Bovine), Catalog No. B4233-40, Euglobulin Lysis Set	Bottle: 2 ml	Apr. 10, 1973
Do	Fibrin Monomer Control, Catalog Nos. B4233-30 and B4233-38.	Bottle: 1.5 ml	Feb. 16, 1973

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Moni-Trol I-X Chemistry Controls (Level I), Catalog Nos.:		
	B5106-1	Vial: 5 ml	Jan. 20, 1975
	B5106-5	Vial: 10 ml.	
	B5106-3	Bottle: 25 ml.	
Do	Moni-Trol II-X Chemistry Controls (Level II) Catalog Nos.:		
	B5106-2	Vial: 5 ml	Do.
	B5106-6	Vial: 10 ml	
	B5106-4	Bottle: 25 ml.	
Do	Owren's veronal buffer No. B4234-25	Bottle: 15 ml	Jan. 22, 1973
Do	Phosphatase substrate No. B5312-1 and No. B5312-5.	Bottle: 73 mg. dry powder.	Do.
Do	Serum reagent No. B4233-1 and No. B4233-2.	Bottle: 2 ml	Do.
Do	Thrombin reagent (bovine) No. B4233-15.	Bottle: 1 ml	Do.
Do	DATA-topem T 125 4. Buffered I thyroxine, catalog No. B5644-21.	Bottle: 55 ml	June 11, 1975
Do	DATA-topem T 125 4. Buffered I thyroxine, catalog No. B5644-25.	Bottle: 255 ml	Do.
Do	DATA-topem T 125 4. Buffered I thyroxine, catalog No. B5644-29.	Bottle: 505 ml	Do.
Do	DATA-topem CT 125 4. Buffered I thyroxine, catalog No. B5644-40.	Bottle: 55 ml	Do.
Do	DATA-topem CT 125 4. Buffered I thyroxine, catalog No. B5644-45.	Bottle: 255 ml	Do.
Do	DATA-topem T 125 4. Buffered I thyroxine, catalog No. B5644-35.	Bottle: 506 ml	Do.
American Hospital Supply Corp. (Harleco Division).	Barbital buffer B-1 No. 96772	Vial: 12.12 grams per 7 dram vial.	Sept. 15, 1971
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 938-34.	Vial: 36.36 grams	Do.
Do	Barbital-sodium buffer salt, No. 11731.	Bottle: 250 ml	June 6, 1972
Do	Barbital-acid buffer salt, No. 1173	Bottle: 250 ml	Do.
Do	Buffer salt mixture Spinco B-1, pH 8.6, 0.05 ionic strength, No. 3947.	Vial: 12.12 grams per 29.5 x 80 mm. vial.	Sept. 15, 1971
Do	Buffer salt mixture Spinco B-2, pH 8.6, 0.075 ionic strength, No. 3948.	Vial: 18.18 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer for serum protein electrophoresis No. 96099.	Vial: 10 dram	July 25, 1973
Do	Clinicard, pseudo-cholinesterase, catalog No. 32307.	Clinicard cuvette containing a powder to be reconstituted by adding 3 ml water.	May 31, 1973
American Monitor Corp.	Qualify I	Glass vial: 10 ml	Oct. 9, 1975
Do	Qualify II	Do	Do.
Amersham/Searle	Amobarbital-2-C14, No. CFA-401.	Ampule: 110 mm. x 13 mm. or Vial: 38.40 mm. x 11 ml.	Sept. 19, 1972
Do	HPL Immunoassay Kit No. IM-63.	Bottle: 30 ml	May 18, 1973
Do	Morphine (N-methyl-C14) Hydrochloride No. CFA-363.	Do	Mar. 27, 1972
American/Searle	Pentothal—S35 sodium salt, No. SJ-77.	Ampule: 110 mm. x 13 mm. or Vial: 38.40 mm. x 11 mm.	Sept. 19, 1972
Do	Codeine (N-methyl-C14) Hydrochloride No. CFA-421.	Ampule: 10 cc.	Mar. 27, 1972

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	d-(side chain ^{3}H) Amphetamine Sulfate Number TRK-444.	Ampoule: 5 ml	Sept. 20, 1973
Do	Lysergic acid di[1—^{14}C] ethylamide, catalog No. C.F.A. 534.	Ampoule: 0.6 mg. to 8.1 mg.	July 2, 1974
Do	T-3 RIA Kit Catalog No. IM. 74	Kit	Nov. 4, 1974
Do	Pheno [2—^{14}C] barbital Catalog No. C.F.A. 537.	Ampoule: 50 microcuries.	Nov. 5, 1974
Do	Do	Ampoule: 250 microcuries.	Do.
Do	[15, 16(n)—^{3}H] Etorphine, Catalog No. T.R.K. 476.	Ampoule: 250 microcuries.	Nov. 19, 1974
Do	[2(n)—^{3}H] Lysergic acid diethylamide, No. T.R.K. 461.	Ampoule: 0.003 mg. to 0.04 mg.	May 22, 1974
Do	[15, 16(n)—^{3}H] Etorphine Catalog No. T.R.K. 476.	Ampoule: 1 millicurie	Feb. 17, 1975
Do	(—)Δ^{1}—Tetrahydro [3', 5'—^{14}C] Cannabinol Catalog No. C.F.A. 538.	Ampoule: 10 and 50 microcuries.	Mar. 5, 1975
Do	d-[methylene ^{14}C] Amphetamine Sulphate, catalog No. C.F.A. 544.	Ampoule: 110 x 13 mm.	June 11, 1975
Do	T-4 RIA Kit, catalog No. IM 80.	Kit containing: 50 tests.	Nov. 25, 1975
Do	T-4 RIA Kit, catalog No. IM 801.	Kit containing: 100 tests.	Do.
Do	T-4 RIA Kit, catalog No. IM 801A.	Do	Do.
Amersham/Searle Corp.	Δ1-[G—^{3}H] Tetrahydrocannabinol, No. T.R.K. 446.	Ampoule: 0.005 mg. to 0.06 mg.	Feb. 26, 1974
Do	[1(n)—^{3}H] Morphine, No. T.R.K. 447.	Ampoule: 0.002 mg. to 0.015 mg.	Do.
Do	[1(n)—^{3}H] Codeine, No. T.R.K. 448.	Do	Do.
Do	Diacetyl [1(n)—^{3}H] morphine, No. T.R.K. 449.	Ampoule: 0.003 mg. to 0.012 mg.	Do.
Do	[1,7,8(n)—^{3}H] Dihydromorphine, No. T.R.K. 450.	Ampoule: 0.0008 mg. to 0.008 mg.	Do.
Analytical Chemists, Inc.	Sodium Barbital Buffer, Catalog Nos. 1-5100 and 1-5200.	Vial: 20.6 g	Aug. 14, 1972
Do	Agarose Universal Electrophoresis Film, Catalog No. 1-1000.	Plate: 5 ml	Do.
Analytical Systems	Toxi-Disc™ A, 121, A-1; 122, A-2; 124, A-4.	Disc: ⅛ in x 0.2 mm	May 6, 1975
Do	Toxi-Disc™ B, 125, B-1; 126, B-2; 127, B-3; 128, B-4.	Do	Do.
Applied Sciences Laboratories, Inc.	Mixture 1—opiates	Vial: 1 ml	Oct. 4, 1972
Do	Mixture 2—stimulants	Do	Do.
Do	Mixture 3—depressants	Do	Do.
Do	Mixture 4—barbiturates	Do	Do.
Do	Mixture 5—kit of representatives	Do	Do.
Do	Opiates, Mixture 1 Number 01830	Vial: 10 ml	Oct. 4, 1973
Do	Stimulants, Mixture 2 Number 01831.	Do	Do.
Do	Depressants, Mixture 3 Number 01832.	Do	Do.
Do	Barbiturates, Mixture 4 Number 01833.	Do	Do.
Do	Allylisobutylbarbituric acid, No. 01742.	Vial: 1 ml	Jan. 24, 1973
Do	Alphenal, No. 01743	Do	Do.
Do	Amobarbital, No. 01744	Do	Do.
Do	Amphetamine HCL, No. 01745	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Aprobarbital, No. 01746	Do	Do.
Do	Barbital, No. 01747	Do	Do.
Do	Butabarbital, No. 01748	Do	Do.
Do	Butethal, No. 01749	Do	Do.
Do	Cocaine, No. 01750	Do	Do.
Do	Codeine, No. 01751	Do	Do.
Do	Diallybarbituric acid, No. 01752	Do	Do.
Do	Ethchlorvynol, No. 01753	Do	Do.
Do	Ethinamate, No. 01754	Do	Do.
Do	Ethylmorphine HCL, No. 01755	Do	Do.
Do	Glutethimide, No. 01756	Do	Do.
Do	Hexobarbital, No. 01757	Do	Do.
Do	Hydrocodone Bitartrate, No. 01758	Do	Do.
Do	Meperidine HCL, No. 01759	Do	Do.
Do	Mephobarbital, No. 01760	Do	Do.
Do	Meprobamate, No. 01761	Do	Do.
Do	Mescaline, No. 01762	Do	Do.
Do	Methadone HCL, No. 01763	Do	Do.
Do	Methamphetamine HCL, No. 01764	Do	Do.
Do	Methylphenidate, No. 01774	Do	Do.
Do	Morphine, No. 01765	Do	Do.
Do	Nalorphine, No. 01766	Do	Do.
Do	Pentobarbital, No. 01767	Do	Do.
Do	Phenazocine H Br, No. 01768	Do	Do.
Applied Sciences Laboratories, Inc.	Phencyclidine HCL, No. 01769	Vial: 1 ml.	Jan. 24, 1973
Do	Phenobarbital, No. 01770	Do	Do.
Do	Secobarbital, No. 01771	Do	Do.
Do	Thebaine, No. 01772	Do	Do.
Do	Thiamylal, No. 01773	Do	Do.
Beckman Instruments, Inc. (Spinco Division)	ASO buffer, pH 7.2	Tube: 2.7 grams	Aug. 31, 1973
Do	Beckman buffer B-1	Packet: 12.14 gm	Apr. 24, 1971
Do	Beckman buffer B-2	Packet: 18.16 gm	Do.
Beckman Instruments, Inc. (diagnostic operations)	Human thyroid stimulating hormone kit, single label:	Kit, containing:	Nov. 26, 1974
	No. 566185	10 tests	
	No. 566186	25 tests	
	No. 566187	50 tests	
	No. 566188	100 tests	
Do	Human thyroid stimulating hormone kit, double label:	Kit, containing:	Do.
	No. 566173	10 tests	
	No. 566174	25 tests	
	No. 566175	50 tests	
	No. 566176	100 tests	
Do	Triiodothyronine kit, single label:	Kit, containing:	Do.
	No. 566177	10 tests	
	No. 566178	25 tests	
	No. 566179	50 tests	
Do	Triiodothyronine kit, double label:	Kit, containing:	Do.
	No. 566181	10 tests	
	No. 566182	25 tests	
	No. 566183	50 tests	
Do	Thyroxine kit, single label:	Kit, containing:	Do.
	No. 566165	10 tests	
	No. 566166	25 tests	
	No. 566167	50 tests	
Do	Thyroxine kit, double label:	Kit, containing:	Do.
	No. 566169	10 tests	
	No. 566170	25 tests	
	No. 566171	50 tests	
Do	Digoxin kit, single label:	Kit, containing:	Do.
	No. 566157	10 tests	
	No. 566158	25 tests	
Do	Digoxin kit, double label:	Kit, containing:	Do.
	No. 566161	10 tests	
	No. 566162	25 tests	

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Becton, Dickinson and Co. (Spectra Biologicals Division)	HepaScreen CEP barbital buffer, No. K-751.	Envelope: 3.5" x 5.5"	Aug. 11, 1972
Do	HepaScreen CEP plates, Nos. K-742 and K-743.	Plate: 3.5" x 3.6"	Do.
Behring Diagnostics, American Hoechst Corp.	Immuno-tecR II Agarose Plates	Foil pouch: 5.35 by 5.25 in.	Jan. 16, 1976
Do	IEP Buffer pH 8.2	Foil pouch: 5.35 by 5.25 in., 65 g	Do.
Biomedical Products Corp.	Barbiturate stock standard, 3-1303	Bottle: 100 ml	Apr. 18, 1975
Do	Mayer's hematoxylin solution, 6-1192.	Bottle: 100 ml, 500 ml, 1,000 ml., 1 gal.	Do.
Bio-Rad Laboratories, Inc.	Bio-Rad electrophoresis buffer	Bottle: 500 ml.	Dec. 14, 1972
Bio-Rad Laboratories	Barbital Buffer-Dry Pack	Package: 9.11 gm.	May 9, 1974
Do	Do	Package: 18.21 gm.	Do.
Do	Do	Package: 12.14 gm.	Do.
Do	Electrophoresis buffer, dry-pack	Package: 6.15 gm.	Dec. 14, 1972
Do	Reagent No. 3	Bottle: 165 cc.	Do.
Do	Immunoelectrophoresis Barbital Buffer I, pH 8.6.	Dry-pack: 25.6 gm.	Aug. 6, 1975
Do	Immunoelectrophoresis Barbital Buffer II, pH 8.6.	Dry-pack: 15.61 gm.	Do.
Do	Immunoelectrophoresis Barbital Buffer III-a, pH 8.8.	Dry-pack: 15.07 gm.	Do.
Bio-Reagents & Diagnostics, Inc.	Prochex No. 700-225	Vial: 25 ml.	Mar. 9, 1973
Do	Prochex No. 1, No. 701-025	Do	Do.
Do	Prochex No. 1 (Alternate Formula) No. 702-025.	Do	Do.
Do	Prochex No. 2, No. 703-025	Do	Do.
Do	Prochex No. 3, No. 704-025	Do	Do.
Do	Prochex No. 4, No. 705-025	Do	Do.
Do	Prochex No. 5, No. 706-025	Do	Do.
Do	Prochex No. 6, No. 707-025	Do	Do.
Do	Prochex No. 7, No. 708-025	Do	Do.
Do	Prochex No. 8, No. 709-025	Do	Do.
Do	Prochex No. 9, No. 710-025	Do	Do.
Do	Prochex No. 10, No. 711-025	Do	Do.
Do	Prochex No. 10 (Alternate Formula) No. 712-025)	Do	Do.
Bio-Reagents & Diagnostics, Inc.	Prochex No. 11, No. 713-025	Vial: 25 ml.	Mar. 9, 1973
Do	Prochex No. 12, No. 714-025	Do	Do.
Do	Prochex No. 13, No. 715-025	Do	Do.
Do	Prochex No. 14, No. 716-025	Do	Do.
Do	Prochex No. 15, No. 717-025	Do	Do.
Do	Prochex No. 15, (Alternate Formula) No. 718-025	Do	Do.
Do	Prochex No. 16, No. 719-025	Do	Do.
Do	Prochex No. 18, No. 721-025	Do	Do.
Do	Prochex No. 19, No. 722-025	Do	Do.
Do	Prochex No. 20, No. 723-025	Do	Do.
Do	Toxicology control urine-dried No. 6716-25.	Bottle: 25 ml.	June 25, 1973
Do	Toxicology control serum-dried No. 6726-10.	Bottle: 10 ml.	Do.
Do	Toxicology urine proficiency control-dried No. 6736-25.	Bottle: 25 ml.	Do.
Do	Urine Control II No. 695-425	Bottle: 25 ml.	June 2, 1975
Brinkmann Instruments, Inc.	Brinkmann Drug-Skreen Drug standard—set I, No. 3505000-1.	Vial: 2 ml.	Aug. 14, 1973
Do	Brinkmann Drug-Skreen Drug standard—set II, No. 3505010-8.	Do	Do.
Buchler Instruments	Buffer salt-type I, barbital-sodium, barbital mixture pH 8.6 No. 3-1035.	Vial: 36.36 gm.	Dec. 6, 1972
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 93834.	Vial: 36.36 grams	Sept. 15, 1971

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Burroughs Wellcome Co.	Lanoxitest beta digoxin radioimmunoassay kit with tritiated digoxin No. KT07.	Bottle: 125 ml.	Nov. 16, 1972
California Bionuclear Corp.	Amobarbital-2-C-14, catalog No. 72077.	Screw cap vial: 50 uCi, 0.1, 0.5, and 1 mCi.	Jan. 8, 1975
Do	D-Amphetamine (propyl-1-C-14) sulfate, catalog No. 72078.	Do	Do.
Do	DL-Amphetamine (propyl-1-C-14) sulfate, catalog No. 72079.	Do	Do.
Do	Cocaine (methoxy-C-14) catalog No. 72182.	Do	Do.
Do	Meperidine (N-methyl-C-14) hydrochloride, catalog No. 72508.	Do	Do.
Do	Mescaline (aminomethylene-C-14) hydrochloride, catalog No. 72512.	Do	Do.
Do	Methadone (heptanone-2-C-14) hydrochloride, catalog No. 72516.	Do	Do.
Do	Methamphetamine (propyl-1-C-14) sulfate, catalog No. 72517.	Do	Do.
Do	Methyl phenidate (carbonyl-C-14) hydrochloride, catalog No. 72550.	Do	Do.
Do	Morphine (n-methyl-C-14) hydrochloride, catalog No. 72560.	Do	Do.
Do	Pentobarbital-2-C-14, catalog No. 72618.	Do	Do.
Do	Secobarbital-2-C-14, catalog No. 72675.	Ampoule: 50 uCi, 0.1, 0.5, and 1 mCi.	Do.
Chemed Corp. (Dearborn Chemical Division)	Zinc reagent No. 2, No. 704	Pillow: 10 mg. each	June 23, 1971
Collaborative Research, Inc.	Kit to include: LSD antiserum No. Z-20; I-125-LSD-Polymer No. Z-11; LSD standard.	Bottle: 1 and 2 dram	Nov. 14, 1972
Clarkson Laboratory and Supply, Inc.	Hematoxylin stain, Mayer's No. S-1302.	Gallon	Dec. 12, 1972
Collaborative Research, Inc.	Radioimmunoassay of Tetrahydrocannabinol.	Kit containing: Δ^9-THC antiserum ^{3}H—Δ^9-THC antigen Assay buffer Dextran coated charcoal ^{14}C Δ^9-THC standard Normal rabbit serum	Jan. 5, 1976
Do	^{3}H Δ^9-THC Antigen	Vial: 1 ml.	Do.
Do	^{14}C HΔ^9-THC Standard	Do	Do.
Cordis Laboratories	Barbital-acetate buffer, powder 709-317.	Package: 20 envelopes—10.65 grams per envelope.	July 27, 1972
Do	CEP V No. 709-308	Plate: 80 mm. x 100 mm. x 2.2 mm.	Aug. 9, 1973
Do	CEP V No. 709-328	Plate: 40 mm. x 80 mm. x 2.5 mm.	Do.
Do	CEP VII No. 709-323	Do	Do.
Do	CEP V No. 709-338	Plate: 40 mm. x 80 mm. x 2.5 mm..	Do.
Do	CEP VI No. 709-309	Plate: 80 mm. x 100 mm. x 2.2 mm.	Do.
Cordis Laboratories	CEP VI No. 709-329	Plate: 40 mm. x 80 mm. x 2.5 mm.	Aug. 9, 1973
Do	CEP VI No. 709-339	Do	Do.
Do	CEP plate-amebiasis testing 10 test No. 730-271.	Plate: 40 mm. x 80 mm. x 2.5 mm.	Do.
Do	CEP plate-amebiasis testing 40 test No. 730-274.	Do	Do.
Do	Counterelectrophoresis, plates CEP I 709-304.	Package: 5 plates—18 ml. per plate.	Do.
Do	Counterelectrophoresis, plates CEP II 709-305.	Do	Do.
Do	Counterelectrophoresis, plates CEP III 709-306.	Do	Do.
Do	Counterelectrophoresis, plates CEP IV 709-307.	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Counterelectrophoresis, plates CEP I 709-324.	Package: 10 plates—8.5 ml. per plate.	Do.
Do	Counterelectrophoresis, plates CEP II 709-325.	Do	Do.
Do	Counterelectrophoresis, plates CEP III 709-326.	Do	Do.
Do	Counterelectrophoresis, plates CEP IV 709-327.	Do	Do.
Do	Counterelectrophoresis (CEP) Plates for Trichinosis Testing.	Plastic Plates: 40 mm x 80 mm x 2.5 mm.	June 16, 1975
Do	GVB^{++} buffer, 753-087	Bottle: 50 ml.	Aug. 9, 1973
Do	Glucose—GVB^{++} buffer, 753-036	Do	Do.
Do	EDTA (0.014AM)—GVB buffer, 753-034.	Bottle: 5 ml.	Do.
Do	EDTA (0.01M)—GVB buffer, 753-031.	Do	Do.
Do	5X Isotonic veronal buffer	Bottle: 1,000 ml.	Do.
Curtis Nuclear Corp.	FeRRONEX Kit No. 00250	Vial: 8 ml.	Sept. 19, 1973
Diagnostics, Inc.	DiAgAu Buffer, No. 65	Bottle: 1 gal.	May 7, 1973
Do	DiAgAu Plates, No. 50	Plate: 16 ml.	Do.
Do	DiAgAu Plates, No. 55	Do	Do.
Diagnostic Products Corp.	T-3 Antiserum	Serum Vial: 10 ml.	June 12, 1975
Do	125 I T-3	Do	Do.
Do	T-4 Antiserum	Do	Do.
Do	125 I T-4	Do	Do.
Do	Goat Anti-Rabbit Gamma Globulin	Do	Do.
Dow Chemical Co.	Iodine-125 Triiodothyronine Lyophilized.	Vial: 20.5 ml.	May 22, 1975
Do	Antitriiodothyronine Serum Lyophilized.	Do	Do.
Do	ANSA Buffer Lyophilized	Do	Do.
Do	Dextran Lyophilized	Do	Do.
Do	Activated charcoal, T3 RIA	Vial: 3 g	May 1, 1975
Paul B. Elder Co.	Fisher body heat indicator	Bottle: pint	July 30, 1973
Do	338° F Tempilaq	Glass bottle: 16 fl. oz.	July 3, 1975
Electro-Nucleonics Laboratories, Inc.	Morphine (3H), List No. 4005	Glass vial: 5 ml.	June 20, 1975
Do	Morphine Positive Control, List No. 4006.	Glass vial	Do.
Environmental Chemical Specialties, Inc.	Dextran Coated Charcoal Solution	Bottle: 1,000 ml.	Mar. 26, 1973
Do	TBG-Radiothyroxine Solution	Do	Do.
Fisher Scientific Co.	Electrophoretic buffer No. 1, pH 8.60, ionic strength 0.05, catalog No. E-1.	Packet: 12.14 grams	Oct. 27, 1973
Do	Electrophoretic buffer No. 2, pH 8.60, ionic strength 0.075, catalog No. E-2.	Packet: 18.16 grams	Do.
Flow Laboratories	DGV No. 3-080	Bottle: 125 ml.	Apr. 16, 1973
Do	CEP Buffer No. 3-083	Bottle: 125 ml.	Do.
Do	CEP Plate No. 5-076	Plate: 20 ml.	Do.
Do	Merthiolate No. 6-088B	Bottle: 20 ml.	Do.
Do	Barbitone acetate buffer for electrophoresis code No. BR 11g.	Bottle: 100 gms.	June 21, 1974
Do	Complement fixation test, diluent tablets code No. BR. 16.	Bottle: 100 tablets	Do.
Gelman Instruments Co.	Drug Standard Set, No. 51910	Set: 3 vials of 2 ml. each.	Apr. 6, 1972
Do	Drug Control Set, No. 51911	Set: 3 vials of 50 ml. each.	Do.
Do	High Resolution, buffer-Tris Barbital buffer, No. 51104.	Vial: 10 dr.	Dec. 22, 1971
General Diagnostics	fas T_4 No. 36903	Vial: 10.5 cm x 1.2 cm	Aug. 26, 1972
Grand Island Biological Co.	Dextrose-Gelatin-Veronal Buffer Solution NDC No. 815-0566-1 and No. 815-0566-2.	Bottle: 100 ml. and 500 ml.	July 5, 1973

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Complement Fixation Buffer Solution, pH 7.3-7.4, NDC 011815 0247 1.	Bottle: 1 Liter	Jan. 28, 1974
Do	Diseragen, NDC 011815 1548 1	Vial: 50 ml.	Nov. 21, 1973
Do	Diseragen, NDC 011815 1548 2	Vial: 100 ml.	Do.
Do	Dextrose-Gelatin-Veronal with Bovine Albumin.	Do	Do.
Do	Do	Vial: 500 ml.	Do.
Grand Island Biological Co.	Electrophoresis Buffer Solution, pH 8.6, NDC 011815 0245 1.	Bottle: 1 Liter	Jan. 28, 1974
Do	I.E.P. Buffer Solution, pH 8.2, NDC 011815 0246 1.	Do	Do.
Do	Gibform Indicator Cells, NDC 011815 0220.	Vial: 40 ml.	Feb. 21, 1975
Do	Gibform Adsorption Cells, NDC 011815 0225.	Vial: 20 ml.	Do.
Do	GIBFORM RBC Diluent	Glass bottle: 500 ml.	July 23, 1975
Gugol Science Corp.	Gugol concentrate No. 10109	Vials: 20 ml., 90 ml., and 450 ml.	Mar. 23, 1972
Hach Chemical Co.	pH 8.5 buffer powder pillows, No. 920-85.	Pillow: 0.5 gm. each	Nov. 30, 1971
Do	pH 8.3 buffer powder pillows, No. 898-98.	Pillow: 1 gram each	Do.
Do	Zincover II powder pillows, No. 2917.	Do	Do.
Do	Buffered substrate, glycerophosphate, Roe & Whitmore, pH 9.6, No. 20060.	Vial: 0.855 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart, pH 10.9, No. 20063.	Vial: 0.925 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart—Stock, No. 20061.	Vial: 1.85 gram per 100 ml.	Do.
Do	Buffered substrate, glycerophosphate, Shinowara, Jones & Reinhart, pH 5.0, No. 20062.	Vial: 0.925 gram per 100 ml.	Do.
Helena Labs.	Electra HR Buffer Catalog No. 5806.	Packet: 18.1 g, 10 packets per box.	Dec. 28, 1973
Do	Electra B_1 Buffer Catalog No. 5016	Packet: 12.14 g, 10 packets per box.	Do.
Do	Electra B_2 Buffer Catalog No. 5017	Packet: 18.21 g, 10 packets per box.	Do.
Do	Titan III Agar Catalog No. 5023	Vial: 2 ml.	Do.
Do	Titan IV IE Plate (small)	Package: plates, 1 by 3 in.	Do.
Do	Titan IV IE Plate (large)	Package: plates, 3 by 4 in.	Do.
Do	Titan IV IE Plate Kit	Kit: 12 small (1 by 3 in.) IE Plates, 1 box B_1 Buffer.	Do.
Do	Titan IV IE Plate Kit	Kit: 10 large (3 by 4 in.) IE Plates, 1 box B_1 Buffer.	Do.
Hoffman-La Roche, Inc.	Abuscreen radio-immunoassay for morphine (125I), No. 43021.	Vial: 30 ml.	Sept. 27, 1972
Do	Abuscreen radio-immunoassay for morphine (^{3}H), No. 43016.	Vial: 60 ml.	Do.
Do	Abuscreen Radioimmunoassay for Barbiturates (^{3}H).	Vial: 60 ml. and 5 ml.	July 6, 1973
Do	Abuscreen Radioimmunoassay for Barbiturates (^{125}I).	Vial: 60 ml. and 5 ml.	Do.
Do	Abuscreen Radioimmunoassay for Barbiturates (125I).	Vial: 30 ml. and 500 ml.	Do.
Do	Abuscreen™ Mor-Barb Radioimmunoassay for Morphine-Barbiturates.	Vial: 5 ml., 60 ml., and 100 ml. Bottle: 500 ml.	Dec. 27, 1973

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Abuscreen™ Radio-immunoassay for Amphetamine.	Kit containing Vials of 5 ml., 30 ml., and 100 ml. and Bottle: 500 ml.	Jan. 14, 1974
Do	Abuscreen Radioimmunoassay for Morphine (^{125}I).	Vial: 100 ml. and 500 ml.	Sept. 27, 1972
Do	Abuscreen Radioimmunoassay for Morphine (^{3}H).	Do	Do.
Do	Latex tube test kit for morphine:	Kit: 30 to 200 tests	Dec. 6, 1974
Do	TM Abuscreen radioimmunoassay for Methadone.	Kit containing vials of: 5 ml., 30 ml., and 100 ml., and bottle: 500 ml.	June 17, 1974
Do	TM Abuscreen radioimmunoassay for Methaqualone.	Do	Do.
Hyland Division Travenol Laboratories, Inc.	Agar gel plates No. 3008	Package: 8 plates—25 ml. per plate.	Aug. 31, 1971
Do	Agar gel plates No. 3016	Package: 10 plates—25 ml. per plate.	Do.
Do	Agar gel plates No. 3068	Do	Do.
Do	Buffer No. 3017	Vial: 250 ml.	Do.
Do	Buffer No. 3069	Do	Do.
Do	Diluting fluid No. 3400	Vial: 10 ml.	Do.
Do	Partial thromboplastin liquid No. 3481.	Vial: 0.1 ml.	Do.
Do	PTC reagent dried, No. 3497	Vial: 1 ml.	Do.
Hyland Division Travenol Laboratories, Inc.	Supplemental urine clinical chemistry control, dried, No. 0402 and No. 0521.	Vial: 25 ml.	Aug. 31, 1971
Do	Partial thromboplastin, dried, No. 3491.	Vial: 1 ml. and 5 ml.	Do.
Do	Agar gel plates, No. 8794	Plate: 25 ml.	Aug. 1, 1972
Do	Buffer, No. 8793	Vial: 250 ml.	Do.
Do	Toxicology serum control, dried, No. 0541.	Vial: 10 ml.	Oct. 26, 1972
Do	Toxicology urine control, dried, No. 0542.	Do	Do.
Do	T-1	Vial: 20 ml.	Jan. 13, 1976
Do	T-2	Do	Do.
Do	T-4	Vial: 50 ml.	Do.
Do	T-5	Do	Do.
Do	T-6	Vial: 20 ml.	Do.
Do	T-7	Do	Do.
Do	T-8	Vial: 50 ml.	Do.
Do	T-9	Do	Do.
Do	T-10	Do	Do.
Do	T-11	Vial: 20 ml.	Do.
Do	T-12	Do	Do.
Do	T-14	Vial: 50 ml.	Do.
Do	T-15	Do	Do.
Do	T-16	Vial: 20 ml.	Do.
Do	T-18	Vial: 50 ml.	Do.
Do	T-20	Do	Do.
Do	TC-1	Vial: 5 ml.	Do.
Do	TC-2	Do	Do.
ICL Scientific	EIQ Intensifier	Bottle: 7.6 gm.	Feb. 26, 1975
Do	Diluent 1	Vial: 10 and 25 ml.	Do.
Industrial Biological Laboratories, Inc.	DGV solution	Vial: 100 cc.	Dec. 28, 1971
Instrumentation Laboratory, Inc.	Tris-Barbital Buffer No. 33205	Vial: 12 dram	Feb. 21, 1971
Do	Barbital Buffer (B-2) No. 33206	Do	Do.
Do	EDTA-Barbital Buffer No. 33207	Do	Do.
Do	Barbital-Acetate Buffer No. 33208	Do	Do.
Inolex Corp. Biomedical Division.	Barbitone Acetate Buffer, Product Code 71-161-01.	Bottle: 125 gm.	May 29, 1974
Do	Barbitone Acetate Buffer with Calcium Lactate, Product Code 71-162-01.	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Barbitone C.F.T. Diluent, Product Code 63-163-10.	Bottle: 100 tablets	Do.
J.W.S. Delavau., Inc., and the Theta Corp.	Allobarbital No. FP305	Vial: 2 ml.	Apr. 10, 1973
Do	Amobarbital No. FP313	Do	Do.
Do	Amphetamine No. FP604	Do	Do.
Do	Anileridine No. FP203	Do	Do.
Do	Aprobarbital No. FP306	Do	Do.
Do	Barbital No. FP314	Do	Do.
Do	Butabarbital No. FP315	Do	Do.
Do	Butalbital No. FP307	Do	Do.
Do	Chloral Betaine No. FP502	Do	Do.
Do	Chloral Hydrate No. FP501	Do	Do.
Do	Cocaine No. FP601	Do	Do.
Do	Codeine No. FP102	Do	Do.
Do	Cyclobarbital No. FP308	Do	Do.
Do	Diphenoxylate No. FP205	Do	Do.
Do	Dyhydrocodeine No. FP108	Do	Do.
Do	Ethchlorvynol No. FP508	Do	Do.
Do	Ethylmorphine No. FP106	Do	Do.
Do	Fentanyl No. FP211	Do	Do.
Do	Glutethimide No. FP404	Do	Do.
Do	Heptabarbital No. FP309	Do	Do.
Do	Hexobarbital No. FP303	Do	Do.
Do	Hydrocodone No. FP107	Do	Do.
Do	Hydromorphine No. FP103	Do	Do.
Do	Levorphanol No. FP208	Do	Do.
Do	Marker Mixture No. FPM-104	Do	Do.
Do	Marker Mixture No. FPM-201	Do	Do.
Do	Meperidine No. FP201	Do	Do.
Do	Mephobarbital No. FP301	Do	Do.
Do	Meprobamate No. FP402	Do	Do.
Do	Methadone No. FP206	Do	Do.
Do	Methamphetamine No. FP603	Do	Do.
Do	Metharbital No. FP302	Do	Do.
Do	Methohexital No. FP304	Do	Do.
Do	Methylphenidate No. FP605	Do	Do.
Do	Monthly Urine Test No. FPM-103	Do	Do.
J.W.S. Delavau Co., Inc., and the Theta Corp.	Morphine No. FP101	Vial: 2 ml.	Apr. 10, 1973
Do	Oxycodone No. FP109	Do	Do.
Do	Oxymorphone No. FP104	Do	Do.
Do	Paraldehyde No. FP506	Do	Do.
Do	Pentobarbital No. FP318	Do	Do.
Do	Phenazocine No. FP213	Do	Do.
Do	Phenametrazine No. FP606	Do	Do.
Do	Phenobarbital No. FP320	Do	Do.
Do	Piminodine No. FP202	Do	Do.
Do	Probarbital No. FP319	Do	Do.
Do	Secobarbital No. FP310	Do	Do.
Do	Talbutal No. FP311	Do	Do.
Do	Thiamylal No. FP322	Do	Do.
Do	Thiopental No. FP321	Do	Do.
Do	Vinbarbital No. FP312	Do	Do.
Do	Weekly urine test (FDA) No. FPM-101.	Do	Do.
Do	Weekly urine test (States) No. FPM-102.	Do	Do.
Do	Test mixture TM No. 1	Do	June 19, 1974
Do	Test mixture TM No. 2	Do	Do.
Do	Test mixture SM No. 1	Do	Do.
Do	Test mixture SP No. 1	Do	Do.
Do	Test mixture SM No. 2	Do	Do.
Do	Test mixture SP No. 2	Do	Do.
Do	Test mixture SM No. 3	Do	Do.
Do	Test mixture SP No. 3	Do	Do.
Do	Test mixture SM No. 4	Do	Do.
Do	Test mixture SP No. 4	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Kallestad Labs, Inc.	Osmotect Buffer No. M 101	Vial: 7 dram, 7.4 g per vial, 5 vials per package.	May 17, 1972
Do	Buffer No. C135	Vial: 7 dram	Do.
Do	Osmotect Agar Gel Plate Kit No. M 100.	Plate: 2 ml., 6 per kit.	Do.
Lederle Laboratories Division of American Cyanamid Co.	DGV buffer, 5x No. 2606-37	Vial: 20 ml.	Nov. 19, 1971
Do	Serum toxicology control drugs A, No. 2040-69.	Vial: 10 ml.	Do.
Do	Abnormal urine control, No. 2921-80.	Vial: 25 ml.	Do.
Do	Urine toxicology control drugs I, No. 2950-61.	Do	Do.
Do	Urine toxicology drugs I screening proficiency, No. 2951-61.	Do	Mar. 13, 1972
Do	Urine toxicology control drugs 2—barbiturates, No. 2952-61.	Do	Do.
Do	Urine toxicology control drugs 2—barbiturates, proficiency No. 2953-61.	Do	Do.
Do	Urine toxicology control drugs 3—amphetamines No. 2954-61.	Do	Do.
Do	Urine toxicology control drugs 3—amphetamines, proficiency No. 2955-61.	Do	Do.
Do	Urine toxicology control, drugs 4—alkaloid No. 2956-61.	Do	Do.
Do	Urine toxicology control, drugs 4—alkaloid, proficiency No. 2957-61.	Do	Do.
Lederle Laboratories	Urine drug check kit No. 2958-91 to include: UDC 1 No. 2959-38.	Bottle: 25 ml.	Apr. 4, 1973
Do	UDC 1a No. 2979-38	Do	Do.
Do	UDC 2 No. 2960-38	Do	Do.
Do	UDC 3 No. 2961-38	Do	Do.
Do	UDC 4 No. 2962-38	Do	Do.
Do	UDC 5 No. 2963-38	Do	Do.
Do	UDC 6 No. 2964-38	Do	Do.
Do	UDC 7 No. 2965-38	Do	Do.
Do	UDC 8 No. 2966-38	Do	Do.
Do	UDC 9 No. 2967-38	Do	Do.
Do	UDC 10 No. 2968-38	Do	Do.
Do	UDC 10a No. 2980-38	Do	Do.
Do	UDC 11 No. 2969-38	Do	Do.
Do	UDC 12 No. 2970-38	Do	Do.
Do	UDC 13 No. 2971-38	Do	Do.
Do	UDC 14 No. 2972-38	Do	Do.
Do	UDC 15 No. 2973-38	Do	Do.
Do	UDC 15a No. 2981-38	Do	Do.
Do	UDC 16 No. 2974-38	Do	Do.
Lederle Laboratories	UDC 17 No. 2975-38	Bottle: 25 ml.	Apr. 4, 1973
Do	UDC 18 No. 2976-38	Do	Do.
Do	UDC 19 No. 2977-38	Do	Do.
Do	UDC 20 No. 2978-38	Do	Do.
LKB Instruments, Inc.	Barbital Buffer pH 8.6, No. LKB-5104-180.	Vial: 290 ml.	Jan. 3, 1974
Mallard, Inc.	High resolution buffer-tris barbital buffer No. 51104.	Vial: 1½ dram	Dec. 22, 1971
Mallinckrodt Chemical Works.	Res-O-Mat ETR solution	Vial: 1½ dram	Feb. 17, 1972
Do	Res-O-Mat T4 solution	Do	Do.
Do	Res-O-Mat ETR Solution	Bottle: 16 oz. and imperial gallon.	Aug. 28, 1974
Do	Res-O-Mat T4 Solution	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Mallinckrodt	RIA-MAT Circulating T3 I125 Kit, Cat. No. 501:	Kit containing the following:	Jan. 28, 1974
	RIA-MAT T3 Buffer	Bottle: 100 ml.	
	RIA-MAT T3 Antiserum	Vial: 2.5 ml.	
	RIA-MAT T3 Reaction Vial	Vial: 1 ml.	
	RIA-MAT T3 Standard 0 ng/ml	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 0.5 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 1.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 2.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 6.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T4 I-125 kit	Kits containing: 100 tests and 250 tests.	Apr. 3, 1975
Materials & Technology Systems, Inc.	Carboxymethylmorphine Sensitized RBC.	Vial: 50 ml.	May 3, 1973
Do	Carboxymethyl-morphine	Vial: 8 ml.	Do.
Do	Carboxymethyl-morphine bovine serum albumin or rabbit serum albumin.	Do	Do.
Do	Ectonine Sensitized RBC	Do	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid Sensitized RBC.	Do	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid.	Vial: 8 ml. and 10 ml.	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid bovine serum albumin or rabbit serum albumin.	Vial: 8 ml.	Do.
Do	Ecgonine bovine serum albumin or rabbit serum albumin.	Do	Do.
Do	Tropinecarboxylic acid	Vial: 8 ml. and 10 ml.	Do.
Do	Morphine standard	Vial: 10 ml	July 17, 1973
Do	Morphine-urine standard	Vial: 25 ml	Do.
Do	Ecgonine-urine standard	Do	Do.
Do	Barbiturate-urine standard	Do	Do.
Do	Benzoyl Ecgonine	Vial: 25 mg. and 100 mg.	Apr. 18, 1974
Do	Benzoyl Ecgonine-Urine Standard	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Benzoyl Ecgonine-Urine Standard -- Lyophilized.	Vial: 75 mcg.	Do.
Do	Cocaine-Urine Standard	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Cocaine-Urine Standard Lyophilized	Vial: 75 mcg.	Do.
Do	Methadone-Urine Standard	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Methadone-Urine Standard Lyophilized.	Vial: 75 mcg.	Do.
Do	Phenobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Phenobarbital-Urine Standard Lyophilized.	Vial: 125 mcg.	Do.
Do	Secobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Secobarbital-Urine Standard Lyophilized.	Vial: 125 mcg.	Do.
Do	Amobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Amobarbital-Urine Standard Lyophilized.	Vial: 125 mcg.	Do.
MCI Biomedical	IEP buffer; pH 8.2, 0.04 ionic strength.	Package: 6.510 grams.	Aug. 28, 1972
MEAD Diagnostics	T-3 test fas T, No. L6902	Vial: ½" x 1 13/16"	May 31, 1972
Do	T-4 test fas T, No. L6905	Vial: ½" x 1 13/16"	Do.
Medi-Chem, Inc.	Thymol-Barbital Buffer Concentrate pH 7.55.	Vial: 10 ml.	July 11, 1974
Do	Thymol-Barbital Buffer Concentrate pH 7.8.	Do	Do.
Medical Chemical Corp.	Secobarbital Standard 10 mg. percent, Cat. No. 250.	Bottle: 120 cc.	Feb. 22, 1974

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Meloy Laboratories	Counterelectrophoresis Plates, G-301.	Plates: 10 determinations.	Sept. 5, 1973
Do	Immunoelectrophoresis Plates, G-201.	Plates: 6 per Unit	Do.
Do	Immunostatim T3 Kit, No. K130	Cardboard box: 8⅝" x 5¼" x 2¼".	July 7, 1975
Do	Immunostatim T4 Test Kit, No. K140.	Cardboard box: 8⅝" x 5¼" x 2¼".	Do.
Lederle Laboratories	UDC 17 No. 2975-38	Bottle: 25 ml.	Apr. 4, 1973
Do	UDC 18 No. 2976-38	Do	Do.
Do	UDC 19 No. 2977-38	Do	Do.
Do	UDC 20 No. 2978-38	Do	Do.
LKB Instruments, Inc.	Barbital Buffer pH 8.6, No. LKB-5104-180.	Vial: 290 ml.	Jan. 3, 1974
Mallard, Inc.	High resolution buffer-tris barbital buffer No. 51104.	Vial: 1½ dram	Dec. 22, 1971
Mallinckrodt Chemical Works.	Res-O-Mat ETR solution	Vial: 1½ dram	Feb. 17, 1972
Do	Res-O-Mat T4 solution	Do	Do.
Do	Res-O-Mat ETR Solution	Bottle: 16 oz. and imperial gallon.	Aug. 28, 1974
Do	Res-O-Mat T4 Solution	Do	Do.
Mallinckrodt	RIA-MAT Circulating T3 I125 Kit, Cat. No. 501:	Kit containing the following:	Jan. 28, 1974
	RIA-MAT T3 Buffer	Bottle: 100 ml.	
	RIA-MAT T3 Antiserum	Vial: 2.5 ml.	
	RIA-MAT T3 Reaction Vial	Vial: 1 ml.	
	RIA-MAT T3 Standard 0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 0.5 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 1.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 2.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T3 Standard 6.0 ng/ml.	Vial: 1.5 ml.	
	RIA-MAT T4 I-125 kit	Kits containing: 100 tests and 250 tests.	Apr. 3, 1975
Materials & Technology Systems, Inc.	Carboxymethylmorphine Sensitized RBC.	Vial: 50 ml.	May 3, 1973
Do	Carboxymethyl-morphine	Vial: 8 ml.	Do.
Do	Carboxymethyl-morphine bovine serum albumin or rabbit serum albumin.	Do	Do.
Do	Ectonine Sensitized RBC	Do	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid Sensitized RBC.	Do	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid.	Vial: 8 ml. and 10 ml.	Do.
Do	5-ethyl-5-(1-carboxy-n-propyl) barbituric acid bovine serum albumin or rabbit serum albumin.	Vial: 8 ml.	Do.
Do	Ecgonine bovine serum albumin or rabbit serum albumin.	Do	Do.
Do	Tropinecarboxylic acid	Vial: 8 ml. and 10 ml.	Do.
Do	Morphine standard	Vial: 10 ml.	July 17, 1973
Do	Morphine-urine standard	Vial: 25 ml.	Do.
Do	Ecgonine-urine standard	Do	Do.
Do	Barbiturate-urine standard	Do	Do.
Do	Benzoyl Ecgonine	Vial: 25 mg. and 100 mg.	Apr. 18, 1974
Do	Benzoyl Ecgonine-Urine Standard.	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Benzoyl Ecgonine-Urine Standard Lyophilized.	Vial: 75 mcg.	Do.
Do	Cocaine-Urine Standard	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Cocaine-Urine Standard Lyophilized.	Vial: 75 mcg.	Do.
Do	Methadone-Urine Standard	Vial: 25 ml. 3 mcg./ml.	Do.
Do	Methadone-Urine Standard Lyophilized.	Vial: 75 mcg.	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Phenobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Phenobarbital-Urine Standard Lyophilized.	Vial: 125 mcg.	Do.
Do	Secobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Secobarbital-Urine Standard Lyophilized.	Vial: 125 mcg.	Do.
Do	Amobarbital-Urine Standard	Vial: 25 ml. 5 mcg./ml.	Do.
Do	Amobarbital-Urine Standard Lyophilized.	Vial :125 mcg.	Do.
MCI Biomedical	IEP buffer; pH 8.2, 0.04 ionic strength.	Package: 6.510 grams	Aug. 28, 1972
MEAD Diagnostics	T-3 test fas T, No. L6902	Vial: ½" x 1 13/16"	May 31, 1972
Do	T-4 test fas T_4, No. L6905	Vial: ½" x 1 13/16"	Do.
Medi-Chem, Inc.	Thymol-Barbital Buffer Concentrate pH 7.55.	Vial: 10 ml.	July 11, 1974
Do	Thymol-Barbital Buffer Concentrate pH 7.8.	Do	Do.
Medical Chemical Corp.	Secobarbital Standard 10 mg. percent, Cat. No. 250.	Bottle: 120 cc.	Feb. 22, 1974
Meloy Laboratories	Counterelectrophoresis Plates, G-301.	Plates: 10 determinations.	Sept. 5, 1973
Do	Immunoelectrophoresis Plates, G-201.	Plates: 6 per Unit	Do.
Do	Immunostat™ T3 Kit, No. K130	Cardboard box: 8⅝" x 5¼" x 2¼".	July 7, 1975
Do	Immunostat™ T4 Test Kit, No. K140.	Cardboard box: 8⅝" x 5¼" x 2¼".	Do.
Purex Laboratories, Inc.	Cannabis sativa, allergenic extract, 1,000 pnu/cc.	Vial: 2 cc.	Sept. 29, 1971
Do	Cannabis sativa, allergenic extract, 20,000 pnu/cc.	Vial: 50 cc.	Do.
Ortho Diagnostics	Activated Thromobo FAX No. 721000.	Bottle: 3.2 ml.	Sept. 21, 1971
Do	Hapindex, agar gel plate, No. 74000.	Plate: 43 ml. per plate	Do.
Do	Ortho abnormal plasma coagulation control.	Packet: 96.5 mg.	Sept. 21, 1971
Do	Ortho HAA positive control No. 740100.	Vial: 1 mg.	Mar. 27, 1972
Ortho Diagnostics	Ortho Control Urine II, No. 9040	Vial: 25 ml. Lyophilized	Oct. 10, 1974
Oxford Laboratories	StaT4 Adsorbent, Catalog No. 991.	Bottle: 95 ml.	Oct. 28, 1974
Do	StaT4 Adsorbent, Catalog No. 992.	Bottle: 315 ml.	Do.
Oxy Metal Industries Corp.	Compound N Solution	Steel drum: 55 gal.	Oct. 1, 1975
Regis Chemical Co.	Urine drug control set	Vial: 5 ml.	Aug. 20, 1973
Do	Drug reference standards set containing:	Vial:	Do.
	Group A	5 ml.	
	Group B	Do	
	Group C	Do	
	Group D	Do	
	Group E	5 ml.	
Schering Corp.	Hepaquik	Vial: 9 dram and plate.	July 16, 1972
Schwarz/Mann Division, Becton Dickson and Co.	D L-amphetamine sulfate C14 sterile aqueous solution.	Flask: 0.05 mc, 0.1 mc, 0.5 mc, 1.0 mc.	Sept. 14, 1972
Do	D-amphetamine sulfate C14 sterile aqueous solution.	Do	Do.
Do	L-amphetamine sulfate C14 sterile aqueous solution.	Do	Do.
Do	Secobarbital 5 C14	Do	Do.
Do	Secobarbital 2 C14	Do	Do.
Do	Barbital buffer salt mixture, No. 0752-04 and No. 0752-07.	Vial: 50 cc.	Nov. 4, 1971
SGA Scientific Corp.	Barbital-acid buffer salt, No. 1173.	Bottle: 4 oz.	Do.
Do	Barbital-sodium buffer salt, No. 11731.	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Barringer & Woodard buffered substrate No. 23695.	Vial: 0.73 gram per 15 x 45 mm. vial.	Sept. 15, 1971
Do	Buchler instrument buffer B-2 double strength, pH 8.6, 0.075 m No. 93834.	Vial: 36.36 grams	Do.
Do	Buffer barbital, pH 8.8, No. 7691.	Vial: 11.76 grams per 10 dram vial.	Do.
Do	Buffer salt—barbital acetate, mixture pH 8.6, No. 3787.	Vial: 14.7 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture pH 8.8, No. 7644.	Vial: 17.85 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-1, pH 8.6, 0.05 ionic strength, No. 3947.	Vial: 12.12 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffer salt mixture Spinco B-2, pH 8.6, 0.075 ionic strength, No. 3948.	Vial: 18.18 grams per 29.5 x 80 mm. vial.	Do.
Do	Buffered barbital, sodium chloride, pH 7.5, No. 646-7.	Vial: 14.7 grams per vial.	Do.
Do	Buffered substrate glycerophosphate Bodansky No. 23681.	Vial: 0.924 gram per 15 x mm. vial.	Do.
Do	Buffered veronal, pH 7.5, No. 64322.	Vial: 16.48 grams per vial.	Do.
Do	Gilerees & Davis buffered substrate, No. 23701.	Vial: 1.228 grams per 15 x mm. vial.	Do.
Do	King & Armstrong buffered substrate, No. 23721.	Vial: 1.14 grams per 15 x 45 mm. vial.	Do.
Do	Roe & Whitmore buffered substrate, No. 23686.	Vial: 0.854 gram per 15 x 45 mm. vial.	Do.
Do	Scientific products buffer salt mixture B-2, No. 93953.	Vial: 18.18 grams per 10 dram vial.	Do.
Do	Shinowara, Jones & Reinbart buffered substrate, No. 23738.	Vial: 0.945 gram per 15 x 45 mm. vial.	Do.
Do	Thymol barbital buffer McLagan Modified pH 7.8, No. 29944.	Vial: 1.256 grams per 15 x 45 mm. vial.	Do.
Do	Thymol buffer 100 ml—100 mg., Huerga & Pepper, No. 29959.	Vial: 0.964 gram per 15 x 45 mm. vial.	Do.
Do	Thymol buffer pH 7.8, MacLagan, No. 29949.	Vial: 1.02 grams per vial.	Do.
Do	Thymol buffer pH 7.55 Mateer, No. 29951.	Vial: 0.96 gram per 15 x 45 mm. vial.	Do.
Do	Thymol turbidity test set, No. 3105.	Packet: 1 gram	Nov. 4, 1971
Do	Zinc sulfate pH 7.5 (Kunkel), No. 64050.	Vial: 0.514 gram per vial.	Sept. 15, 1971
Do	Adenosine phosphate substrate No. 675-1.	Bottle: 4 oz	July 25, 1973
Do	Glycerophosphate substrate No. 675-2.	Do	Do.
Do	Glycerophosphate substrate No. 704-1.	Do	Do.
SGA Scientific Corp.	Acid hematoxylin solution No. 285-2.	Bottle: 25 ml. and 100 ml.	Aug. 6, 1973
Do	Mayer's hematoxylin solution No. MHS-1.	Do	Do.
Do	SGOT Single Assay Vial, No. 55-1.	Vial: 3 ml.	May 29, 1973
Do	SGOT Assay Vial, No. 55-5	Vial: 15 ml.	Do.
Do	SGOT 10 Assay Vial, No. 55-10	Vial: 30 ml.	Do.
Do	SGPT Single Assay Vial, No. 55-1P.	Vial: 3 ml.	Do.
Do	SGPT 5 Assay Vial, No. 55-5P	Vial: 15 ml.	Do.
Do	SGPT 10 Assay Vial, No. 55-10P.	Vial: 30 ml.	Do.
Do	SGOT Reagent No. 155-10	Do	Do.
Do	SGOT Reagent No. 155-100	Vial: 100 ml.	Do.
Do	SGPT Reagent No. 155-10P	Vial: 30 ml.	Do.
Do	SGPT Reagent No. 155-100P	Vial: 100 ml.	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	LDH-P Reagent No. 125-10	Vial: 30 ml.	Do.
Do	LDH-P Reagent No. 125-100	Vial: 100 ml.	Do.
Sherwood Medical Industries	Lancer fibrinogen determination, Re-agent kit catalog No. 8889-007608.	Kit	April 17, 1975
Smith Kline Instruments, T-8 Inc.	Uptake Diagnostic Test	Test Kit containing: 25 plastic tubes coated with antibody. Standards. 1 vial of radioactive isotope. 1 vial of barbital buffer.	Oct. 15, 1975
E. R. Squibb & Sons	Barbital Buffer Mixture for use with Gastrin Immutope Kit No. 09510.	Vial: 5 cc.	Nov. 21, 1972
E. R. Squibb & Sons, Inc.	AuSure II Barbital Buffer Powder, No. B79209.	Vial: 1.51 gm.	July 28, 1971
Do	AuSure II CEP Plate No. B78209.	Plate: 30 microliters per well.	Sept. 16, 1971
Do	Barbital buffer mixture No. 09501.	Vial: 6.055 gm.	Dec. 21, 1972
Do	Barbital buffer mixture for use with digoxin immutope kit No. 09350.	Vial: 5 cc.	July 30, 1973
Do	Thyrostat-4 Kit, Catalog No. 09125.		Feb. 26, 1973
	To include:		
	(a) Thyrostat-4 Standard Solution.	Vial: 7 ml.	
	(b) Thyrostat-4 Buffer Solution.	Bottle: 60 ml.	
Do	Barbital Buffer Mixture for use with Digoxin Immutope Kit No. 09360.	Vial: 2.4 g. per 5 ml. vial.	Aug. 6, 1974
Supelco, Inc.	Cocaine, 04-9188	1,000 ug/glass ampul	June 5, 1975
Do	Methaqualone, 04-9183	Do	Do.
Do	Lysergic Acid Diethylamide Tartrate, 04-9195.	500 ug/glass ampul	Do.
Do	Psilocin, 04-9190	1,000 ug/glass ampul	Do.
Do	Psilocybin, 04-9191	Do	Do.
Do	Amobarbital No. 04-9170	Ampule: 1 ml.	Dec. 22, 1972
Do	Amphetamine No. 04-9165	Do	Do.
Do	Aprobarbital No. 04-9171	Do	Do.
Do	Barbital No. 04-9169	Do	Do.
Do	Butetehal No. 04-9172	Do	Do.
Do	Codeine No. 04-9161	Do	Do.
Do	Cyclobarbital No. 04-9175	Do	Do.
Do	Glutethimide No. 04-9178	Do	Do.
Do	Heptabarbital No. 04-9176	Do	Do.
Do	Heroin No. 04-9162	Do	Do.
Do	Hexobarbital No. 04-9177	Do	Do.
Do	Methadone No. 04-9163	Do	Do.
Do	Methamphetamine No. 04-9168	Do	Do.
Do	Mephobarbital No. 04-9178	Do	Do.
Do	Morphine No. 04-9160	Do	Do.
Do	Pentobarbital No. 04-9179	Do	Do.
Do	Phenobarbital No. 04-9181	Do	Do.
Do	Phenylmethylbarbituric acid No. 04-9182.	Do	Do.
Do	Secobarbital No. 04-9180	Do	Do.
Do	Barb mix-1	Vial: 1 ml.	Aug. 28, 1973
Do	Barb mix-2	Do	Do.
Do	Amph mix	Do	Do.
Do	Alk mix	Do	Do.
Do	Cannabichromene, No. 04-9220	Ampoule: 1 ml.	Nov. 27, 1974
Do	Cannabidiol, No. 04-9221	Do	Do.
Do	Cannabidiolic Acid, No. 04-9222	Do	Do.
Do	Cannabigerol, No. 04-9223	Do	Do.
Do	Cannabinol, No. 04-9225	Do	Do.
Do	Cannabinol Acetate, No. 04-9226	Do	Do.

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Δ^1-THC, No. 04-9227	Do	Do.
Do	Δ^6-THC, No. 04-9228	Do	Do.
SYVA Co.	Frat benzoyl ecgonine calibrator	Vial: 1 ml.	Sept. 13, 1972
Do	Frat methadone calibrator	Do	Do.
Do	Frat opiate calibrator	Do	Do.
Do	Frat amphetamine calibrator	Do	Do.
Do	Frat barbiturate calibrator	Do	Do.
Do	Frat Opiate Spin Label Reagent B	Bottle: 5 ml.	May 22, 1973
Do	Frat Methadone Spin Label Reagent B.	Do	Do.
Do	Frat Barbiturate Spin Label Reagent B.	Do	Do.
Do	Frat Amphetamine Spin Label Reagent B.	Do	Do.
Do	Frat Cocaine Metabolite Spin Label Reagent B.	Do	Do.
Do	Emit Opiate Enzyme Reagent B	Do	Do.
Do	Emit Methadone Enzyme Reagent B.	Do	Do.
Do	Emit Barbiturate Enzyme Reagent B.	Do	Do.
Do	Emit Amphetamine Enzyme Reagent B.	Do	Do.
Do	Emit Cocaine Metabolite Enzyme Reagent B.	Do	Do.
Do	Emit Opiate Enzyme Reagent B	Bottle: 60 ml.	Do.
Do	Emit Methadone Enzyme Reagent B.	Do	Do.
Do	Emit Barbiturate Enzyme Reagent B.	Do	Do.
Do	Emit Amphetamine Enzyme Reagent B.	Do	Do.
Do	Emit Cocaine Metabolite Enzyme Reagent B.	Do	Do.
Do	Emit High Calibrator	Do	May 5, 1973
Do	Products of the following substances either alone or in combination with one another and not to exceed 10 micrograms per milliliter lyophilized human urine. (1) Amphetamine (2) Benzoyl Ecgonine, (3) Codeine, (4) Ecgonine, (5) 2-Ethilidene-1,5-dimethyl-3,3-diphenyl-pyrrolidine, (6) Glutehimide, (7) Methadone, (8) Methamphetamine, (9) Methaqualone, (10) Morphine, (11) Morphine Glucuronide, (12) Pentobarbital, (13) Phenobarbital, (14) Secobarbital.	Vial: 60 ml.	May 31, 1973
Do	Emit AED-No. 1 Calibrator	Vial: 3 ml., lyophilized	Aug. 27, 1976
Do	Emit AED-No. 2 Calibrator	Do	Do.
Do	Emit AED-No. 3 Calibrator	Do	Do.
Do	Emit AED-No. 4 Calibrator	Do	Do.
Do	Emit AED-No. 5 Calibrator	Do	Do.
Do	Emit AED-No. 1 Calibrator	Vial: 10 ml. lyophilized	Do.
Do	Emit AED-No. 2 Calibrator	Do	Do.
Do	Emit AED-No. 3 Calibrator	Do	Do.
Do	Emit AED-No. 4 Calibrator	Do	Do.
Do	Emit AED-No. 5 Calibrator	Do	Do.
Do	Antiepileptic Drug Control	Vial: 10 ml. lyophilized	Do.
Do	Emit Phenobarbital Enzyme Reagent B.	Vial: 5.5 ml., lyophilized.	Do.
Do	Coulter Tox Cut-Off Calibrator	Vial: 1 ml.	Apr. 24, 1975

Manufacturer or supplier	Product name and supplier's catalog number	Form of product	Date of application
Do	Coulter Tox Opiate Enzyme Reagent.	Vial: 1 and 2 ml.	Do.
Do	Coulter Tox Methadone Enzyme Reagent.	Do	Do.
Do	Coulter Tox Amphetamine Enzyme Reagent.	Do	Do.
Do	Coulter Tox Barbiturate Enzyme Reagent.	Do	Do.
Do	Coulter Tox Cocaine Metabolite Enzyme Reagent.	Do	Do.
Do	Emit DAU LOW Calibrator	Vial: 3 ml.	July 29, 1975
Do	Emit DAU MEDIUM Calibrator	Do	Do.
Do	Emit BENNODIAZEPINE METABOLITE Enzyme Reagent B.	Glass bottle: 5.5 ml.	Do.
Do	Do	Glass bottle: 50.0 ml.	Do.
Taylor Chemicals, Inc.	Code 1307D—Zinc Reagent D	Bottle: 2 oz, 4 oz, 8 oz, 16 oz.	Aug. 31, 1973
Do	Special Zinc Reagent catalog No. 1307-D.S.	Bottle: 1 qt. (32 fl oz), 1 pt (16 fl oz), 4 oz (4 fl oz).	Sept. 29, 1975
Technam, Inc.	Benzoyl Ecgonine-BSA, lot No. 81-172-A.	Glass vial: 8 ml.	July 21, 1975
Do	Benzoyl Ecgonine-RSA, lot No. 81-172-B.	Do	Do.

(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 enathate 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 Research Pharmaceuticals 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 Marietta, GA
PAN estra test	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Pan American Labs Covington, LA
Premarin with methyltestosterone	Tablet; conjugated estrogens 1.25 mg; methyltestosterone 10.0 mg	Ayerst Labs, Inc. New York, NY
Premarin with methyltestosterone	Tablet; conjugated estrogens 0.625 mg; methyltestosterone 5.0 mg	Ayerst Labs, Inc. New York, NY
Test-ESTRO cypionates	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Rugby Laboratories Rockville Center, NY
Testosterone Cyp 50 estradiol Cyp 2	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	I.D.E. - Interstate Amityville, NY

Testosterone cypionate-estradiol cypionate injection	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Best Generics No. Miami Beach, FL
Testosterone cypionate-estradiol cypionate injection	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Goldline Labs Ft. Lauderdale, FL
Testosterone cypionate-estradiol cypionate injection	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Scein Pharmaceuticals Port Washington, NY
Testosterone cypionate-estradiol cypionate injection	Vial; testosterone cypionate 50 mg-ml; estradiol cypionate 2 mg-ml	Steris Labs, Inc. Phoenix, AZ
Testosterone enanthate-estradiol valerate injection	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 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 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* 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 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* 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 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 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* and 836 IAC 2-1-1 insofar as they administer controlled substances within the applicable requirements and standards of IC 16-1-40 *[IC 16-1 was repealed by P.L.2-1993, SECTION 209, effective July 1, 1993.]* 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, 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

(iv) In which all 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)*

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)*

Rule 2. Licensing and Operational Requirements

856 IAC 3-2-1 Persons required to register

Authority: IC 25-26-14-13
Affected: IC 25-26-14

Sec. 1. (a) Every person who engages in wholesale drug distribution is required to obtain a wholesale drug distributor license as required by IC 25-26-14. Only persons actually engaged in such activities are required to obtain a license; related or affiliated persons who are not engaged in such activities are not required to be licensed. For example, a stockholder or parent corporation of a corporation distributing legend drugs is not required to obtain a license.

(b) A separate license is required for each facility directly or indirectly owned or operated by the same person in Indiana.

(c) For the purpose of enforcement of the licensing requirement, "facility" means one (1) building or two (2) or more buildings in close geographic proximity to each other, such as a campus. A facility shall be identified by the wholesale drug distributor as constituting a single business operation. *(Indiana Board of Pharmacy; 856 IAC 3-2-1; 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 3-2-2 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, Health Professions Bureau, 402 West Washington Street, Room 041, Indianapolis, Indiana 46204.

(b) Wholesale drug distributor licenses shall expire on September 30th 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

Authority: IC 25-26-14-13
Affected: IC 25-26-14-14

Sec. 7. (a) An out-of-state wholesale drug distributor may obtain a license on the basis of reciprocity after payment of the licensure fee provided in section 2 of this rule and upon a demonstration to the board that the distributor qualifies under IC 25-26-14-14(f).

(b) A person who possesses one (1) or more wholesale drug distributor licenses for facilities located in Indiana shall not be required to obtain a license for facilities located outside of Indiana. *(Indiana Board of Pharmacy; 856 IAC 3-2-7; 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 3-2-8 Minimum conditions for licensure, renewal, and operations

Authority: IC 25-26-14-13
Affected: IC 25-26-14-17

Sec. 8. As a condition for receipt, renewal, and retention of a license, the following minimum requirements for the storage and handling of legend drugs, and for establishment and maintenance of legend drug distribution records, by wholesale drug distributors, their officers, agents, representatives, and employees are provided:

(1) All facilities at which legend drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(A) be of suitable size and construction to facilitate cleaning maintenance and proper operations;

(B) have storage areas designed to provide sufficient lighting, ventilation, temperature, humidity control, sanitation, working space, equipment, and security measures to assure safe and secure operation of the installation;

(C) have a quarantine area for storage of legend drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in outer or secondary sealed containers that have been opened;

(D) be maintained in a clean and orderly condition; and

(E) be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Provide security as follows:

(A) All facilities used for wholesale drug distribution shall be secure from unauthorized entry. To this end, licensees who handle and store controlled substances listed in Schedule II, Schedule III, Schedule IV, and Schedule V shall assure that their facilities meet the requirements of 856 IAC 2. In addition, facilities which handle or store controlled

substances also shall meet the requirements of item (v). All other licensees shall meet the following requirements:

(i) Nonscheduled legend drugs shall, at a minimum, be stored in a building of substantial construction, with walls, roof, doors, and windows made or covered by materials which render unauthorized access difficult.

(ii) All doors providing access to such buildings shall, at a minimum, be constructed of a heavy wooden core covered by a steel plate or jacket on their outer surface, or be of equivalent construction. Primary access doors shall be equipped with a five (5) pin tumbler dead bolt lock at a minimum. Secondary access doors may be secured from the inside by means of a crossbar during periods when the facility is not in operation.

(iii) All ground floor windows shall be equipped with window locks.

(iv) Facility security systems shall include a central alarm or comparable intrusion detection system which will disclose attempts at unauthorized entry during hours when the facility is closed.

(v) The outside perimeter of these facilities shall be illuminated to a degree sufficient to disclose the presence of an unauthorized person or vehicle adjacent to the exterior surfaces of the building during hours of darkness.

(vi) Licensees of these facilities shall establish and practice measures of personnel control which will assure that only those persons authorized by the management shall have access to areas of the facility wherein legend drugs are handled or stored. In addition, procedures also shall be followed which control the access of personnel authorized to enter the facility on a temporary basis to perform necessary maintenance or for other useful purposes.

(vii) Whenever practicable, facilities shall be protected, additionally, by arrangement with local law enforcement agencies or central guard forces for employment of a quick reaction force in event of forcible entry or other occurrences beyond facility control.

(viii) The security system also shall provide protection against theft or diversion which is facilitated or hidden by tampering with computer systems or electronic records used by licensee.

(B) Facilities which include administrative offices in the same building wherein drugs are handled or stored are not required to comply with the requirements under clause (A)(i), (A)(ii), or (A)(iii) for the office portion of the building; provided, that any door or window connecting the offices with the storage areas of the building meets the requirements of clause (A)(i), (A)(ii), or (A)(iii).

(3) All legend drugs shall be stored at temperatures and under conditions in accordance with manufacturers' requirements, if any, in the labeling of such drugs:

(A) if no storage requirements are established for a legend drug, the drug may be held at a temperature maintained thermostatically between fifty-nine degrees Fahrenheit (59°F) and eighty-six degrees Fahrenheit (86°F) to help ensure that its identity, strength, quality, and purity are not adversely affected;

(B) appropriate manual, electro-mechanical, or electronic temperature and humidity recording equipment, devices, and logs shall be utilized to document proper storage of legend drugs; and

(C) the record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(4) Examination of materials shall be as follows:

(A) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated legend drugs or legend drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal damage or tampering that would suggest possible contamination or other damage to the contents.

(B) Each outgoing shipment shall be carefully inspected for identity of the legend drug products and to ensure that there is no delivery of legend drug products that have been damaged in storage or held under improper conditions.

(C) The record keeping requirements under subdivision (6) shall be followed for all incoming and outgoing legend drugs.

(5) Returned, damaged, and outdated prescription drugs shall be handled as follows:

(A) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be held in a quarantine area and physically separated from other legend drugs until they are destroyed or returned to their manufacturer or other agency of origin.

(B) Any legend drugs which have sealed outer or secondary containers that have been opened or used shall be identified as such and shall be quarantined and physically separated from other legend drugs until they are either destroyed or returned to the supplier.

(C) If the conditions or circumstances under which a legend drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be properly destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not circumstances under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(D) The record keeping requirements in subdivision (6) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated legend drugs.

(6) Record keeping shall be as follows:

(A) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of legend drugs. At a minimum, these records shall include the following information:

(i) The source of the drugs, including the name and principal address and telephone number of the seller or transferor, and the address of the location from which the drugs were shipped.

(ii) The identity and quantity of the drugs received, distributed, or disposed of.

(iii) The dates of receipt and distribution or other disposition of the drugs.

(iv) The identity, principal address, and telephone number of recipients of the drugs.

(B) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials, including the board or its agents for a period of two (2) years following disposition of the drugs.

(C) Records described in this section which are kept at the inspection site, or which can be retrieved immediately by computer or other electronic means, shall be made 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 a federal, state, or local law enforcement agency, including the board or its agents.

(7) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of legend drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(A) A procedure whereby the oldest approved stock of a legend drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and necessary.

(B) A procedure to be followed for handling recalls and withdrawals of legend drugs. Such procedures shall be adequate to deal with recalls and withdrawals due to:

(i) any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

(ii) any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) any action undertaken to promote public health and safety by replacement of existing merchandise with an improved product or new package design.

(C) A procedure to ensure that their facility is prepared to react to crises caused by natural disasters or catastrophic events in a manner which will limit losses through looting, theft, or burglary as much as possible under circumstances existing at the time.

(D) A procedure to ensure that any outdated legend drugs will be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of the outdated legend drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs concerned.

(E) A procedure to be followed in instances wherein thefts or losses of legend drugs are established, which will assure complete reporting of the incident to the board, within ten (10) days of when it is established, and to other law enforcement agencies as required by law.

(8) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug reception, storage, handling, and distribution including a description of their duties and a summary of their qualifications.

(9) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. To this end, distributors shall:

(A) permit the board or its agents and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures to the extent authorized by law; and

(B) wholesale drug distributors who deal in controlled substances shall register with the Indiana controlled substance advisory committee and with the Drug Enforcement Administration and shall comply with all applicable federal, state, and local laws and regulations.

(10) Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations which pertain to the reprocessing or salvage of legend drug products.

(Indiana Board of Pharmacy; 856 IAC 3-2-8; 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)

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