Table of Contents

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - Rules of the Idaho State Board of Pharmacy

IDAPA 27
TITLE 01
CHAPTER 01

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

000. LEGAL AUTHORITY.
This chapter is adopted in accordance with Section 54-1717, Idaho Code. (4-2-08)

001. TITLE AND SCOPE.

01. Title. These rules shall be cited in full as IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy." (4-2-08)

02. Scope. These rules include, but are not limited to, the minimum standards for and the control and regulation of the practice of pharmacy in the state of Idaho and the registration of drug outlets. (4-2-08)

002. WRITTEN INTERPRETATIONS.
In accordance with Title 54, Chapter 17, Idaho Code, the Board may have written statements that pertain to the interpretation of the rules of this chapter or to the documentation of compliance with the rules of this chapter. These documents, if any, are available for public inspection at the Board office. (4-2-08)

003. ADMINISTRATIVE APPEALS.
The Idaho Rules of Administrative Procedure of the Attorney General on contested cases, IDAPA 04.11.01, "Idaho Rules of Administrative Procedure," Section 100, et seq., shall apply in addition to Board of Pharmacy Rules, IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy." (4-2-08)

004. INCORPORATION BY REFERENCE.
There are no documents that have been incorporated by reference into these rules. (4-2-08)

005. OFFICE INFORMATION.

01. Street Address. The office of the Board is located at 3380 Americana Terrace, Suite 320, Boise, Idaho. (4-2-08)

02. Mailing Address. The mailing address of the Board is P. O. Box 83720, Boise, Idaho 83720-0067. (4-2-08)

03. Telephone Number. The telephone number of the Board is (208) 334-2356. (4-2-08)

04. Facsimile Number. The fax number of the Board is (208) 334-3536. (4-2-08)

05. Electronic Address. The Board website. (4-2-08)

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records are subject to and in compliance with the provisions of the Idaho Public Records Act, Title 9, Chapter 3, Idaho Code. (4-2-08)

007. -- 009. (RESERVED).

010. DEFINITIONS.

01. Board. Idaho Board of Pharmacy. (5-8-09)

02. Pharmacist Extern. Any person enrolled in an approved college of pharmacy who has not

received his first professional degree in pharmacy and who is obtaining experience under the supervision of a pharmacist preceptor. (6-30-95)

03. Pharmacist Intern. Any person who has successfully completed a course of study at an accredited college or school of pharmacy and who has received the first professional degree in pharmacy and who is obtaining practical experience under the supervision of a pharmacist preceptor. (6-30-95)

04. Preceptor. A licensed pharmacist in good standing engaged in the practice of pharmacy at a registered training site and directly responsible for supervising the training of a student pharmacist. The preceptor shall be responsible for: (5-8-09)

a. Personally providing the student pharmacist with training experience that, in his judgment, will increase the student pharmacist's proficiency; (5-8-09)

b. Reporting to the Board, upon request, the progress of any student pharmacist under his supervision; and (5-8-09)

c. Certifying the student pharmacist's experience affidavits when the extern or intern leaves his supervision. (5-8-09)

05. Student Pharmacist. A term inclusive of intern and extern when differentiation is not needed. (5-8-09)

011. FILING OF DOCUMENTS.

01. Place and Time for Filing. All documents in rulemakings or contested cases shall be filed with the executive director of the Board at the office of the Board in Boise, Idaho, between the hours of 8 a.m. and 5 p.m. each day except Saturdays, Sundays and holidays. For purposes of such filing, the mailing and street addresses, telephone number, and facsimile number of the Board are as follows:

Idaho State Board of Pharmacy
3380 Americana Terrace, Suite 320
PO Box 83720
Boise, Idaho 83720-0067
Telephone: (208) 334-2356
Facsimile: (208) 334-3536 (3-30-01)

02. Manner of Filing. One (1) original of each document is sufficient for filing; however, the person or officer presiding over a particular rulemaking or contested case proceeding may issue orders requiring the filing of additional copies for use in such proceeding. Any pleading or document, not over ten (10) pages in length and not requiring a filing fee, may be transmitted to the Board for filing by facsimile machine (FAX). The FAX transmission must be legible and received in its entirety during the office hours set forth in Subsection 011.01 of these rules. It shall be the responsibility of the filing party to verify with Board staff that a FAX transmission was successfully and legibly completed in its entirety. (4-5-00)

012. -- 099. (RESERVED).

100. REGISTRATION.

01. Interns. Prior to obtaining practical experience, interns shall make application for registration to the Board on forms provided by the Board along with the appropriate fee. Registrations and the renewals of registrations are the responsibility of the intern and expire annually on June 30. (5-8-09)

02. Externs. Prior to obtaining practical experience, externs shall be enrolled in an accredited college of pharmacy and make application for registration to the Board on forms provided by the Board along with the appropriate fee. The registration will remain in effect as long as the extern remains in the college of pharmacy and until July 15 following graduation from the college of pharmacy provided the registration has not been revoked or

suspended by the Board. (3-15-02)

03. Forms. Registration forms issued to student pharmacists will provide a personal registration-receipt copy that shall be carried by the registrant whenever engaged in extern or intern training. (5-8-09)

04. Registration. An approved training site shall be registered by the Board as a place providing practical and professional training deemed applicable for preparing the student pharmacist for licensure. Application for registration shall be completed on the form provided by the Board and submitted with the appropriate fee. This registration expires annually on June 30. (5-8-09)

05. Credit. Credit for practical experience will not be accepted unless the student pharmacist and the training site have been registered. (5-8-09)

101. OUT-OF-STATE EXPERIENCE.
Experience earned out of state must be certified to the Board by the board of pharmacy of the state in which the experience was earned. (6-30-95)

102. PRACTICAL EXPERIENCE TIME REQUIRED.
The student pharmacist must acquire one thousand five hundred (1,500) hours of practical pharmacy experience under a licensed pharmacist at a registered training site. The one thousand five hundred (1,500) hours are to be acquired after the individual is enrolled in a college of pharmacy. Practical experience may be acquired concurrently with college attendance. (5-8-09)

103. CERTIFICATION OF EXPERIENCE.

01. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit will be supplied by the Board and will be certified by a pharmacist in the following situations: (6-30-95)

a. For student pharmacists at the termination of any specific training period or training site; and (5-8-09)

b. For interns as of the date the intern reaches the aggregated total of required experience hours. (6-30-95)

02. Experience. Experience time will not be accredited until the affidavit is submitted by the student pharmacist. The affidavit must be submitted to the Board within thirty (30) days of the ending date of the training period. The student pharmacist will be notified of the acceptance or denial of the experience submitted. (5-8-09)

104. PRACTICE LIMITATION OF STUDENT PHARMACIST.

01. Activities. The student pharmacist shall be allowed to engage in any of the practice activities of a licensed pharmacist provided that: (5-8-09)

a. Such activity is under the immediate supervision of a licensed pharmacist who is present in the pharmacy; (6-30-95)

b. Any activity of a compounding, dispensing, or interpretive nature is checked by a licensed pharmacist; and (7-1-93)

c. Any recording activity that requires the initial or signature of a licensed pharmacist is countersigned by a licensed pharmacist. (7-1-93)

02. Violation. Violation of practice limitations will result in the revocation of the registration of the training site, disciplinary action against the pharmacist and an evaluation for acceptance or rejection of the hours the student pharmacist has obtained while under the supervision of a preceptor at this training site. (5-8-09)

105. LICENSURE EXAMINATIONS.

A person who has successfully completed a course of study at an accredited college or school of pharmacy and received the first professional degree in pharmacy may file an application to sit for the North American Pharmacists Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Exam (MPJE), or any other Board approved programs. Both exams must be passed in accordance with National Association of Boards of Pharmacy (NABP) standards. Failure will subject the applicant to re-examination and payment of the original fee in accordance with NABP standards. (5-8-09)

106. FOREIGN PHARMACY GRADUATES.
Prior to applying for the NAPLEX and MPJE, graduates of schools or colleges of pharmacy located outside the United States must provide a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification or other Board approved program. (5-8-09)

107. ACCREDITED PHARMACY COLLEGE.
For the purposes of Section 54-1722, Idaho Code, a college recognized by the Board is an institution that meets the minimum standards of the Accreditation Council for Pharmacy Education (ACPE) and appears on its list of accredited colleges of pharmacy. (5-8-09)

108. RECIPROCITY.
The Board will reciprocate through NABP's Electronic Licensure Transfer Program (ELTP) or any other Board approved program and reserves the right to approve ELTP applications. Applicants are also required to pass the MPJE. An applicant who has not actively engaged in the practice of pharmacy as a registered pharmacist during the year preceding the time of filing the application may be required to complete forty (40) intern hours for each year away from the profession of pharmacy. (5-8-09)

109. -- 130. (RESERVED).

131. CONTINUING PHARMACY EDUCATION.

01. License Renewal. Commencing with the licensing period beginning July 1, 1980, and for licensing periods thereafter, no pharmacist license renewal will be issued by the Board unless the applicant has fulfilled the requirements set forth in these rules. (7-1-93)

02. Exemption. Subsection 131.01 does not apply to pharmacists applying for the first renewal of their license if they have not been licensed by the Board for at least one (1) year prior to July 1 of the renewal period. (7-1-93)

132. PROGRAMS.

01. Explanation. A continuing education program for pharmacists means classes of postgraduate studies, informal study group participation, institutes, seminars, lectures, conferences, workshops, extension study, correspondence courses, teaching, planned and professional meetings, self-study courses, cassette or audiovisual tapes/slides or materials, other self-instructed units, and such other methods that may be approved by the Board. (7-1-93)

a. A program shall consist of postgraduate education in the general areas of socioeconomic and legal aspects of health care; the properties and actions of drugs and dosage forms; and the etiology, characteristics and therapeutics of the disease state. (7-1-93)

b. A program shall provide for examination or other evaluation method to assure satisfactory completion by participants. (7-1-93)

c. The person who is to instruct or who is responsible for the delivery or content of the program shall be qualified in the subject matter by education, experience, or preparation to the tasks and method of delivery. (7-1-93)

02. Approval. Continuing pharmacy education programs shall be approved by the Board. (7-1-93)

03. Application for Approval. Application for approval shall be made on, and in accordance with, forms established by the Board. Forms shall require information relating to the name of provider or sponsor, type of program offered, description of subject matter, number of clock hours offered, method of evaluating satisfactory completion of program, dates and location of program and names and qualifications of instructors or other persons responsible for the delivery or content of the program. (7-1-93)

133. CREDIT FOR INSTRUCTORS.

01. Pharmacists. Any pharmacist whose primary responsibility is not the education of health professionals but who leads, instructs or lectures to groups of nurses, physicians, pharmacists or others on pharmacy-related topics in organized continuing education or in-service programs shall be granted continuing education credit for such time expended during actual presentation upon adequate documentation to the Board. (7-1-93)

02. Educators. Any pharmacist whose primary responsibility is the education of health professionals shall be granted continuing education credit only for time expended in leading, instructing or lecturing to groups of physicians, pharmacists, nurses or others on pharmacy-related topics outside his formal course responsibilities in a learning institution. (7-1-93)

134. AMOUNT OF CONTINUING EDUCATION.
The equivalent of one and one-half (1.5) continuing education units (CEU) shall be required annually of each applicant for renewal of license. One (1) continuing education unit is the equivalent of ten (10) clock hours of participation in programs approved by the Board. (7-1-93)

01. ACPE or CME. At a minimum, eight (8) clock hours (0.8 CEU) shall be all or a combination of Accreditation Council for Pharmacy Education (ACPE) or Continuing Medical Education (CME) approved programs. As of January 1, 2008, all ACPE accredited activities with a release date of January 1, 2008 are required to have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. (5-8-09)

02. Pharmacy Law. One (1) clock hour (0.1 CEU) must be Board approved jurisprudence (pharmacy law) programs. (7-1-93)

03. Non-ACPE Approved. A maximum of six (6) clock hours (0.6 CEU) may be non-ACPE approved programs. (12-7-94)

04. Live Attendance. Three (3) clock hours (0.3 CEU) of the required one and one-half (1.5) continuing education units (CEU) must be obtained by attendance at live continuing education programs. (7-1-97)

05. Carryover of Certain Unused Units. Clock hours of CEU accrued during June of any given licensing period may be carried over into the next licensing period to the extent that a pharmacist's total clock hours of CEU for the given licensing period exceed the total CEUs required under these rules for the given licensing period. (5-3-03)

135. CONTINUING EDUCATION-RECIPROCITY.
The Board recognizes reciprocal licensing of only pharmacists who are licensed in good standing in some other state at the time of application to the Board and at the time of issuance of the Idaho license. Continuing pharmacy education will be required after the licensee has been licensed by reciprocity for one (1) year in Idaho. (7-1-93)

136. CONTINUING EDUCATION-DUAL LICENSEES.

01. Idaho Licensee. In order to receive Idaho license renewal, any Idaho licensed pharmacist residing in another state shall meet Idaho requirements for continuing pharmacy education. (7-1-93)

02. Approval. Continuing pharmacy education programs attended by Idaho licensed pharmacists for purposes of satisfying licensing requirements of another state must be approved by the Board in order to be recognized for purposes of renewal of Idaho license. (7-1-93)

03. Certification. Upon request, the Board may certify to another state's licensing authority the status

of a licensee's continuing education participation. The Board may request certification from another state's licensing authority regarding the status of an applicant's continuing education participation. (7-1-93)

137. LICENSE RENEWAL NOTIFICATION.
The Board will develop an appropriate annual renewal notice to be mailed to all licensed pharmacists prior to June 1 of each year. (7-1-93)

01. Fee. The notice will state the annual pharmacist license renewal fee. (7-1-93)

02. Other. The notice will include the continuing pharmacy education time requirement and any other information considered pertinent for the licensee's understanding of the renewal requirements. (7-1-93)

138. RENEWAL APPLICATION.

01. Annual Renewal. The notice shall be returned to the Board with the appropriate fee and with certification of satisfactory completion of continuing pharmacy education requirements signed by the licensee. Proof of continuing education credits must be kept by the pharmacist for a period of three (3) years. Incomplete renewal applications will not be processed and will be returned to the applicant with an explanatory note. (12-7-94)

02. Audit of Submitted Renewal Notice Forms. The Board may randomly select submitted renewal notice forms for audit and verification of contents. (7-1-93)

139. NON-COMPLIANCE.
Failure to meet the annual license renewal requirements by July 1 of any year will cause the license to lapse. Reinstatement may be considered as provided in Section 54-1728, Idaho Code. For reinstatement after July 1 and before June 30 of the next year, the applicant shall have completed the continuing pharmacy education requirements and certify that fact to the Board as stated in Subsection 138.01 of these rules. (7-1-93)

140. LICENSE REINSTATEMENT.
Any applicant for a restored license as provided within Section 54-1728, Idaho Code, shall produce evidence satisfactory to the Board of satisfactory completion of the continuing pharmacy education requirements by examination or approved continuing pharmacy education program prior to restoration of license. (7-1-93)

141. LICENSE ELIGIBILITY.
Any person who is ineligible for any license, registration, or certification granted by the Board by reason of Board discipline, unprofessional conduct, criminal activity, or the official actions of the courts or pharmacy board of another state is thereby ineligible for any and all other types of licenses, registrations, or certifications granted by the Board. (7-1-98)

142. PROFESSIONAL RESPONSIBILITIES.
A failure to fulfill any of the following duties may constitute a violation of Section 54-1726(a), Idaho Code. (3-29-10)

01. Duty to Cooperate in Investigation. It is the duty of every licensee and registrant to cooperate with a disciplinary investigation, and any failure or refusal to do so is grounds for disciplinary action. (3-29-10)

02. Duty to Report Theft, Loss, or Adulteration. It is the duty of every pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances and any adulteration of any prescription drug to the Board, even if the theft, loss, or adulteration has been accounted for and the employee disciplined internally. The report of theft or loss, required hereunder, shall contain all of the information reported to the Drug Enforcement Administration (DEA), as required under 21 CFR 1301.74(c), and shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

03. Duty to Provide Current Contact Information. It is the duty of every licensee and registrant to provide the Board with notice of any change to the licensee's or registrant's name, address, or telephone number within ten (10) business days from the change. (3-29-10)

143. -- 150. (RESERVED).

151. PHARMACY MINIMUM STANDARDS.

01. Application for Registration of Pharmacy. Application for registration to operate, maintain, open or establish a pharmacy, drug store or apothecary shop shall be made on an application blank provided by the Board. (7-1-93)

02. Inspection. Prior to the issuance of a registration, the Board will inspect the pharmacy for minimum standards in regard to drugs, chemicals, reference library, technical equipment, space, fixtures, sanitation, and security. (7-1-93)

03. Drugs, Chemicals and Preparations. A stock of FDA approved drugs, chemicals, and preparations sufficient to compound and dispense ordinary prescriptions as indicated by the practice type and experience in the community where the pharmacy is located. (7-1-93)

a. All stock and materials held for ultimate sale or supply to the consumer shall be free of contamination. (7-1-93)

b. All stock and materials that have exceeded their expiration dates shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

c. All stock and materials that appear and can be presumed to have deteriorated by reason of age, heat, light, cold, moisture, crystallization, chemical reaction, rupture of coating, disintegration, change of odor, precipitation, or other change that can be determined by organoleptic examination or by other means shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

d. All stock and materials that are improperly labeled shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

e. All stock and materials in defective containers shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

152. REFERENCE LIBRARY.

01. Required References. Required references include the latest editions and supplements, either in book, computer diskette or on-line web application, of the following: (5-8-09)

a. Idaho Pharmacy Law and Rules; (3-20-04)

b. One (1) of the following current pharmacy references: (3-20-04)

i. Facts and Comparisons; (3-20-04)

ii. Clinical Pharmacology; (3-20-04)

iii. Micromedex; and (3-20-04)

c. One (1) other current pharmacy reference of your choice. (5-8-09)

153. TECHNICAL EQUIPMENT.
The equipment necessary for compounding and dispensing should include the following: (7-1-93)

01. Graduates. Graduates capable of measuring volumes from five (5) ml to at least five hundred (500) ml. (7-1-93)

02. Mortars and Pestles. At least two (2) porcelain or glass mortars and pestles. (7-1-93)

03. **Non-Metallic Spatula**. At least one (1) non-metallic spatula. (7-1-93)

04. **Steel Spatulas**. Three (3) steel spatulas of assorted sizes. (7-1-93)

05. **Funnels**. Two (2) funnels of assorted sizes. (7-1-93)

06. **Files**. Prescription files. (7-1-93)

07. **Poison Register**. (7-1-93)

08. **Idaho Register**. Official Idaho Register. (7-1-93)

09. **Balance**. A balance that meets requirements of a Class A prescription balance. (7-1-93)

10. **Weights**. Apothecary and metric weights, one (1) set of each. (7-1-93)

11. **Typewriter**. (7-1-93)

12. **Labels Equipment**. Label moistener or pressure sensitive labels. (7-1-93)

13. **Numbering Machine**. (7-1-93)

14. **Miscellaneous Equipment**. (7-1-93)

154. SPACE AND FIXTURES.

01. **Requirements**. The stock, library, and equipment should be housed in a suitable, well-lighted, well-ventilated room or department with temperatures maintained within the comfort zone, and with clean and sanitary surroundings devoted primarily to the compounding of prescriptions, the manufacturing of pharmaceutical preparations, and other operations necessary to assure the strength and purity of medicines. (7-1-93)

02. **Space**. The space should be adequate to prevent overcrowding and be equipped with necessary counters, tables, drawers, shelves, storage cabinets, a sink with hot and cold water, refuse disposal, a proper sewerage outlet, and refrigerated storage equipment of reasonable capacity. There must be facilities for the proper cleaning of the premises, equipment, and utensils. (7-1-93)

03. **Lavatory**. There must be lavatory facilities restricted to pharmacy staff adjoining or in the pharmacy. (7-1-93)

04. **New or Remodeled Pharmacy**. Any new pharmacy or any existing pharmacy that is being remodeled must comply with the following provisions: (7-1-97)

a. Approval of plans. The prescription area (including patient consultation area, merchandising area, and waiting area, when applicable), storeroom, restroom, partitions (including, but not limited to, walls, doors and windows), and trade fixtures shall be indicated on floor plans showing appropriate elevations. Floor plans shall be submitted to the Board at the time the application for a new pharmacy is filed or prior to remodeling an existing pharmacy. Such plans shall be submitted to the Board prior to proceeding with any construction. All plans submitted must receive Board approval before a pharmacy permit is issued. (7-1-97)

b. A patient consultation area must be provided. The patient consultation area must afford the patient privacy from auditory and visual detection by any person other than persons authorized by the patient. The patient consultation area must be accessible by the patient through an entrance and exit that does not require the patient to enter or traverse any part of the prescription or drug storage areas. The patient consultation area must be handicapped accessible. (7-1-97)

155. INSPECTIONS.

The Board shall inspect each pharmacy and drug outlet for compliance with Idaho Code and Board rules. Where deficiencies exist, one (1) follow-up inspection will be performed by the Board at no cost to the establishment. Inspections beyond the one (1) follow-up visit will be at the expense of the establishment or owner. Charges for said inspection will be actual travel and personnel costs incurred in the inspection and will be payable prior to approval. (7-1-93)

156. PHARMACIES.

01. Change of Ownership or Location. In case of change of ownership or location of a pharmacy, the original registration becomes void and must be returned with a new pharmacy application. (7-1-93)

02. Annual Employee Report. Annually on the date of renewal of registration the pharmacist-in-charge must notify the Board of the pharmacist-in-charge of the pharmacy, each licensed employee-pharmacist, and each student pharmacist training in the pharmacy on the place provided on the application. However, any change in pharmacist, pharmacy technician, or student pharmacist employment shall be reported by the pharmacist-in-charge to the Board within ten (10) days of the change. (5-8-09)

03. Reporting Change in Pharmacist-In-Charge. The pharmacist-in-charge shall report any change in the pharmacist-in-charge of the pharmacy to the Board immediately. (5-8-09)

04. Qualifications and Responsibility of the Pharmacist-In-Charge. The pharmacist-in-charge shall be responsible for the management of and shall be under the full and complete control of every part of the drug outlet and its operations that are regulated by the pharmacy laws. No pharmacist shall be designated as the pharmacist-in-charge of a pharmacy and no pharmacist shall function as the pharmacist-in-charge of a pharmacy unless the person so designated and so functioning spends a substantial part of his working time each month working in the pharmacy of which he has been designated the pharmacist-in-charge. (5-8-09)

05. Return of Drugs or Other Items. In the interest of public health, drugs, medicines, sickroom supplies, devices, and items of personal hygiene shall not be accepted for return by any pharmacist or pharmacy after such drugs, medicines, sickroom supplies, devices, and items of personal hygiene have been taken from the premises where sold, distributed, or dispensed, except that medications for in-patients of residential or assisted living facilities, licensed skilled nursing care facilities, and hospitals may be returned to the dispensing pharmacy for credit if the medications are liquid medications that have been supplied in manufacturer sealed containers and remain unopened, or the medications are in unopened “unit dose” packaging. In addition, the conditions set forth in Paragraph 156.05.b. of these rules must be satisfied: (3-20-04)

a. Unit dose is defined as medications packaged in individual, sealed doses with tamper-evident packaging (for example, single unit of use, blister packaging, unused injectable vials, and ampules). (3-20-04)

b. The following conditions must be satisfied: (3-20-04)

i. The medications must be returned with tamper-evident packaging intact and with no evidence of tampering. (3-20-04)

ii. In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity. (4-5-00)

iii. Policies and procedures are followed for the appropriate storage and handling of medications at the facility and for the transfer, receipt, and security of medications returned to the dispensing pharmacy. (4-5-00)

iv. A system is in place to track restocking and reuse to allow medications to be recalled if required. (4-5-00)

v. No controlled substance may be returned except those delivered by unit dose on a daily delivery system. (4-5-00)

vi. If the drug is prepackaged by the pharmacy, each prepackaged container must be labeled in

accordance with the following (For purpose of this rule, any change from the original manufacturer's packaging prior to delivery of the medication to the hospital or the facility shall be considered prepackaged): (3-20-04)

(1) Name and strength of the medication; (3-20-04)

(2) A suitable expiration date that shall not be later than the expiration date on the original manufacturer's container or one (1) year from the date the drug is prepackaged (If a medication that was prepackaged and delivered to the hospital or facility is thereafter returned to the pharmacy and subsequently prepackaged again, the expiration date hereunder shall not be later than the expiration date used when the medication was initially prepackaged.); (3-20-04)

(3) The date the medication was prepackaged; (3-20-04)

(4) The manufacturer's lot number, expiration date, and identity; and (3-20-04)

(5) The identity of the pharmacist responsible for the prepackaging. (3-20-04)

c. If the information required under Subparagraphs 156.05.b.vi.(4) and 156.05.b.vi.(5) of these rules is maintained in the internal records of the pharmacy, those requirements may be omitted from the labeling. The labeling requirements of Subparagraph 156.05.b.vi. of these rules shall apply in addition to the labeling requirements under Section 159 of these rules. (3-20-04)

d. Medications that have been outside the custody and control of the hospital or facility for any reason are not eligible for return. To be considered as having been in the custody and control of the hospital or facility, the medications must have been delivered by the dispensing pharmacy directly to the hospital or facility or to an agent thereof who is authorized and qualified to accept delivery, and the medications must then be held by the hospital or facility in an area suitable for storing medications and not accessible to patients. Once a medication has passed from the hospital or facility storage area to the patient or to the patient's designee for any reason, the medication is no longer eligible for return. (3-20-04)

e. Medications otherwise eligible for return under this rule by virtue of their packaging but that have become ineligible for return for any reason must be marked as follows: (3-20-04)

i. Medications released for self-administration by the patient or for administration outside the hospital or facility premises or otherwise released to be taken outside the custody and control of the hospital or facility shall first be clearly marked and identified "Not Eligible For Return"; however, the foregoing requirement for marking shall not apply to the daily dose of medication released to a patient on the day such dose is to be administered if the hospital or facility does not allow the medication to be returned to the same medication storage area as medications eligible for return. (3-20-04)

ii. Medications that are received by the hospital or facility from the patient or the patient's representative, and not directly from the dispensing pharmacy, and that are to be stored in the same storage area as medications which are eligible for return, shall first be clearly marked and identified "Not Eligible for Return." (3-20-04)

iii. In the event medications otherwise eligible for return under this rule by virtue of their packaging are discovered to be ineligible for return because they have been outside the custody and control of the hospital or facility, or for any other reason, such medications shall be clearly marked and identified "Not Eligible for Return" immediately upon discovery if they are to remain stored in the same storage area as medications that are eligible for return. (3-20-04)

f. Each pharmacy and its pharmacist-in-charge shall be responsible for consulting with each hospital or facility from which the pharmacy will accept returns under Section 156 of these rules to ensure that the hospital or facility has an employee who is trained and knowledgeable in the proper storage, use, and administration of medications at the hospital or facility and to ensure that the hospital or facility has in place and enforces written protocols that will ensure compliance with the conditions necessary to allow returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval

thereof, on file in the pharmacy and produce them for Board inspectors upon request. (3-20-04)

g. Each pharmacy and its pharmacist-in-charge that will be accepting returns under Section 156 of these rules shall establish written protocols for the pharmacy that will ensure compliance with Section 156 for all returns. The pharmacist-in-charge must review and approve the protocols. The pharmacy must keep a copy of the protocols, as well as the written approval thereof, on file in the pharmacy and produce them for Board inspectors upon request. (3-20-04)

06. Damaged Drugs. To sell, offer for sale, barter, or give away drugs damaged by fire, water, or any other means that might affect the potency of the drug is prohibited without first obtaining the written approval of the Board. (7-1-93)

07. Dangerous Drugs. Legend drugs, controlled substances, or other limited sale items must be stored in accordance with United States Pharmacopoeia/National Formulary requirements in the prescription area (where prescriptions are compounded, dispensed or filled) and in a manner as to limit access to licensed pharmacists or authorized personnel of that area only. Failure to comply with this requirement shall be *prima facie* evidence of unprofessional conduct. (7-1-93)

157. PATIENT PROFILES.

01. Pharmacies' Daily Record. In pharmacies not maintaining patient profiles, a daily record will be maintained for prescriptions filled and refilled. The record will contain the following information: (7-1-93)

a. The name of the patient; (7-1-93)

b. The date the prescription is filled; (7-1-93)

c. The name of the medication prescribed; (7-1-93)

d. The amount dispensed; (7-1-93)

e. The name of the prescriber; and (7-1-93)

f. The file number of the prescription. (7-1-93)

02. Patient Profile Information. Patient profiles will contain all of the information of a patient record and will include summarization of the known, pertinent, personal medical data, that may significantly affect the proper determination of a regimen of medication. Examples are chronic and acute disease states, allergies or idiosyncrasies to medications, age, and weight. The daily record and patient profile record will be maintained in the pharmacy for a period of three (3) years. (7-1-93)

158. PRESCRIPTION DRUGS.

01. Designated Drugs. In addition to drugs designated as prescription or legend drugs, as defined in Section 54-1705(30), Idaho Code, the Board includes preparations containing ephedrine or salts of ephedrine as prescription drugs. (7-1-93)

02. Exempt Drugs. A product that meets all the criteria set forth in Paragraph 158.02.a. of these rules is exempt from the designation as a prescription drug under Subsection 158.01 and from inclusion as a Schedule II controlled substance under Section 37-2707, Idaho Code, unless it is being used or possessed as an immediate precursory of another controlled substance. (7-1-98)

a. Products containing a formula with a ratio of twelve and one half (12.5) milligrams ephedrine to two hundred (200) milligrams guaifenesin or twenty-five (25) milligrams ephedrine to four hundred (400) milligrams guaifenesin, not exceeding a maximum of twenty-five (25) milligrams of ephedrine per tablet, capsule, or dose, and in addition to such formula, may include only inert or inactive ingredients or substance. (7-1-98)

b. Hemorrhoidal ointments containing not more than two tenths percent (0.2%) ephedrine sulfate and suppositories not exceeding four (4) milligrams ephedrine sulfate per suppository are also exempt pursuant to Subsection 158.02. of these rules. (7-1-98)

159. PRESCRIPTION DRUG ORDER MINIMUM REQUIREMENTS.

01. Prescription Drug Order Requirements. A prescription drug order must comply with applicable requirements of federal law and must include at least the following: (4-7-11)

a. The name and, if for a controlled substance, the full name and address of the patient; (4-7-11)

b. The date issued; (4-7-11)

c. The name, strength, quantity, and if for a controlled substance, the dosage form of the medication prescribed; (4-7-11)

d. The directions for use; (4-7-11)

e. The name and, if for a controlled substance, the address and DEA registration number of the prescriber; and (4-7-11)

f. If paper, the pre-printed, stamped, or hand-printed name of the prescriber and, if paper or electronic, the prescriber's written or electronic signature. (4-7-11)

02. Prescription Labels. Unless otherwise directed by these rules, any prescription drug must be dispensed in a container that bears the following information: (4-7-11)

a. The name, address, and telephone number of the dispenser (person or business); (4-7-11)

b. The serial number; (4-7-11)

c. The date the prescription is filled; (4-7-11)

d. The name of the prescriber; (4-7-11)

e. The name of the patient; (4-7-11)

f. Unless otherwise directed on the order by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name); (4-7-11)

g. The quantity of item dispensed; (4-7-11)

h. The directions for use; (4-7-11)

i. Any cautionary information as may be required or desirable for proper use and patient safety; (4-7-11)

j. An expiration date which is the lesser of: (4-7-11)

i. One (1) year from the date of dispensing; (4-7-11)

ii. The manufacturer's original expiration date; (4-7-11)

iii. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (4-7-11)

iv. A shorter period when warranted, pursuant to the pharmacist's professional judgment, to protect the

health or safety of the individual; (4-7-11)

k. The number of refills authorized; and (4-7-11)

l. The initials of the dispensing pharmacist. (4-7-11)

160. PRESCRIPTION DRUG ORDER TRANSFER.

01. Communicating Prescription Drug Order Transfers. Except for prescription drug orders for Schedule II controlled substances, a pharmacist may transfer prescription drug order information for the purpose of filling or refilling a prescription if the information is communicated verbally directly from pharmacist to pharmacist. (4-7-11)

a. Prescription drug order information may also be communicated verbally by a student pharmacist, under the direct supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. (4-7-11)

b. When transferring by facsimile transmission, the transfer document must be signed by the transferring pharmacist. (4-7-11)

02. Documentation Required of the Transferring Pharmacy. The pharmacist transferring prescription drug order information must void or otherwise invalidate the original prescription drug order and record the following information: (4-7-11)

a. The name of the transferring pharmacist; (4-7-11)

b. The name of the receiving pharmacist; (4-7-11)

c. The name of the receiving pharmacy; (4-7-11)

d. The date of the transfer; (4-7-11)

e. The number of authorized refills available; and (4-7-11)

f. For a prescription drug order written for a controlled substance, the address and DEA registration number of the receiving pharmacy. (4-7-11)

03. Documentation Required of the Receiving Pharmacy. The pharmacist receiving a transferred prescription drug order must document that the prescription drug order is a "transfer" and record the following information: (4-7-11)

a. The name of the receiving pharmacist; (4-7-11)

b. The name of the transferring pharmacist; (4-7-11)

c. The name of the transferring pharmacy; (4-7-11)

d. The date of issuance of the original prescription drug order; (4-7-11)

e. The number of refills authorized by the original prescription drug order; (4-7-11)

f. The number of authorized refills available; and (4-7-11)

g. If transferring a prescription drug order written for a controlled substance: (4-7-11)

i. The date and locations of all previous refills; and (4-7-11)

ii. The address, DEA registration number, and assigned prescription number of the transferring pharmacy that originally filled the prescription, when different. (4-7-11)

04. Pharmacies Using Common Electronic Files. (4-7-11)

a. Pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other pharmacies sharing the common electronic file. (4-7-11)

b. Common electronic files must contain complete and accurate records of each prescription and refill dispensed. (4-7-11)

05. Transferring Prescription Drug Orders for Controlled Substances. A prescription drug order for a controlled substance listed in Schedules III, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. (4-7-11)

06. Transferring Prescription Drug Order Refills. Prescription drug orders for non-controlled substances may be transferred more than one (1) time if there are refills remaining and all other legal requirements are satisfied. (4-7-11)

161. FACSIMILE PRESCRIPTION TRANSMISSION.
The receipt of prescriptions by fax transmission for dispensing purposes will be allowed from an authorized prescribing practitioner to a pharmacy only when in compliance with the following provisions: (7-1-98)

01. Fax Transmission. Fax transmission of the signed prescription is performed by the prescribing practitioner or the practitioner's authorized agent. (6-30-95)

02. Voice Verification. Practitioners or their authorized agents must provide voice verification upon request of the pharmacist receiving the prescription. If voice verification is refused, the prescription may not be filled. (6-30-95)

03. Facsimile Equipment Provision. Pharmacies are precluded from supplying facsimile equipment to practitioners, hospitals, nursing homes, or any health care provider or facility. (6-30-95)

04. Facsimile Machine Location. The receiving facsimile machine must be located within the prescription department of the pharmacy. (6-30-95)

05. Faxed Prescription Documentation. The faxed prescription must be received as a non-fading document retaining legibility for a minimum of three (3) years. (6-30-95)

06. Schedule II Faxed Prescription Documentation. A prescription for a Schedule II substance may be faxed by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original written and signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. Prescriptions for the following Schedule II substances may be dispensed on receipt of a faxed prescription and the faxed copy shall serve as the original written prescription: (7-1-99)

a. A Schedule II prescription to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion. (7-1-99)

b. A Schedule II prescription for a resident of a Long Term Care Facility (LTCF). (7-1-99)

c. A Schedule II prescription for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state. The practitioner or the practitioner's agent shall note on the prescription that the patient is a hospice patient. (7-1-99)

d. Copies of Schedule II facsimile prescriptions will not be required to be sent to the Board office. (6-30-95)

07. Schedules III, IV, and V Faxed Prescription Documentation. For substances in Schedules III, IV, and V, a faxed copy of a written, signed prescription transmitted directly by the prescribing practitioner to the pharmacy can serve as an original prescription. All federal and state laws and rules pertaining to written prescriptions for Schedule III, IV, and V substances apply to faxed prescriptions. (6-30-95)

08. Pharmacist Verification. The pharmacist receiving a faxed prescription will be responsible for verifying the authenticity of the prescription and for ensuring that a prescription for a controlled substances has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice pursuant to 21 CFR 1306.04(a). Orders purporting to be prescriptions that are not issued in the usual course of professional treatment are not considered prescriptions within the meaning and intent of the Controlled Substances Act. A person who issues or fills such an order shall be subject to penalties provided by law. Responsibility for verification applies equally to an order transmitted by facsimile. (6-30-95)

162. PRESCRIPTION DRUG ORDER EXPIRATION.
Prescription drug orders expire no later than fifteen (15) months after the date of issue. A new prescription drug order must be obtained and a new file number issued at least every fifteen (15) months for maintenance medications. (4-7-11)

163. EMERGENCY PRESCRIPTION REFILL.
In an emergency a pharmacist may refill a prescription for a patient if the prescribing practitioner is not available for authorization and, in the professional judgment of the pharmacist, the prescription should be refilled. Only sufficient medication may be furnished for the emergency period and the practitioner must be contacted as soon as possible for further refill instructions. (7-1-93)

164. (RESERVED).

165. PHARMACEUTICAL CARE.
A licensed pharmacist's scope of pharmacy practice may include, but is not limited to, the provision of those acts or services necessary to provide pharmaceutical care as defined in these rules. (5-8-09)

01. Definitions. (7-1-99)

a. Collaborative pharmacy practice. Means that practice of pharmacy whereby one (1) or more pharmacists have jointly agreed to work in conjunction with one (1) or more practitioners under protocol whereby the pharmacist may perform certain patient care functions authorized by the practitioner under certain specified conditions or limitations. (5-8-09)

b. Collaborative pharmacy practice agreement. Means a written and signed agreement between one (1) or more pharmacists and one (1) or more practitioners that provides for collaborative pharmacy practice for the purpose of conducting drug therapy management services, as defined in these rules. (5-8-09)

c. Drug therapy management. Means a distinct service or group of services that optimize therapeutic outcomes for individual patients. Drug therapy management services are independent of, but can occur in conjunction with, the provision of a drug or a device. Drug therapy management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's scope of practice. These services may include, but are not limited to, the following, according to the individual needs of the patient: (5-8-09)

i. Performing or obtaining necessary assessments of the patient's health status; (5-8-09)

ii. Formulating a drug treatment plan; (5-8-09)

iii. Selecting, initiating, modifying, or administering drug therapy; (5-8-09)

iv. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness; (5-8-09)

v. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (5-8-09)

vi. Documenting the care delivered and communicating essential information to the patient's other primary care providers; (5-8-09)

vii. Providing information, support services and resources designed to enhance patient adherence with his therapeutic regimens; (5-8-09)

viii. Coordinating and integrating drug therapy management services within the broader health care-management services being provided to the patient; and (5-8-09)

ix. Such other drug therapy management services as may be allowed by law. (5-8-09)

d. Health information. Means any information, whether oral or recorded in any form or medium, that: (5-8-09)

i. Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (5-8-09)

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of healthcare to an individual. (5-8-09)

e. HIPAA. Means the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) and any amendments thereof. (5-8-09)

f. Individually identifiable health information. Means information that is a subset of health information, including demographic information collected from an individual and that: (5-8-09)

i. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (5-8-09)

ii. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (5-8-09)

(1) Identifies the individual; or (5-8-09)

(2) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (5-8-09)

g. Other pharmaceutical patient care services. Means services that may include, but are not limited to, the following: (5-8-09)

i. Collaborative pharmacy practice. (5-8-09)

ii. Such other pharmaceutical patient care services as may be allowed by law. (5-8-09)

h. Pharmaceutical care. Means the provision by a pharmacist of drug therapy management services and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in these rules. (5-8-09)

i. Pharmacist's scope of practice pursuant to the collaborative practice agreement. Means those duties and limitations of duties placed upon one (1) or more pharmacists by the collaborative practitioner or practitioners,

the Board, and applicable law and includes the limitations implied by the scope of practice of the collaborating practitioner or practitioners. (5-8-09)

j. Practitioner. Means, for purposes of Section 165, an individual currently licensed, registered, or otherwise authorized in Idaho to prescribe and administer drugs in the course of professional practice. (5-8-09)

k. Protected health information. Means individually identifiable health information that, except as provided in Subparagraph 165.01.k.iv. of these rules, is: (5-8-09)

i. Transmitted by electronic media; (5-8-09)

ii. Maintained in any medium described in the definition of electronic media at 45 CFR 162.103 (HIPAA privacy rules); and (5-8-09)

iii. Transmitted or maintained in any other form or medium. (5-8-09)

iv. Protected health information excludes individually identifiable health information in: (5-8-09)

(1) Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1231(g)); (5-8-09)

(2) Records described at 20 U.S.C. Section 1231 (g)(4)(B)(iv); and (5-8-09)

(3) Employment records held by a licensee in its role as an employer. (5-8-09)

02. Collaborative Pharmacy Practice. Collaborative pharmacy practice is subject to the following requirements: (5-8-09)

a. Collaborative pharmacy practice agreement. A pharmacist planning to engage in collaborative pharmacy practice shall have on file at his place of practice the written collaborative pharmacy practice agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the collaborative pharmacy practice agreement including the agreement itself, shall be made available to the Board for review upon request. The agreement may allow the pharmacist, within the pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement, to conduct drug therapy management services approved by the practitioner and as defined by these rules. The collaboration that the practitioner agrees to conduct with the pharmacist must be within the scope of the practitioner's current practice. Patients or caregivers shall be advised of such agreement. (5-8-09)

b. Contents. The collaborative pharmacy practice agreement shall include: (5-8-09)

i. Identification of the practitioner and pharmacist who are parties to the agreement; (5-8-09)

ii. The types of drug therapy management decisions that the pharmacist is allowed to make; (5-8-09)

iii. A method for the practitioner to monitor compliance with the agreement and clinical outcomes and to intercede where necessary; (5-8-09)

iv. A provision that allows the practitioner to override a collaborative practice decision made by the pharmacist whenever he deems it necessary or appropriate; (5-8-09)

v. A provision that allows either party to cancel the agreement by written notification; (5-8-09)

vi. An effective date; and (5-8-09)

vii. Signatures of each collaborating pharmacist and practitioner who are parties to the agreement as well as dates of signing. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and dated. (5-8-09)

c. Initiation of the collaborative pharmacy practice agreement. The collaborative pharmacy practice agreement must be coupled with a medical order from the practitioner to initiate allowed activities for any particular patient. (5-8-09)

d. Documentation of pharmacist activities. Documentation of allowed activities must be kept as part of the patient's permanent record and must be readily available to other health care professionals providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered protected health information. (5-8-09)

e. Review. At a minimum, the written agreement shall be reviewed and renewed and, if necessary, revised every year. (5-8-09)

03. Independent Practice. A licensed pharmacist may provide pharmaceutical care outside of a licensed pharmacy if all of the following conditions are met: (3-29-10)

a. The pharmacist has access to prescription records, patient profiles, or other relevant medical information for purposes of pharmaceutical care and appropriately reviews such information before performing any such functions; (3-29-10)

b. Access to the information described in Paragraph 165.03.a. of these rules is secure from unauthorized access and use, and all access by pharmacists is documented; and (3-29-10)

c. A pharmacist providing pharmaceutical care outside of the premises of a licensed pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services or, if acting independent of a pharmacy, a secure system maintained by the pharmacist. Such records or information shall: (3-29-10)

i. Provide accountability and an audit trail; (3-29-10)

ii. Be provided to the Board upon request; and (3-29-10)

iii. Be preserved for a period of at least two (2) years from the date relied upon or consulted for the purposes of performing any such function. (3-29-10)

166. IMMUNIZATION RECORD.

01. Definitions. (4-7-11)

a. "Absolute Contraindication" means a situation that makes a particular treatment or procedure inadvisable. (4-7-11)

b. ACPE means the Accreditation Council for Pharmacy Education. (4-7-11)

c. AED means automated electronic defibrillator. (4-7-11)

d. AHA means American Heart Association. (4-7-11)

e. CDC means the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. (4-7-11)

f. "Compromised Patient" means an individual who may have an absolute or relative contraindication to receive immunizations. (4-7-11)

g. CPR means cardiopulmonary resuscitation. (4-7-11)

h. "Healthy Patient" means an individual with no contraindications to receive immunizations. (4-7-11)

i. IRIS means the Idaho Immunization Reminder Information System. (4-7-11)

j. "Relative Contraindication" means a condition that makes a particular treatment or procedure somewhat inadvisable but does not rule it out. (4-7-11)

k. VAERS means Vaccine Adverse Event Reporting System. (4-7-11)

02. Qualifications. (4-7-11)

a. A pharmacist may administer immunizations to healthy patients, and pursuant to a prescription drug order to compromised patients. (4-7-11)

b. To qualify to administer immunizations, a pharmacist must first; (4-7-11)

i. Successfully complete an ACPE accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the CDC's Advisory Committee on Immunization Practices and includes at least; (4-7-11)

(1) Basic immunology, vaccine and immunization protection; (4-7-11)

(2) Diseases that are preventable through vaccination and immunization; (4-7-11)

(3) Recommended immunization schedules; (4-7-11)

(3) Current recommended immunization schedules; (4-7-11)

(4) Vaccine and immunization storage and management; (4-7-11)

(5) Informed consent; (4-7-11)

(6) Physiology and techniques for administration of immunizations; (4-7-11)

(7) Pre-immunization and post-immunization assessment and counseling; (4-7-11)

(8) Immunization reporting and records management; and (4-7-11)

(9) Identification, response, documentation, and reporting of adverse events. (4-7-11)

ii. Hold a current certification in basic life support for healthcare providers (CPR and AED program) offered by AHA or any nationally recognized training program that follows AHA guidelines for said healthcare provider certification that includes AED training and requires hands-on skills assessment by an authorized instructor; (4-7-11)

c. Pharmacists qualified to administer immunizations must also annually complete a minimum of one (1) hour of ACPE approved continuing education related to vaccines, immunizations, or their administration within the continuing education required by Section 134 of these rules. (4-7-11)

d. The authority to administer immunizations may not be delegated; however, a registered student pharmacist that has satisfied the immunizing pharmacist qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. (4-7-11)

e. An immunizing pharmacist must maintain written policies and procedures for disposal of used or contaminated supplies. (4-7-11)

f. An immunizing pharmacist must report: (4-7-11)

i. Any adverse events to the health care provider identified by the patient, if any, and to the VAERS. (4-7-11)

ii. Any applicable immunization to IRIS. (4-7-11)

03. Immunization Administration. Immunizations must be administered pursuant to the latest recommendations issued by the CDC or other qualified government authorities. A pharmacist must have a current copy of, or on-site access to, the CDC's "Epidemiology and Prevention of Vaccine-Preventable Diseases." (4-7-11)

04. Vaccine Information Statement. A current CDC-issued Vaccine Information Statement corresponding to the vaccine administered must be provided to the patient or the patient's representative for each immunization administered. (4-7-11)

05. Recordkeeping. For each immunization administered, the following information must be maintained in the patient profile: (4-7-11)

a. The name, address, allergies, and date of birth of the patient; (4-7-11)

b. The date of administration; (4-7-11)

c. The product name, manufacturer, dose, lot number, and expiration date of the vaccine; (4-7-11)

d. Documentation identifying the Vaccine Information Statement provided; (4-7-11)

e. The site and route of administration and the dose in series, if applicable; (4-7-11)

f. The name of the patient's health care provider, if any; (4-7-11)

g. The names of the immunizing pharmacist and student pharmacist, if any; (4-7-11)

h. Any adverse events encountered; (4-7-11)

i. The date on which an adverse event was reported to the patient's health care provider, if any; and (4-7-11)

j. Completed informed consent forms. (4-7-11)

06. Emergencies. (4-7-11)

a. An immunizing pharmacist must maintain a immediately-retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. (4-7-11)

b. An immunizing pharmacist may initiate and administer auto-inject epinephrine, injectable diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association (APhA). (4-7-11)

167. -- 175. (RESERVED).

176. POISONS.

01. Definition -- Poison. A poison is any substance that when applied to the body, either internally or externally, is capable of destroying the action of vital functions. (7-1-93)

02. Packaging of Poisons. In addition to meeting all the requirements of the Federal Food, Drug and Cosmetic Act of 1938; the Poison Prevention Packaging Act of 1970; and the Idaho Food, Drug and Cosmetic Act

relevant to repackaging and distributing items included by definition or listed as poisons, the pharmacist must comply with the following rules: (7-1-93)

a. Any poison item sold as a non-prescription, over-the-counter transaction must be in unopened, properly labeled (including name and strength of contents, warning, antidote, and name of distributor) manufacturer's or distributor's containers. Such sales are permitted without recordkeeping requirements. (7-1-93)

b. All sales of prepackaged items defined as poisons shall: (7-1-93)

i. Be sold only to persons at least eighteen (18) years of age; (7-1-93)

ii. Be placed in a suitable container with a safety closure; and (7-1-93)

iii. Be labeled with the name and strength of contents, antidote, warning statements, and the name and address of the pharmacy distributing the item. (7-1-93)

c. All sales of poisons in repackaged containers require entry in a POISON REGISTER, which is a bound book containing at least the following information: (7-1-93)

i. Signature and age of purchaser; (7-1-93)

ii. Time and date of sale; (7-1-93)

iii. Item sold and quantity; (7-1-93)

iv. Intended use of item; and (7-1-93)

v. Signature (initials) of pharmacist. (7-1-93)

d. The Poison Register must be maintained in the pharmacy during its use and for three (3) years after the date of the last sale. (7-1-93)

03. List of Poisons. The following list of poisons is not considered exhaustive and is subject to change: (7-1-93)

a. All acids capable of destroying vital human functions; (7-1-93)

b. Arsenic, its salts and compounds; (7-1-93)

c. Mercury, its salts and compounds; (7-1-93)

d. Cyanide, its salts and compounds; (7-1-93)

e. Phenol and phenolic preparations; (7-1-93)

f. Potassium or sodium hydroxide and their compounds; (7-1-93)

g. Silver nitrate and its preparations; (7-1-93)

h. Strychnine and strychnine salts; and (7-1-93)

i. Chloroform and related compounds. (7-1-93)

177. LIMITED SERVICE PHARMACIES.
Pharmacists proposing to operate retail drug outlets that are not community pharmacies but limit the types of drug orders that may be filled shall submit lists of suggested equipment and drug stocks to the Board with the application for pharmacy registration. The Board, or its designee, shall review the lists and either approve or deny the equipment

and stocks contained therein. No pharmacy registration application may be granted for such a pharmacy until the lists of equipment and stocks are approved. The rules applicable to institutional and retail pharmacies, where appropriate, may be applied to such limited service pharmacies. All required equipment and stock are to be maintained on a continuing basis. (7-1-93)

178. PHARMACIES, PARENTERAL ADMIXTURE.

01. Definition -- Parenteral Admixture. Parenteral admixture is the preparation and labeling of sterile products intended for intravenous or intramuscular administration. (7-1-93)

02. General Requirements for Parenteral Admixture. (7-1-93)

a. The environment for this type of practice shall be set apart, designed and equipped to facilitate aseptic techniques and conditions. (7-1-93)

b. The Board must be notified prior to construction of such pharmacies to allow approval of floor plans per Section 156 of these rules. (7-1-93)

c. A registration separate from the regular pharmacy registration is required of all such pharmacies prior to opening and after inspection by the Board. (7-1-93)

d. A policy and procedure manual must be available at the time of initial inspection and at the annual inspection that shows proper procedures and techniques for the protection of the employee and the safety of the patient. (7-1-93)

e. Such pharmacies shall be under the supervision and control of a licensed pharmacist. (7-1-93)

03. Equipment for Parenteral Admixture. (7-1-93)

a. A sink with hot and cold water in close proximity to the hood; (7-1-93)

b. A laminar airflow hood or other appropriate environmental control device capable of maintaining a compounding area environment equivalent to "Class 100 conditions" as described in the Federal Standard 209 Clean Room and Work Station Requirements; (7-1-98)

c. A refrigerator for proper storage of additives and finished parenteral products prior to delivery when necessary; (7-1-93)

d. All library requirements in Section 154 of these rules plus the most recent copy of "*Handbook of Injectable Drugs*" by Lawerence A.Trissel; (7-1-93)

e. A separate vertical flow biohazard safety hood is required, if hazardous materials are prepared; and (7-1-93)

f. All supplies necessary for handling both hazardous and biohazardous spills and disposal of wastes shall be available and maintained in the area at all times. (7-1-93)

04. Distribution and Control of Prescriptions. (7-1-93)

a. Proper prescription files with all required information shall be maintained. (7-1-93)

b. In addition to the requirements for other prescriptions, labels shall include the name and amounts of additives and the diluent, storage requirements and an expiration date and time. (7-1-93)

05. Quality Control of Equipment. (7-1-93)

a. All equipment monitoring and maintenance must be documented. (7-1-93)

b. All hoods shall be certified as often as recommended by the manufacturer or at least annually. (7-1-93)

179. PHARMACIES, DEPOT.
No licensed pharmacist shall participate in any arrangement or agreement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not licensed as a pharmacy. (7-1-93)

01. Application. This prohibition applies to both the prescription order blank and the completed prescription medication container. (7-1-93)

02. Other. Nothing in this rule shall prohibit a licensed pharmacist or a licensed pharmacy, by means of its employee or by use of a common carrier, from picking up prescriptions or delivering prescriptions at the office or home of the prescriber, at the residence of the patient, or at the hospital or medical care facility in which a patient is confined. (7-1-93)

180. DIFFERENTIAL HOURS.

01. Security at Pharmacy. A pharmacy must provide adequate security for its drug supplies, equipment, and records and in the absence of a pharmacist, the pharmacy must be closed. If a pharmacy is located within a larger business establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy must be totally enclosed by a partition, such as a glass or metal mesh screen or a security fence, that is sufficient to provide adequate security for the pharmacy, as approved by the Board or its representatives. In the absence of a pharmacist, the pharmacy must be locked. Employees of the business establishment may not be authorized to enter the closed pharmacy during those hours that the business establishment is open to the public for business. (7-1-93)

02. Equipment, Records, Drugs, and Other Items. All equipment and records referred to in these rules and all drugs, devices, poisons, and other items or products that are restricted to sale either by or under the personal supervision of a pharmacist must be kept in the pharmacy area. (7-1-93)

03. Prescription Orders and Refill Requests. Written prescription orders and refill requests can be delivered to a pharmacy at any time. If no pharmacist is present, the prescription orders must be deposited by the patient, or his agent delivering the prescription order or refill request, into a "mail slot" or "drop box" that deposits the prescription order into the pharmacy area. The times that the pharmacy is open for business must be displayed in a manner that is prominently visible to the person depositing the prescription order. (7-1-93)

04. Storage of Prescriptions. Prescriptions shall be stored in the pharmacy and cannot be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place. (7-1-93)

05. Sale Restrictions. No drugs, devices, poisons, or other items or products that are restricted to sale either by or under the personal supervision of a pharmacist may be sold or delivered without a pharmacist being present in the pharmacy. (7-1-93)

06. Separate Telephone. Any pharmacy having hours differing from the remainder of a business shall have a separate and distinct telephone number from that of the business. The telephone shall not be answerable in the remainder of the establishment unless all telephone conversations during a pharmacist's absence are recorded and played back by the pharmacist. (7-1-93)

07. Oral Prescriptions. An oral prescription may not be accepted if the pharmacist is not present unless the prescription is taken on a recording that must inform the caller of the times the pharmacy is open. (7-1-93)

08. Hours Open for Business. A pharmacy must notify the Board, on a form prescribed by the Board, of the hours that the pharmacy is open for business. Any pharmacy desiring to change the hours that it is open for business, must notify the Board, on a form prescribed by the Board, at least seven (7) days prior to commencing such

hours. A pharmacy desiring to change its hours for a holiday as set forth in Section 73-108, Idaho Code, does not need to provide notice of the changes to the Board, but must provide at least seven (7) days notice to the public. A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the hours it is open for business. A pharmacy must remain open for business the hours for which the Board has received such notification and that are prominently displayed. A pharmacy must maintain sufficient staffing by pharmacists in order to ensure that the pharmacy will be open during the hours of operation for which the pharmacy provided notice to the Board. If a pharmacy is located within a larger business establishment that has hours of operation different from the pharmacy, the hours the pharmacy is open for business shall be prominently displayed, in a permanent manner, at the pharmacy area and on, or adjacent to, the entrance to the mercantile establishment. (3-29-10)

09. Advertising. Any advertising by the business establishment that references the pharmacy or products sold only in the pharmacy, and that includes the hours that the business establishment is open to the public for business, must also indicate the hours that the pharmacy is open to the public for business. (7-1-93)

10. Notification to the Board of Differential Hours. Any person desiring to operate a pharmacy within an establishment having hours of business differing from the pharmacy, must notify the Board at least thirty (30) days prior to commencing such differential hours. To constitute notification, the applicant must complete and file the form provided by the Board with the required information. Board inspection and approval shall be completed prior to commencing differential hours. The inspection and approval or disapproval shall be completed within ten (10) days of receiving notification that the premises are ready for inspection. Approval or disapproval shall be predicated upon compliance with this rule and the pharmacy minimum standards set forth in Section 151 of these rules. (7-1-93)

181. RECORD KEEPING, ALTERNATE SYSTEMS.

01. Automated Record Keeping System. An automated data processing system may be used for the storage and retrieval of refill information for prescription orders, only in the pharmacy with the original on file pursuant to Section 162 of these rules, subject to the following conditions: (7-1-93)

a. Any such proposed computerized system must provide on-line retrieval (via CRT display or hardcopy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. (7-1-93)

b. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner for Schedule III and IV controlled substances, and the name, strength, dosage form, quantity prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner. (7-1-93)

02. On-Line Retrieval of Records. Any proposed computerized system must also provide on-line retrieval (via CRT display or hardcopy printout) of the current refill history of prescription orders, including refill authorization for Schedule III and IV controlled substances for the past six (6) months, and for other drugs for the past year. This refill history shall include, but is not limited to, the name of the drug, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order. (7-1-93)

03. Documentation That Entered Refill Information Is Correct. Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order is correct must be provided by the individual pharmacist who makes use of such system. (7-1-93)

a. If such a system provides a hardcopy printout of each day's prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. (7-1-93)

b. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (for example, J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of three (3) years from the dispensing

date. (7-1-93)

c. This printout of the day's prescription order refill data must be provided to each pharmacy using such a computerized system within seventy-two (72) hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. (7-1-93)

d. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. (7-1-93)

e. Such a book or file must be maintained at the pharmacy employing such a system for a period of three (3) years after the date of dispensing the appropriately authorized refill. (7-1-93)

04. Capability to Produce Refill Data. Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining, for example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any drug (by either brand or generic name or both). (7-1-93)

a. Such a printout must indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. (7-1-93)

b. In any computerized system employed by a user pharmacy the central record keeping location must be capable of sending the printout to the pharmacy within forty-eight (48) hours, and if a Board inspector or peace officer or a DEA special agent or compliance investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by such an investigator verify the printout transmittal capability of its system by documentation (for example, post-mark). (7-1-93)

05. Computer System Down-Time. In the event that a pharmacy which employs such a computerized 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 data entry as soon as the computer system is available for use again. (7-1-93)

06. Filing Refill Information. When filing refill information for original prescription orders, a pharmacy may use only one (1) of the two (2) systems described in Subsections 108.01 or 181.02 of these rules. (7-1-93)

07. Application for Permit. Any registrant who intends to use a system provided by Subsection 181.06 of these rules must first apply for a permit from the DEA to maintain central records as required by 21 CFR 1304.04 (A). (7-1-93)

08. Recording of Prescription Order. A pharmacist shall continue to record the filling of the original prescription order on the front, and refills on the back of the prescription order blank, as required in these rules. (7-1-93)

09. Revocation of Approval of Computer Use. The Board reserves the right to revoke the approval of the use of a computer for cause. (7-1-93)

182. DRUGS, USE OF TERMS IN SALE.

It shall be unlawful for any person who is not legally licensed as a pharmacist under the laws of the state of Idaho or any person, firm, or corporation who does not have in continuous employ at each place of business a pharmacist licensed under the laws of the state of Idaho and in good standing to take, use, or exhibit the title or descriptive term "drug," "drugs," "drugstore," "pharmacy," or "apothecary," or any combination of such titles or descriptive terms or any title or any description of like import or any term designated to take the place of such title or descriptive term. (7-1-93)

183. PRESCRIBER, CHANGE OF STATUS.
Following the death of the prescriber, surrender or termination of the prescriber's license, or permanent relocation of the prescriber that precludes a continued patient-prescriber relationship, a valid prescription or drug order of record in Idaho shall remain valid only to the extent necessary to ensure the continuity of care that will best serve the medical needs of the patient. (2-23-94)

01. Advising Patient of Change of Status. A pharmacist who becomes aware of any of the events referenced in these rules shall advise the patient to the resultant change concerning the status of the prescription, advise the patient to engage a physician, and provide only that amount of prescribed medication necessary to ensure the short-term continuity of care that will best serve the needs of the patient. (7-1-93)

02. Knowledge of Change of Status. A pharmacist shall not dispense, refill, or provide medication in accordance with these rules that is in violation of state or federal law restricting the dispensing or refilling of controlled substances or legend drugs. In no event shall a pharmacist provide medication hereunder beyond ninety (90) days after learning of any of the events referenced in these rules. (7-1-93)

03. Prescription Order Becomes Null and Void. After the expiration of the period necessary to ensure the continuity of care or ninety (90) days, whichever comes first, the prescription or drug order shall be null and void. Failure to act in the manner prescribed herein will constitute unprofessional conduct and subject the pharmacist to penalties pursuant to Section 54-1726, Idaho Code. (7-1-93)

184. UNPROFESSIONAL CONDUCT.
The following acts or practices by a licensed pharmacist or a pharmacy owner declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest: (7-1-93)

01. General. Manufacturing, compounding, selling, or dispensing or permitting to be manufactured, compounded, sold, or dispensed substandard drugs or preparations. (7-1-93)

02. Secret Formulas. Using secret formulas. (7-1-93)

03. Prescriber Incentives. Allowing a commission or rebate to be paid to a person writing, making, or otherwise ordering a prescription, or providing consultant services at no charge to receive prescription business. (7-1-93)

04. Prescription Order Noncompliance. Failing to strictly follow the instructions of the person writing, making, or ordering a prescription as to refills, contents, or label, or giving a copy of a prescription to any person without marking said prescription across the face: "Copy for Information Only. Not to Be Filled," except that a pharmacist, utilizing his best professional judgment, may provide up to a three-month supply of a legend drug that is not a controlled substance when the practitioner has written a drug order to be filled with a smaller supply but which includes refills in sufficient numbers to fill a three-month supply. (3-29-10)

05. Errors or Omissions. Failing to confer with the person writing, making or ordering a prescription, if there is an error or omission therein which should be questioned. (7-1-93)

06. False or Deceptive Advertising. Advertising in a manner that is false, misleading or deceptive, which includes making material claims of professional superiority that cannot be substantiated. (7-1-93)

07. Addiction. Being addicted or habituated to the use of alcohol or controlled substances. (7-1-93)

08. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices, legally sold in pharmacies, that allows unqualified persons to circumvent laws pertaining to the legal sale of such articles. (7-1-93)

09. Fraudulent Practice. Performing, or in any way being a party to, any fraudulent or deceitful practice or transaction. (7-1-93)

10. Incompetency and Negligence. Performing duties as a pharmacist or pharmacy owner in an incompetent, unskilled, or negligent manner. (7-1-93)

11. Unprofessional Conduct. Exhibiting unprofessional conduct toward customers, employees, colleagues, inspectors or others. (7-1-93)

12. Insubordination. Failure to follow an order of the Board. (2-23-94)

13. Inappropriate Conduct. Any activity by a pharmacist that is inappropriate to the conduct of the profession of pharmacy. (2-23-94)

14. Disciplinary Actions in Other States. Conduct that results in a suspension, revocation or other disciplinary proceeding or action with respect to a pharmacy or pharmacist license that the Idaho licensee holds in another state. (7-1-98)

15. Reporting Theft, Loss, or Adulteration. Failure of any pharmacist-in-charge or pharmacy director to report any theft or loss of controlled substances or any adulteration of a prescription drug to the Board, even if the theft, loss, or adulteration was accounted for and the employee was disciplined by the employer. (4-6-05)

16. Cooperating in an Investigation. Failure of any licensee to cooperate with a disciplinary investigation. (4-6-05)

185. PRODUCT SELECTION DEFINITIONS.

01. Substitution of Drug Products. The dispensing or causing to be dispensed a drug product other than ordered or prescribed without the express permission of the orderer, or, for a prescription, the prescriber. (8-4-94)

02. Drug Product Selection. The act of selecting either the brand or a therapeutically equivalent generic drug product. (7-1-93)

03. Bioavailability. The rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action. (7-1-93)

04. Bioequivalence. A situation in which pharmaceutical equivalent or pharmaceutical alternative drug products display comparable bioavailability when studied under similar experimental conditions. For example, equivalent (molar) doses of the therapeutic component (moiety) of such drugs similarly studied are bioequivalent when their rate and extent of absorption are not significantly different. Bioequivalence may also be demonstrated on in vitro bioequivalence standard when such an in vitro test has been correlated with human in vitro bioavailability data. (7-1-93)

05. Pharmaceutical Equivalents. Drug products that contain the same active ingredients and are identical in strength or concentration and route of administration. Pharmaceutically equivalent drug products, sometimes referred to as chemical equivalents, are formulated to contain the same amount of active ingredient to meet the same or comparable standards (such as identity, strength, purity, and quality), but may differ in characteristics such as color, taste, shape, packaging, preservatives, expiration time, and within certain limits, labeling. (8-4-94)

06. Pharmaceutical Alternatives. Drug products that contain the same therapeutic moiety but differing in the salt or ester of that moiety in the dosage form, or strength (for example, tetracycline hydrochloride two hundred and fifty (250) mg capsules vs. tetracycline phosphate complex two hundred and fifty (250) mg capsules or quinidine sulfate two hundred (200) mg tablets vs. quinidine sulfate two hundred (200) mg. capsules). Different dosage forms and strengths within a product line by a single manufacturer are thus pharmaceutical alternatives, as are controlled release products when compared with conventional formulations of the same active ingredient. (7-1-93)

186. THERAPEUTIC EQUIVALENTS.

01. Pharmaceutical Equivalents. Drug products considered to be therapeutic equivalents are pharmaceutical equivalents and can be expected to have the same therapeutic effect when administered to patients under the conditions specified in the labeling. (7-1-93)

a. Therapeutic equivalence applies only to products containing the same active ingredients and does not encompass a comparison of different therapeutic agents used for the same conditions (for example, propoxyphene hydrochloride vs. pentazocine hydrochloride for the treatment of pain). (7-1-93)

b. The Board evaluates as therapeutically equivalent those drug products that meet the following general criteria: (7-1-93)

i. They are pharmaceutical equivalents in that they contain identical amounts of the same active drug ingredients in the same dosage form and meet compendial or other applicable standards of identity, strength, quality, and purity; (7-1-93)

ii. They are bioequivalent in that they do not present a known or potential bioequivalence problem or, if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; and (7-1-93)

iii. They are adequately labeled and are manufactured under conditions that, at a minimum, comply with FDA Current Good Manufacturing Practice Regulations. (7-1-93)

02. Therapeutically Equivalent Drug Product Selection Criteria. The Board considers drug products to be therapeutically equivalent if they meet the criteria of Subsection 186.01.b. despite differences in other characteristics: for example, color, flavor, packaging, preservatives, expiration time, and minor aspects of labeling. (7-1-93)

a. When such differences are important in the care of a particular patient, it is appropriate for the prescribing physician to require that a particular brand be dispensed as a medical necessity. (7-1-93)

b. As long as this consideration is met, however, Board believes that products considered therapeutically equivalent can be selected with the full expectation that the selected product will produce the same therapeutic effect as the prescribed product. (7-1-93)

03. Controlled Release Dosage Formulations. (7-1-93)

a. Controlled release dosage formulations are subject to bioavailability and bioequivalence differences, primarily because different manufacturers that develop controlled release products for the same active ingredient rarely employ the same approach to formulating their controlled release products. (7-1-93)

b. The Board does not evaluate different controlled release dosage formulations containing the same active ingredient in equal strength but from different manufacturers as bioequivalent unless equivalence between individual products has been specifically demonstrated through appropriate bioequivalence studies. (7-1-93)

187. PROHIBITED ACTS - DRUG PRODUCT SUBSTITUTION.

01. Substitution Prohibition. Drug Product substitution is prohibited and is grounds for revocation of a pharmacist's license pursuant to Section 54-1726, Idaho Code, and a drug outlet's registration pursuant to Section 54-1732, Idaho Code. (6-1-94)

02. Substitution Prohibition Exception. Substitutions are allowed only in situations requiring compliance with a formulary or drug list prepared by: (5-8-09)

a. The pharmacy and therapeutics committee of a hospital and agreed to by the staff physicians of the hospital. (5-8-09)

b. The quality assessments and assurance committee of a skilled nursing facility, consisting of the

director of nursing services, a physician designated by the facility, and at least three (3) other members of the facility's staff. For purposes of this rule, a "skilled nursing facility" means an institutional facility, or a distinct part of an institutional facility, which is primarily engaged in providing daily skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for injured, disabled or sick persons. (5-8-09)

188. DRUG PRODUCT SELECTION.
Drug product selection is allowed only between bioequivalent products. (7-1-93)

01. Method of Drug Product Selection. For non-Medicaid patients a brand must be dispensed only if the prescriber has indicated "BRAND ONLY" by checking the appropriate box on the face of the prescription. (4-11-06)

02. Sign. The pharmacy must have a sign posted, readily visible, stating:

"IT MAY BE POSSIBLE TO USE AN EQUIVALENT BUT LESS EXPENSIVE DRUG TO FILL YOUR PRESCRIPTION PROVIDED YOUR PRACTITIONER WILL PERMIT DRUG PRODUCT SELECTION BY THE PHARMACIST. PLEASE CONSULT YOUR PHARMACIST OR PRACTITIONER FOR MORE INFORMATION." (7-1-93)

03. Consumer's Right of Refusal. The consumer shall have the right to refuse generic equivalents when product selection has been allowed by the practitioner. (7-1-93)

04. Labeling. Unless the prescriber indicates "Do not label," the pharmacist shall label the prescription with the brand name dispensed or, if filled with a generic, the name of the drug and the manufacturer. In addition, he must indicate the same information on the face of the prescription. (7-1-93)

05. Definition of Drug Product Selection. Drug product selection is the act of selecting either the brand or a therapeutically-equivalent generic drug product and is permitted in the state of Idaho. (7-1-93)

06. Coercion. In no way shall the employer coerce an employee pharmacist to engage in product selection if the above provisions are not fulfilled. (7-1-93)

189. ADVERTISING.

01. Legality. It is unlawful for any person or drug outlet licensed or registered under Title 54, Chapter 17, Idaho Code, to disseminate or cause to be disseminated any form of public communication containing a false, misleading, or deceptive statement or claim for the purpose of, or likely to induce either directly or indirectly, the rendering of professional services or the furnishing of products in connection with the professional practice or business for which the license or registration was issued. (7-1-93)

02. Statements. A false, fraudulent, misleading or deceptive statement of claim includes a statement or claim that does any of the following: (7-1-93)

a. Contains a misrepresentation of facts; (7-1-93)

b. Is likely to mislead or deceive due to a failure to disclose material facts; (7-1-93)

c. Is intended or is likely to create unjustified expectations of favorable results; or (7-1-93)

d. Relates to cost without fully and specifically disclosing all variables and other material factors. (7-1-93)

03. Price Advertising. Price advertising shall not be fraudulent, misleading or deceitful. The price advertised for products shall include charges for any related services, including dispensing and delivery services, unless the advertisement indicates otherwise. (7-1-93)

04. Advertisement of Prescription Drug. An advertisement of the retail price for a drug that requires a prescription shall be limited to quantities of the drug that are consistent with good medical practice and shall include the strength, dosage form, and the exact dates during which the advertised price will be in effect. (7-1-93)

05. Information Required in Prescription Drug Advertising. In prescription drug advertising, the following information is required: (7-1-93)

a. The drug's brand name, if any. (7-1-93)

b. The established or generic name. (7-1-93)

c. The drug's strength if the product contains a single active ingredient or, if the product contains more than one active ingredient, a relative strength may be assigned without listing all ingredients. Products with multiple active ingredients without special identification may be listed by brand name without strength for any ingredients. (7-1-93)

d. Dosage form. (7-1-93)

e. Price charged for specific quantity of the drug product. (7-1-93)

f. Manufacturer's name. (7-1-93)

06. Violations. A violation of any provision of this Section by a person or facility so licensed or registered shall constitute cause for revocation, suspension of license or registration, or other disciplinary action pursuant to Section 54-1728, Idaho Code. (7-1-93)

190. INSPECTION REPORTS AND CITATIONS.
A person to whom a license or registration has been issued shall retain copies of inspection reports and citations issued by inspectors or investigators in the performance of their regular duties and shall maintain such reports and citations on the licensed premises in such a manner as to make them readily available upon request of the Board for a period of two (2) years or until destruction is authorized. (7-1-93)

191. INACTIVE STATUS LICENSE.
An inactive status pharmacist license may be issued by the Board for a fee set by the Board. (8-4-94)

01. Requirements for Inactive License. The inactive license may be offered in circumstances in which the applicant: (8-4-94)

a. Is a registered pharmacist in the state of Idaho; (8-4-94)

b. Is at least sixty-five (65) years of age or unable to practice pharmacy because of a physical disability; and (7-1-97)

c. Has completed the required application. (7-1-97)

02. Inactive Status Licenses. Inactive status licensees are exempt from continuing education requirements and are prohibited from engaging in the practice of pharmacy while on inactive status. (8-4-94)

03. Return to Active Status. If an inactive status licensee wishes to return to active status, the licensee shall: (7-1-97)

a. Take a practical examination or serve an internship approved by the Board under a licensed pharmacist at a licensed preceptor site; (7-1-97)

b. Take and pass the Board jurisprudence examination; (8-4-94)

c. Complete thirty (30) hours of continuing education; (8-4-94)

d. Pay a reinstatement fee as set by the Board; and (8-4-94)

e. Make an appearance before the Board. (8-4-94)

192. -- 250. (RESERVED).

251. PHARMACY TECHNICIANS.

01. Definitions. (5-8-09)

a. Pharmacy Technician. Means an individual who is registered with the Board and who may, under the supervision of a licensed pharmacist, assist in the pharmacy and perform such functions in connection with the preparing, compounding, distribution or dispensing of medications as are routine, do not require the professional judgment of a licensed pharmacist, and are within the individual's training. (5-8-09)

b. Pharmacy Technician in Training. Means an individual who registers with the Board subsequent to June 30, 2009, as a pharmacy technician in training and who may, under the supervision of a licensed pharmacist, assist in the pharmacy and perform any of the duties of a registered pharmacy technician during the one-year period of registration. Registration as a pharmacy technician in training may be renewed once for a consecutive one-year period. (5-8-09)

02. Responsibility of Pharmacy and Pharmacist-in-Charge -- Assignment of Functions. (5-8-09)

a. The pharmacy and the pharmacist-in-charge are each responsible for all aspects of the sale at retail and the dispensing of medications, drugs, devices, and other materials at the pharmacy, including the preparing, compounding, distribution or dispensing of medications. No pharmacy or pharmacist-in-charge shall assign to, or permit performance by, any person, other than a registered pharmacy technician, registered pharmacy technician in training, registered student pharmacist, or licensed pharmacist, of any functions connected to the preparing, compounding, distribution or dispensing of medications at the pharmacy. Except as otherwise provided by this rule, no pharmacy or pharmacist-in-charge shall permit any person other than a licensed pharmacist, registered student pharmacist, registered pharmacy technician, or registered pharmacy technician in training to work in the secured area of the pharmacy where medications are prepared, compounded, distributed, dispensed, or stored. The pharmacy or pharmacist-in-charge may authorize other persons to be present temporarily in the secured area of the pharmacy for legitimate business purposes, provided that such persons during their temporary presence in the secured area of the pharmacy are under the observation of the pharmacist-in-charge or another pharmacist designated by the pharmacist-in-charge or the pharmacy. (5-8-09)

b. The pharmacy or the pharmacist-in-charge may assign to, or allow performance by, a registered pharmacy technician or registered pharmacy technician in training only those functions connected with the preparing, compounding, distribution or dispensing of medications, which meet all of the following criteria: (5-8-09)

i. The function is routine; (4-5-00)

ii. The function is one for which the pharmacy technician or pharmacy technician in training is adequately trained and supervised; and (5-8-09)

iii. The function does not require the use of a licensed pharmacist's professional judgment. (4-5-00)

c. Only a registered pharmacist may do any of the following (which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a licensed pharmacist's professional judgment): (4-5-00)

i. Receive a new prescription order verbally from a prescriber or other person authorized by law. (4-5-00)

ii. Perform evaluations and interpretations of a prescription and any needed clarifications prior to filling. (4-5-00)

iii. Consult with the prescriber concerning any necessary clarification regarding a patient and his prescription. (4-5-00)

iv. Interpret any clinical data in a patient's medication record system (for example, drug usage, refill frequency, drug interactions, etc.) (7-1-93)

v. Perform professional consultation with any prescriber, nurse or other health care professional. (7-1-93)

vi. Supervise the packaging of drugs and check the completed procedure and product. (7-1-93)

vii. Issue the new prescription to the patient or his agent with consultation. (7-1-93)

viii. Supervise the activities of pharmacy technicians and pharmacy technicians in training to insure that all such activities are performed completely, safely and without risk or harm to patients. (5-8-09)

d. A violation of the rules on pharmacy technicians and pharmacy technicians in training by a pharmacist or a pharmacy is unprofessional conduct, and is grounds for revocation or suspension of the pharmacist's license or the pharmacy registration, or both, issued under Sections 54-1722, 54-1723, 54-1724 or 54-1729, Idaho Code, or other appropriate disciplinary action. (5-8-09)

03. Supervision. Where a pharmacy technician or pharmacy technician in training performs one (1) or more functions in connection with the preparing, compounding, distribution or dispensing of medications, the pharmacy technician or pharmacy technician in training shall be under the supervision of a licensed pharmacist who, in addition to the pharmacy and the pharmacist-in-charge, shall be responsible for all aspects of the filled prescription including, but not limited to, the following: (5-8-09)

a. Verifying drug selection, strength, dosage form and labeling against the prescription and the contents of stock container. (7-1-93)

b. Verifying selection of the proper prescription container. (7-1-93)

04. Ratio. The ratio of pharmacists to the total of student pharmacists, pharmacy technicians and pharmacy technicians in training shall not exceed one (1) pharmacist for every six (6) student pharmacists, pharmacy technicians and pharmacy technicians in training in total in any practice setting; provided, however, that no pharmacy or pharmacist-in-charge shall operate the pharmacy or allow operation of the pharmacy with a ratio, nor shall any pharmacy require a pharmacist-in-charge or any other pharmacist to operate the pharmacy or allow operation of the pharmacy with a ratio, which, under the circumstances of the particular practice setting, results in, or reasonably would be expected to result in, an unreasonable risk of harm to public health, safety, and welfare. Violation of Subsection 251.04 of these rules by a pharmacist-in-charge shall be grounds for suspension, revocation or restriction of the pharmacist-in-charge's license. Violation of Subsection 251.04 of these rules by a pharmacy shall be grounds for suspension or revocation of the pharmacy's registration. (5-8-09)

05. Responsibility of Technicians and Grounds for Discipline. (5-8-09)

a. Pharmacy technicians and pharmacy technicians in training shall perform all functions properly assigned to them with all necessary care. No pharmacy technician or pharmacy technician in training shall accept assignment of, or perform, any functions connected with the preparing, compounding, distribution or dispensing of medications unless such pharmacy technician or pharmacy technician in training is employed or otherwise authorized by the assigning pharmacy and such function meets all of the criteria set forth in Paragraph 251.02.b. of these rules. (5-8-09)

b. The Board may initiate proceedings against pharmacy technicians or pharmacy technicians in training who perform such tasks or functions connected with the preparing, compounding, distribution or dispensing

of medications: (5-8-09)

i. That are not routine functions; (4-5-00)

ii. That the pharmacy technician or pharmacy technician in training is not adequately trained and supervised for; or (5-8-09)

iii. That require the use of a licensed pharmacist's professional judgment. Such persons may be charged by the appropriate authorities with practicing pharmacy without a license in violation of Section 54-1726, Idaho Code. (4-5-00)

c. The Board may refuse to issue or renew, or may suspend, revoke, or restrict the pharmacy technician registration of an individual upon one (1) or more of the following grounds: (5-8-09)

i. Unprofessional conduct as the term is defined in these rules. (5-8-09)

ii. Incapacity of a nature that prevents an individual from performing the functions of a pharmacy technician with reasonable skill, competence, and safety to the public. (5-8-09)

iii. Being found guilty, convicted, or having received a withheld judgment or suspended sentence by a court of competent jurisdiction in this state or any other state for one (1) or more of the following: (5-8-09)

(1) A felony; (5-8-09)

(2) An act involving moral turpitude, gross immorality, or that relates to the qualifications, functions, or duties of a pharmacy technician; or (5-8-09)

(3) A violation of the pharmacy or drug laws of this state, these rules, or of statutes, rules, or regulations of any other state or of the federal government. (5-8-09)

iv. Fraud or intentional misrepresentation by a registrant in securing the issuance or renewal of a pharmacy technician registration. (5-8-09)

v. Being found by the Board to be in violation of any of the provisions of Title 54, Chapter 17, Idaho Code, Title 37, Chapter 27, Idaho Code, or of these rules. (5-8-09)

d. Pharmacy technicians in training are subject to discipline by the Board under Paragraph 251.05.c of these rules to the same extent and in the same manner as pharmacy technicians. The provisions of Subsection 251.08 of these rules apply to disciplinary proceedings against a pharmacy technician in training. (5-8-09)

06. Identification of Pharmacy Technicians and Pharmacy Technicians in Training. (5-8-09)

a. All pharmacy technicians and pharmacy technicians in training working as such in community pharmacies must be identified by a name badge designating that person as a pharmacy technician or pharmacy technician in training, as applicable. The name badge must measure no less than one (1) inch by three (3) inches and must contain the individual's printed name directly above the title of pharmacy technician or pharmacy technician in training, as applicable. The identification badge must be clearly visible at all times. Pharmacy technicians and pharmacy technicians in training working in an institutional setting may be exempt from the above requirement only if the institution requires a specific badge of identification to be worn by the pharmacy technician and pharmacy technician in training. (5-8-09)

b. All pharmacy technicians and pharmacy technicians in training must identify themselves as a pharmacy technician or pharmacy technician in training, as applicable, on any phone calls initiated or received by them while performing pharmacy functions. (5-8-09)

07. Registration of Pharmacy Technician and Pharmacy Technician in Training, Certification, and Exceptions. (5-8-09)

a. Annual Renewal of Pharmacy Technician Registration. All pharmacy technicians shall register annually with the Board, shall meet all the requirements for registration as a pharmacy technician, shall submit the annual renewal application in the form prescribed by the Board, and shall pay the annual pharmacy technician registration renewal fee specified by the Board. (5-8-09)

b. Registration of Pharmacy Technician. No person shall commence duties at a pharmacy as a pharmacy technician unless registered by the Board as a pharmacy technician. To be registered as a pharmacy technician, a person must satisfy all of the following: (5-8-09)

i. For registration prior to July 1, 2009, a person must: (5-8-09)

(1) Be at least eighteen (18) years of age, unless a waiver is granted by the Board's executive director; (5-8-09)

(2) Be a high school graduate or the recipient of a high school equivalency diploma, unless a waiver is granted by the Board's executive director; (5-8-09)

(3) Be of good moral character and temperate habits; (5-8-09)

(4) Have submitted a written application in the form prescribed by the Board; and (5-8-09)

(5) Have paid the registration fee specified by the Board. (5-8-09)

ii. For registration subsequent to June 30, 2009, unless excepted by these rules, a person must: (5-8-09)

(1) Be at least eighteen (18) years of age, unless a waiver is granted by the Board's executive director; (5-8-09)

(2) Be a high school graduate or the recipient of a high school equivalency diploma, unless a waiver is granted by the Board's executive director; (5-8-09)

(3) Be of good moral character and temperate habits; (5-8-09)

(4) Have submitted a written application in the form prescribed by the Board; (5-8-09)

(5) Have obtained and maintains certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB), the Institute for Certification of Pharmacy Technicians (ICPT), or such other certifying organization as may be approved by the Board; and (5-8-09)

(6) Have paid the registration fee specified by the Board. (5-8-09)

c. Registration of Pharmacy Technician in Training. Subsequent to June 30, 2009, a person may be registered by the Board as a pharmacy technician in training, provided that the person satisfies all the requirements for registration as a pharmacy technician under Subparagraph 251.07.b.i. of these rules and pays the registration fee specified by the Board for pharmacy technicians. Upon registration, a pharmacy technician in training may perform, under the supervision of a licensed pharmacist, any of the duties that these rules allow a registered pharmacy technician to perform. The registration of a pharmacy technician in training shall expire one (1) year from the date of registration but may be renewed once for a consecutive one-year period. Subsequent to expiration of a pharmacy technician in training registration, a person must satisfy all the requirements of Subparagraph 251.07.b.ii. of these rules in order to be registered by the Board as a pharmacy technician. (5-8-09)

d. Ineligibility for Registration. No pharmacist whose license has been denied, revoked, suspended, or restricted for disciplinary purposes shall be eligible to be registered by the Board as a pharmacy technician or pharmacy technician in training. (5-8-09)

e. Certification Requirement. As of July 1, 2009, unless excepted by these rules, no person shall be registered by the Board as a pharmacy technician, nor shall any person have their pharmacy technician registration renewed by the Board, unless that person has obtained, and maintains, certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB), the Institute for the Certification of Pharmacy Technicians (ICPT), or such other certifying organization as may be approved by the Board. (5-8-09)

f. Exception to Certification Requirement. No person who has registered with the Board as a pharmacy technician as of June 30, 2009 shall be required to obtain and maintain certification as a pharmacy technician in order to maintain or renew their registration as a pharmacy technician subsequent to June 30, 2009, so long as the person remains continuously employed as a pharmacy technician by the pharmacy employer in whose employment the person was employed as a pharmacy technician as of June 30, 2009. However, if the person, subsequent to June 30, 2009, ceases to be employed as a pharmacy technician by the pharmacy employer by whom the person was employed as of June 30, 2009, then the person's registration as a pharmacy technician shall automatically terminate as of the date of the person's termination of employment as a pharmacy technician by that pharmacy employer. Such person may then register with the Board as a pharmacy technician in training pursuant to Paragraph 251.07.c. of these rules. Subsequent to expiration of such person's pharmacy technician in training registration, the person must then satisfy all the requirements of Subparagraph 251.07.b.ii. of these rules in order to be registered by the Board as a pharmacy technician. (5-8-09)

g. Contents of Registration Form. The annual registration form and the initial registration form for pharmacy technicians and the registration form for pharmacy technicians in training shall be prepared by the Board, and shall require such information regarding the individual as the Board may reasonably require. (5-8-09)

08. Discipline Procedure, Penalties, and Reinstatement. Any proceedings by the Board against any pharmacy technician shall comply in all respects with the Administrative Procedure Act, Title 67, Chapter 52, Idaho Code. Upon finding of the existence of grounds for discipline of any person holding a pharmacy technician registration, or seeking a pharmacy technician registration or a renewal registration under these rules, the Board may impose one (1) or more of the penalties provided for in Section 54-1728, Idaho Code. Petitions for reinstatement shall be subject to the requirements of Section 54-1728(2), Idaho Code. (5-8-09)

252. PHARMACY PRACTICE IN INSTITUTIONS.

01. Definitions. For purposes of these rules the following apply: (7-1-93)

a. Institutional Facility is a hospital, skilled nursing care facility, intermediate care facility, extended care facility, long-term care facility, and any other such facility or institution, including those operated by the state of Idaho, whose primary purpose is to provide a physical environment for patients to obtain health care services, except those places where physicians, dentists, veterinarians, osteopaths, or other licensed practitioners of the healing arts engage in private practice. (5-8-09)

b. Long-Term Care Facility is a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients. (5-8-09)

c. Institutional Pharmacy is the portion of an institutional facility that is engaged in the distribution, prepackaging, or manufacture, production or sale of drugs, medications, devices and other materials used in the diagnosis and treatment of injury, illness, and disease (hereinafter referred to as "drugs") and that shall be registered with the Board pursuant Title 54, Chapter 17, Idaho Code. (5-8-09)

d. Centralized Prescription Filling is the filling by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order. (5-8-09)

e. Centralized Prescription Processing is defined as the processing by a pharmacy of a request from another pharmacy to fill or refill a prescription drug order or to perform processing functions such as dispensing and drug regimen review. (3-29-10)

f. Chart Order is a lawful order entered on the chart or a medical record of an inpatient or resident of an institutional facility by a practitioner or his designated agent for a drug or device and shall be considered a

prescription drug order provided that it contains: (5-8-09)

i. The full name of the patient; (5-8-09)

ii. Date of issuance; (5-8-09)

iii. Name, strength, and dosage form of the drug prescribed; (5-8-09)

iv. Directions for use; and (5-8-09)

v. If written, the prescribing practitioner's signature or the signature of the practitioner's agent, including the name of the prescribing practitioner; or, if electronically submitted, the prescribing practitioner's electronic or digital signature. (5-8-09)

g. Prepackaging is the act of transferring a drug, manually or by use of an automated pharmacy system, from a manufacturer's or distributor's original container to another container in advance of receiving a prescription drug order or for a patient's immediate need for dispensing by a pharmacy or practitioner authorized to dispense in the establishment in which the prepackaging occurred. (5-8-09)

h. Central Pharmacy is defined as a pharmacy within the state of Idaho or a registered telepharmacy drug outlet across state lines to which centralized prescription processing or filling services have been outsourced pursuant to these rules. (3-29-10)

i. Continuous Quality Improvement Program is defined as a system of standards and procedures to identify and evaluate quality-related events, and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system that determine the outcomes of medication use. (3-29-10)

j. Drug Regimen Review is defined as including, but is not limited to, the following activities: (3-29-10)

i. Evaluation of the prescription drug order and patient records for known allergies; (3-29-10)

ii. Rational therapy contraindications; (3-29-10)

iii. Reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors; (3-29-10)

iv. Reasonable directions for use; (3-29-10)

v. Potential or actual adverse drug reactions; (3-29-10)

vi. Drug-drug interactions; (3-29-10)

vii. Drug-food interactions; (3-29-10)

viii. Drug-disease contraindications; (3-29-10)

ix. Therapeutic duplication; (3-29-10)

x. Proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and (3-29-10)

xi. Abuse or misuse. (3-29-10)

02. Purpose. Pursuant to Section 54-1703, Idaho Code, these rules implement the provisions of the Idaho Pharmacy Act concerning registration of facilities as specified in Section 54-1729, Idaho Code. (7-1-93)

03. Applicability. These rules apply to all institutions and institutional pharmacies as defined in these rules. (5-8-09)

04. Registration of Institutional Pharmacies. All institutional pharmacies shall register annually with the Board. Certificates of registration shall be issued only to those institutional pharmacies that satisfy the provisions of Section 54-1729, Idaho Code, and Subsection 251.05 through Section 259 of these rules. (7-1-93)

05. Directors. Each institutional pharmacy and each central pharmacy must be directed by a pharmacist (hereinafter referred to as "the director") who is licensed or registered in this state and who is knowledgeable in, and thoroughly familiar with the specialized functions of institutional pharmacies. Each director will be responsible for all activities of his respective institutional pharmacy or central pharmacy and for meeting the requirements of state and federal law and regulations. (3-29-10)

06. Supportive Personnel. The director of an institutional pharmacy shall be assisted by a sufficient number of additional licensed pharmacists and ancillary personnel as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (7-1-93)

a. Trained technical personnel may be employed. The director shall develop and implement written policies and procedures to specify the duties to be performed by technical personnel. (7-1-93)

b. The policies and procedures shall, at a minimum, specify that ancillary technical personnel are personally and directly supervised by a licensed pharmacist and that ancillary technical personnel may not be assigned duties that may only be performed by a licensed pharmacist. (7-1-93)

c. Secretarial and clerical assistance and support may be utilized as required to assist with recordkeeping, report submission, and other administrative duties; however, such personnel may not perform any technical duties. (7-1-93)

07. Supervision by Director. All activities and operations of an institutional pharmacy shall be personally and directly supervised by its director. (7-1-93)

08. Ancillary Personnel. All functions and activities of ancillary personnel shall be personally and directly supervised by a sufficient number of licensed pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients. (7-1-93)

09. Pharmacist Absence. During times that an institutional pharmacy is anticipated to be unattended by a licensed pharmacist, the director shall make arrangements in advance for the provision of drugs to the medical staff and other authorized personnel of the institutional facility. (7-1-93)

10. Access to Pharmacy. Only one (1) supervisory, registered nurse in any eight-hour (8) shift may be allowed access to the pharmacy and may remove drugs there from. (7-1-93)

11. Designated Nurse. The supervisory nurse shall be designated in writing by the director or the appropriate committee of the institutional facility and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training in the proper methods of access, removal of drugs, and recordkeeping and other required procedures. Such education and training shall be given by the director who shall require, at a minimum, the following records and procedures: (7-1-93)

a. Removal of any drugs from the pharmacy by an authorized nurse must be recorded on a suitable form showing the name and strength of the drug, the amount, the date and time, and signature of the nurse; and (7-1-93)

b. Only prepackaged drugs in amounts sufficient for the immediate therapeutic needs shall be removed from the pharmacy when a pharmacist is not available. (7-1-93)

253. EMERGENCY KITS.

01. Institutional Facility. In a facility that does not have an institutional pharmacy, drugs may be provided for use by authorized personnel in emergency kits located at the facility; however, the kits must meet the following requirements. (7-1-93)

02. Definition -- Emergency Kit Drugs. Emergency kit drugs are those that may be required to meet the immediate therapeutic needs of one (1) or more patients and are not available from any other authorized source in sufficient time to prevent the risk of harm to the patient or patients by delay resulting from obtaining such drugs from such other source. (7-1-93)

03. Supplying Pharmacy. All emergency kit drugs shall be provided by a pharmacy, registered by the Board, and retained by the facility for this purpose. The institutional facility shall notify the Board in writing of the pharmacy retained for this purpose. The retained pharmacy shall meet the requirements of Subsection 257.01 of these rules. (7-1-93)

04. Drugs Included. The supplying pharmacist and the committee responsible for pharmaceutical services of the institutional facility shall jointly determine the drugs, by identity and quantity, to be included in emergency kits. (7-1-93)

05. Storage of Emergency Kits. Emergency kits shall be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs within them. (7-1-93)

06. Labeling, Exterior. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is to be used only in emergencies. Additionally, the label shall also provide a listing of the drugs contained therein that includes the name, strength, quantity, and expiration date of each drug, and the name, address, and telephone number of the supplying pharmacist. (7-1-93)

07. Labeling, Interior. All drugs contained in emergency kits shall be labeled in accordance with Subsection 255.04 of these rules and shall also be labeled with additional information as may be required by the medical staff of the institutional facility to prevent misunderstanding or risk of harm to the patients of the facility. (7-1-93)

08. Removal of Drugs From Emergency Kit. Drugs shall be removed from emergency kits by authorized personnel only pursuant to a valid physician's order, including a chart order, except that an order shall not be required for the supplying pharmacist to replace expired drugs in the kit with current dated drugs. (5-8-09)

09. Notifying Pharmacist When Kit Is Opened. Whenever an emergency kit is opened, the supplying pharmacist shall be notified within a reasonable time and it shall be restocked by the pharmacist or pharmacist designee within a reasonable time so as to prevent risk of harm to patients. (5-8-09)

10. Expiration Dates. Upon the occurrence of any expiration date, the supplying pharmacist shall replace expired drugs with current dated drugs. (7-1-93)

11. Policies and Procedures. The supplying pharmacist, in conjunction with the committee responsible for pharmaceutical services of the institutional facility, shall develop and implement written policies and procedures to insure compliance with the provisions of Section 253 of these rules. (7-1-93)

12. Noninstitutional Facility Home Health Nurses. An Idaho-registered pharmacy may supply certain limited emergency drug kits for state licensed or Medicare certified home health agencies. (7-1-97)

a. All of Section 253 of these rules shall apply to home health agency emergency kits except as modified by this Subsection. (7-1-97)

b. Home health agency emergency kit drugs may only contain such drugs as specifically approved by these rules and are limited to the following: (7-1-97)

i. Epinephrine injection; (7-1-97)

ii. Diphenhydramine injection; (7-1-97)

iii. Corticosteroid injection; (7-1-97)

iv. Narcotic antagonist; (7-1-97)

v. Sterile water; (7-1-97)

vi. Sterile saline solution for injection; and (7-1-97)

vii. Heparin flush. (7-1-97)

c. Home health agency emergency kits shall be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs. However, nurses licensed by the Idaho Board of Nursing and employed by such state licensed or Medicare certified home health agencies may carry such home health agency emergency kits on their person while on duty and in the course and scope of their employment for the home health agency. When not on duty or working within the course and scope of their employment, the nurses must return the home health agency emergency kits to the locked storage area. (7-1-97)

d. The legend drugs included in the home health agency emergency kit shall remain the property of, and under the responsibility of, the Idaho-registered supplying pharmacy. (7-1-97)

254. PHYSICAL REQUIREMENTS.

01. Sufficient Space. An institutional pharmacy shall have sufficient floor space to ensure that drugs are prepared in a sanitary, well-lighted and enclosed setting that meets the requirements of these rules. (7-1-93)

02. Equipment and Materials. Each institutional pharmacy shall have equipment and physical facilities necessary for proper compounding, dispensing and storage of drugs, including parenteral preparations, and at least the following current editions. (7-1-93)

a. Idaho Pharmacy Law and Rules; (7-1-93)

b. A current pharmacy patient counseling reference; (8-4-94)

c. Facts and Comparisons; and (7-1-93)

d. One (1) other current pharmacy reference of choice, (book or electronic). (7-1-93)

03. Storage of Drugs. All drugs shall be stored within the institutional pharmacy in designated areas equipped to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. (7-1-93)

04. Storage of Alcohol and Flammables. (7-1-93)

a. Alcohol and flammables shall be stored in areas separate and apart from areas used for storing, compounding, or dispensing of other pharmaceuticals. (7-1-93)

b. The storage areas shall, at a minimum, meet local building code requirements for the storage of volatiles and other applicable laws, ordinances, or rules. (7-1-93)

05. Unattended Areas. In the absence of authorized personnel and whenever any area of an institutional pharmacy is not under the personal and direct supervision of authorized personnel, the area shall be locked. (7-1-93)

06. Security. All areas occupied by an institutional pharmacy shall be capable of being locked. (7-1-93)

255. DRUG DISTRIBUTION AND CONTROL.

01. Purpose and Mission. The primary purpose and mission of an institutional pharmacy shall be to provide properly prepared drugs for the patients of the facility in minimum time and with maximum accuracy, safety, and professionalism, using written procedures established by the director for the distribution of pharmaceutical materials to achieve this goal. (7-1-93)

02. Responsibility of Director. The Director shall be responsible for the safe and efficient distribution and control of, and accountability for, drugs. The other professional staff of the institutional facility shall cooperate with the director to manage these responsibilities by ordering, administering and accounting for pharmaceutical materials in a manner consistent with these objectives. (7-1-93)

03. Minimum Responsibilities of Director. The director shall be responsible for at least the following: (7-1-93)

a. The preparation and sterilization of parenteral medications manufactured within the institutional facility; (7-1-93)

b. The mixture of parenteral products, including the education and training of nursing personnel concerning incompatibility and the provision of proper incompatibility information when the admixture of parenteral products is not performed within the institutional pharmacy; (7-1-93)

c. The manufacture of drugs, when applicable; (7-1-93)

d. The establishment of specifications for procurement of all materials, including drugs, chemicals and biologicals, subject to approval of the appropriate committee of the institutional facility; (7-1-93)

e. Participation in the development of a formulary or drug list for the facility; (7-1-93)

f. The dispensing of all drugs within the facility pursuant to, and only upon receipt of, an original or a direct copy of a physician's order, including a chart order; (5-8-09)

g. The filling and labeling all containers from which drugs are to be administered; (7-1-93)

h. The maintaining and making available a sufficient inventory of antidotes and other emergency drugs, in both the pharmacy and inpatient-care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as is determined necessary by the appropriate committee of the institutional facility; (7-1-93)

i. The recording of all transactions of the pharmacy as required by applicable law, rule, or regulation to maintain accurate control over, and accountability for, all pharmaceutical materials; (7-1-93)

j. Participation in those aspects of the institutional facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness; (7-1-93)

k. Cooperation with teaching and research programs in the institutional facility; (7-1-93)

l. Implementation of the policies and decisions of the appropriate committee of the institutional facility; and (7-1-93)

m. Meeting all inspection and other requirements of the Idaho Pharmacy Act and these rules. (7-1-93)

04. Dispensing and Labeling of Drugs for Use Inside or Outside a Facility. (7-1-93)

a. All drugs intended for use within the facility shall be dispensed by the pharmacy in appropriate containers and adequately labeled according to current acceptable professional standards. (7-1-93)

b. All drugs dispensed to patients soon to be discharged or to whom it is certain will carry the item dispensed outside of the facility shall be labeled with the following information: (7-1-93)

i. Name, address and telephone number of the institutional pharmacy; (7-1-93)

ii. Date and identifying serial number; (7-1-93)

iii. Full name of patient; (7-1-93)

iv. Name of drug, strength, and number of units; (7-1-93)

v. Directions for use to the patient; (7-1-93)

vi. Name of physician prescribing; (7-1-93)

vii. Initials of pharmacist dispensing; and (7-1-93)

viii. Required precautionary information regarding controlled substances. (7-1-93)

ix. Additional cautionary information as may be required or desirable for proper use and patient safety. (7-1-93)

c. Whenever any drugs are added to parenteral admixtures, whether within or outside of the direct and personal supervision of a registered pharmacist, such admixtures shall be labeled with a distinctive supplementary label indicating the name and amount of the drug added, date and time of addition, and name of person so adding. (7-1-93)

05. Discontinued and Outdated Drugs. The director shall develop and implement policies and procedures to ensure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition, or that the director, or his designee, perform appropriate disposition or disposal of such drugs at the storage site. (7-1-93)

06. Physician's Orders. Drugs may be dispersed from the institutional pharmacy only upon written orders, or direct copies thereof, from authorized physicians, including chart orders. (5-8-09)

07. Authorization of Physicians. The appropriate committee of the institutional facility shall, from time to time, as appropriate, designate those physicians who are authorized to issue orders to the pharmacy. (7-1-93)

08. Use of Abbreviations and Chemical Symbols. Orders employing abbreviations and chemical symbols shall be utilized and filled only if such abbreviations and symbols appear on a published list of accepted abbreviations developed by the appropriate committee of the institutional facility. (7-1-93)

09. Drug Orders for Inpatient Use. Orders for drugs for use by inpatients shall, at a minimum contain the information required of a chart order by Paragraph 252.01.f. of these rules. (5-8-09)

10. Drug Orders for Outpatient Uses. Orders for drugs for use by outpatients shall, at a minimum, contain all of the items required by the preceding rule and in addition, the quantity, physician's address, and DEA identification number, if applicable, and the patient's address, if applicable. (7-1-93)

11. Proofs of Use. Proofs of use of controlled substances and other drugs as may be specified by the appropriate committee of the institutional facility shall be submitted to the director, on forms provided by the director, together with any and all unused portion of the drug. The forms shall specify at least the name of drug, the dose, the name of the ordering physician, the name of the patient, the date and time of administration to the patient, and the name of the individual administering. (7-1-93)

12. Drug Recall Procedure. The director shall develop and implement a recall procedure that can be

readily activated to assure the pharmacy staff and the director that all drugs included on the recall are returned to the pharmacy for proper disposition. (7-1-93)

13. Reporting Suspected Adverse Drug Reactions. All suspected adverse drug reactions shall be reported in writing and immediately communicated to the ordering physician, to the pharmacy and to the appropriate committee of the institutional facility. Entry on the patient's record shall also be made. The director may, at his discretion, make further reports of such suspected reactions to the Hospital Reporting Program of the U. S. Food and Drug Administration, to the manufacturer and to the United States Pharmacopoeia. (7-1-93)

14. Records and Reports. The director shall maintain and submit, as appropriate, the records and reports required to ensure patient health, safety, and welfare, including at least the following: (7-1-93)

a. Proofs of use; (7-1-93)

b. Reports of suspected adverse drug reactions; (7-1-93)

c. Inventories of emergency kits; (7-1-93)

d. Inventories of the pharmacy; (7-1-93)

e. Annual controlled substances inventories; (7-1-93)

f. Alcohol reports; and (7-1-93)

g. Such other and further records and reports as may be required by law and these rules. (7-1-93)

256. ADMINISTRATION OF DRUGS.

01. Administration of Drugs. Drugs shall be administered at an institutional facility, only upon the orders, including chart orders, of those members of the medical staff who have been granted clinical privileges, or who are authorized members of the house staff, by authorized licensed facility personnel in accordance with policies and procedures specified by the appropriate committee of the facility, under applicable law and rules, and in accordance with usual and customary standards of good medical practice. (5-8-09)

02. Self-Administration of Drugs by Patients. Self-administration of drugs by patients shall be permitted only when specifically authorized by the treating or ordering physician and only if the patient has been educated and trained in the proper manner of self-administration and there is no risk of harm to the patient. (7-1-93)

257. OUTSOURCING.

01. Institutional Pharmacies. An institutional pharmacy may outsource centralized prescription processing or filling services to a central pharmacy for the limited purpose of assuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or when the institutional pharmacy cannot provide services on an ongoing basis, provided that the institutional pharmacy: (3-29-10)

a. Has obtained approval from the institutional facility to outsource centralized prescription processing or filling services for its inpatients and residents; (3-29-10)

b. Has a written contract with the central pharmacy outlining the services to be provided by the central pharmacy and the responsibilities and accountabilities of each party in fulfilling the terms of said contract in compliance with federal and state laws and regulations; (3-29-10)

c. Provides a valid chart order and patient profile to the central pharmacy it has contracted with for the centralized prescription processing or filling services; and (3-29-10)

d. Shares a common electronic file or has appropriate technology to allow access by the central pharmacy to sufficient information necessary or required to fill or refill a prescription order. (3-29-10)

02. Policies, Procedures, and Documentation for Institutional Pharmacies and Central Pharmacies. Each party performing or contracting for centralized prescription processing or filling services under Subsection 257.01 of these rules must: (3-29-10)

a. Maintain a policies and procedures manual and documentation that implementation of such policies and procedures is occurring. The manual and documentation must include, but are not limited to, the following: (3-29-10)

i. A copy of the outsourcing approval required under Paragraph 257.01.a. of these rules; (3-29-10)

ii. A copy of the contract required under Paragraph 257.01.b. of these rules; (3-29-10)

iii. The maintenance of appropriate records to identify the pharmacists providing centralized prescription processing or filling services; (3-29-10)

iv. The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process; (3-29-10)

v. The provision of adequate security to protect the privacy of protected health information; (3-29-10)

vi. The protocol for accessing prescription drugs in the institutional pharmacy outsourcing centralized prescription processing or filling services and for maintaining the security of such drugs; (3-29-10)

vii. The protocol to assure that the central pharmacy maintains sufficient Board licensed or registered pharmacists to meet the centralized processing or filling needs of the institutional facility outsourcing such services to the central pharmacy; (3-29-10)

viii. Identification of the director of the central pharmacy and of the institutional pharmacy contracting with the central pharmacy; and (3-29-10)

ix. The maintenance of a continuous quality improvement program for centralized processing or filling services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. (3-29-10)

x. A mechanism for the licensed or registered pharmacist within the central pharmacy to readily communicate with the practitioners within the institutional facility that has outsourced centralized processing or filling services. (3-29-10)

xi. A training and orientation program that ensures that licensed or registered pharmacists who are providing centralized prescription processing or filling services are competent to review and approve medication orders. (3-29-10)

xii. Essential information utilized by the institutional facility, such as its therapeutic interchange list, formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to said information. (3-29-10)

xiii. Protocol for the central pharmacy to perform a review of the patient's profile, including but not limited to performing a drug regimen review. (3-29-10)

b. Implementation documentation must be retained for a period of two (2) years. (3-29-10)

c. Make the policy and procedures manual and implementation documentation available to the Board for review upon request. (3-29-10)

03. Institutional Facilities. Whenever an institutional facility without an institutional pharmacy

obtains drugs, devices, or other pharmacy services from outside the institutional facility, arrangements must be made to ensure that such outside pharmacist provides his services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and to properly serve the needs of the facility. The arrangements shall be made in writing and shall, at a minimum, specify that: (3-29-10)

a. The outside pharmacist is to act in the capacity of a part-time director and therefore, is subject to these rules; (7-1-93)

b. The pharmacist shall provide on-call service at all times; (7-1-93)

c. Adequate storage facilities for drugs will be provided; (7-1-93)

d. All prescription drugs in oral solid dosage form supplied to a licensed skilled nursing care facility, whether from an outside source or in-house pharmacy, shall be limited to no more than an eight (8) day supply except where USP indicates the drug shall be dispensed in the original container. Up to a thirty-four (34) day supply will be allowed if provided in "Unit Dose," as defined in Subsection 156.05 of these rules; (3-20-04)

e. All drugs in liquid form will be supplied in amounts not to exceed sixteen (16) ounces or a thirty-four (34) day supply; (3-20-04)

f. All drugs housed in long term care facilities will be labeled according to Section 159 of these rules; (8-4-94)

g. Automatic refilling of medications is prohibited, except where unit dose is used in a daily delivery system. Any continuation of medications must be reordered by the licensed skilled nursing care facility pursuant to a current physician's order; and (7-01-94)

h. All drugs supplied shall be labeled so as to ensure that recalls can be effected and that proper control and supervision of the drugs may be exercised. (7-1-93)

04. Limited Outsourcing by Outside Pharmacy. An outside pharmacy that provides prescription processing or filling services for an institutional facility that does not have an institutional pharmacy may outsource, pursuant to a contract, prescription processing or filling services to another pharmacy, and the other pharmacy may perform the prescription processing or filling services outsourced to it, if all of the following conditions are met: (3-29-10)

a. The outsourcing of prescription processing or filling services shall be only for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or when the pharmacy outsourcing those services cannot provide services for the institutional facility on an ongoing basis; (5-8-09)

b. The outsourcing pharmacy has obtained approval from the Institutional Facility to outsource centralized prescription processing or filling services for its inpatients and residents; (5-8-09)

c. The outsourcing pharmacy provides a valid chart order to the pharmacy it has contracted with for the centralized prescription processing or filling services; and (5-8-09)

d. The contract between the outsourcing pharmacy and the pharmacy with which it has contracted for centralized prescription processing or filling services is in writing. (5-8-09)

05. Patient's Own Drugs. (7-1-93)

a. Whenever patients bring drugs into an institutional facility, the drugs shall not be administered unless they can be precisely identified and only pursuant to a physician's order, including chart order. (5-8-09)

b. If the patient's drugs are not to be administered, then the director shall, according to procedures specified in writing, have the patient's drugs turned in to the pharmacy, which shall package, seal, and return them to

an adult member of the patient's immediate family or store and return them to the patient upon discharge. (7-1-93)

258. DISTRIBUTION OF MEDICATIONS FROM HOSPITAL EMERGENCY ROOMS BY REGISTERED NURSE (R.N.).
In an emergency and in the absence of a physician or pharmacist, an R.N. may deliver a legend drug from the emergency room that has been prepackaged by a pharmacist, with proper packaging, labeling, and recordkeeping pursuant to a licensed physician's order, with the exception of controlled substances. (7-1-93)

01. Limited Supply. A limited supply of drugs approved for outpatient emergency use may be kept in the emergency room in a secure, locked location designated for that purpose. (7-1-93)

02. List of Legend Drugs. A list of legend drugs that may be delivered to outpatients receiving emergency treatment when a licensed pharmacist is not on duty and the prescribing physician is not present shall be prepared by the licensed pharmacist in charge of a hospital pharmacy or drug room in consultation with the hospital's medical staff. (7-1-93)

03. Legend Drugs Prepackaged by a Pharmacist. Legend drugs identified on the approved list shall be prepackaged by a licensed pharmacist. The number of doses in each package shall be limited to the amount necessary to medicate the patient until the first available pharmacist is on duty in the community, but not more than six (6) doses. (7-1-93)

04. Legend Drugs Labeled by a Pharmacist. Legend drugs identified on the approved list shall be labeled by the pharmacist at the time of packaging. The label must conform to the requirements of Subsection 255.04 of these rules except that blank spaces may be left for the names of the patient and physician and the directions for use. (7-1-93)

05. Delivery of Legend Drugs by an R.N. If a licensed pharmacist is not on duty, the R.N. in charge of the emergency room may deliver legend drugs, prepackaged and labeled in accordance with the labeling requirements in Subsection 255.04 of these rules, to a person receiving emergency out-patient treatment, upon receiving an order from a licensed physician. (7-1-93)

06. Physician's Orders Must Be Written. The physician's order may be by written or telephonic communication. If a telephonic order is issued, it must be promptly reduced to writing by the person taking the call. (7-1-93)

07. Limit. No more than one (1) prepackaged container of the same drug may be delivered to a person receiving emergency outpatient treatment unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community. (7-1-93)

08. Responsibility of Person Delivering Drugs. The person who delivers drugs pursuant to these rules shall: (7-1-93)

a. Complete the label affixed to the container with all required information except that the name and strength of the drug may be deleted on order of the prescribing physician; and (7-1-93)

b. Complete a record of delivery that includes all of the information listed under Paragraph 255.04.b. of these rules and the following: (7-1-93)

i. the expiration date of the drug, if applicable; (7-1-93)

ii. The lot number of the drug; (7-1-93)

iii. The date of prepackaging; (7-1-93)

iv. The initials of the pharmacist who prepackaged the drug; and (7-1-93)

v. A blank space for the name (initials) of the person delivering the drug to patient. (7-1-93)

c. The delivery record shall be returned to the hospital pharmacy upon completion and filed as a permanent record. (7-1-93)

09. Authorization of Drug Delivery in Emergency Room to Outpatients. This rule does not authorize any person other than the R.N. in the emergency room on a hospital's staff to deliver legend drugs to outpatients receiving emergency treatment. (7-1-93)

10. Authority to Deliver Legend Drugs. This rule does not authorize the delivering of controlled legend drugs by any person not authorized by law to dispense such drugs. (7-1-93)

11. Definition. The following terms are defined for the purposes of this rule unless the context requires otherwise: (7-1-93)

a. "Deliver to patient" means completing the blank spaces on the label of the prepackaged drug and actually handing the package to the patient or the patient's representative. (7-1-93)

b. "Dose" means the amount of medication that is to be given at one (1) specific time, as determined by the physician. (7-1-93)

c. "Prepackage" means placing in a container that meets federal and state qualifications as a legal container not more than six (6) doses of a legend drug and affixing a label to the container that includes all of the information required under Paragraph 255.04.b. of these rules. (7-1-93)

259. INVESTIGATIONAL DRUGS.
Investigational drugs shall be properly labeled and shall be administered only under the personal and direct supervision of the principal physician-investigator or his authorized clinician with prior approval of the appropriate committee of the institutional facility. (7-1-93)

01. Administration of Investigational Drugs. Nurses may administer such drugs only after they have been educated and trained concerning relevant pharmacologic information about such drugs by the clinician of the pharmacy. (7-1-93)

02. Information on Investigational Drugs. A central unit shall be maintained wherein essential information regarding such drugs may be obtained. (7-1-93)

260. INSPECTION.

01. Monthly Inspections. The director shall, no less than once per month, personally or by a qualified designee, inspect all matters within his jurisdiction and responsibility and make appropriate written records and notations of such inspections. (7-1-93)

02. Verification by Inspection. Such inspections shall, at a minimum, verify that: (7-1-93)

a. Drugs are dispensed only under the supervision of a pharmacist; (7-1-93)

b. Ancillary pharmacy personnel are properly directed and supervised; (7-1-93)

c. Disinfectants and drugs for external use are stored separately and apart from drugs for internal use or injection; (7-1-93)

d. Drugs requiring special storage conditions to ensure their stability are properly stored; (7-1-93)

e. No outdated drugs are stocked in the institutional pharmacy or the facility it serves; (7-1-93)

f. Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and medical personnel; (7-1-93)

g. Emergency drugs designated pursuant to Paragraph 260.01.f. of these rules are in adequate and proper supply, both within the pharmacy and at outside storage locations; (7-1-93)

h. All necessary and required security and storage standards are met; (7-1-93)

i. Metric-apothecaries weight and measure conversion tables and charts are reasonably available to all medical personnel; and (7-1-93)

j. All policies and procedures of the director and appropriate committees of the institutional facility relevant to pharmacy, or both, are followed. (7-1-93)

03. Annual On-Site Review of Pharmacies. No less than once a year the Board by one (1) of its members or by its qualified designee shall conduct an announced on-site review of all aspects of the management and operation of all institutional pharmacies in this state to verify compliance with the law, these rules, and such other standards as may be appropriate to ensure that the health, safety and welfare of patients of the facility serviced by the pharmacy are protected. (7-1-93)

04. Furnishing Records to Reviewer. Upon request, the hospital or other institution shall furnish to the reviewer all records, invoices, inventories, orders, patient medication profiles and such other records and reports as may be required to conduct an in depth audit of drug distribution by the facility. (7-1-93)

05. Written Reports of Annual Inspections. Such annual inspections shall be made and written reports thereof shall be filed with the Board and the director. A copy of the report shall be forwarded to the administrator of the institution within sixty (60) days of the review. (7-1-93)

06. Exit Interview After On-Site Review. At the conclusion of the on-site review, the Board member or designee who conducted the review shall participate in an exit interview with the director and the administrator of the institution. (7-1-93)

07. Discrepancies or Deficiencies. Discrepancies or deficiencies, or both, shall be discussed at the exit interview. The discrepancies or deficiencies shall be corrected within a reasonable time. (7-1-93)

08. Filing Written Notice of Corrections. Written notice of correction shall be filed with the Board, whose directions may be disputed by written notice filed with the Board. (7-1-93)

261. -- 264. (RESERVED).

265. REMOTE DISPENSING PILOT PROJECT.
The Board, through its executive director, may authorize specific pharmacies and the pharmacists practicing therein to participate in a Remote Dispensing Pilot Program. The following rules shall apply to pharmacies so authorized by the Board for conducting pharmacy through a remote dispensing program. The purpose of the Remote Dispensing Pilot Program is to allow the provision of pharmaceutical care through the use of telecommunications and remote dispensing machines (RDM) to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care. During the pilot project phase of the Remote Dispensing Pilot Program, designation to participate in the Remote Dispensing Pilot Program shall be at the discretion of the Board and the Executive Director. (5-8-09)

266. (RESERVED).

267. REMOTE PHARMACY REGISTRATION - OPERATING MEMORANDUM.

01. Registration. During the pilot project phase of the Remote Dispensing Pilot Project, each remote pharmacy shall be registered with the Board as a pilot remote pharmacy. Pilot remote pharmacies will only be approved for operating in medical care facilities operating in areas otherwise unable to obtain pharmaceutical care on a timely basis. RDMs must be used only in settings with an established program of pharmaceutical care that ensures prescription orders are reviewed by a pharmacist before release to the patient. The responsible pharmacy must

establish the policies and procedures necessary to fulfill the requirements of all applicable state and federal laws, rules, and regulations. (5-8-09)

02. Operating Memorandum. Prior to issuance of a registration for a pilot remote pharmacy, the responsible pharmacy, acting through its pharmacist-in-charge, and the Board, acting through its executive director, shall enter into an operating memorandum that includes the following: (5-8-09)

a. The operating protocols applicable to the pilot remote pharmacy and shall include written policies and procedures that: (5-8-09)

i. Ensure safety, accuracy, security, and patient confidentiality; (5-8-09)

ii. Define access to the RDM and to medications contained within or associated with the RDM, including but not limited to policies that assign, discontinue, or change access to the RDM and medications; and (5-8-09)

iii. Ensure that access to the medications complies with state and federal laws and regulations. (5-8-09)

b. A complete description of the RDM including the operating specifications therefore. (5-8-09)

c. An accurate scale drawing of the facility where the automated pharmacy system, including its RDM, will be located showing the layout of the location of the RDM, the facilities for the operating pharmacy technician operating the system, the location of a patient counseling area, all access points to the system and the RDM. (5-8-09)

d. A description of the training required for personnel who will access the automated pharmacy system (including the RDM) to ensure the competence and ability of all personnel who operate any component of the Automated Pharmacy System and a requirement that adequate documentation of training and continuing education be kept both in the responsible pharmacy and at the pilot remote pharmacy, readily available for inspection by the Board. (5-8-09)

e. A description of the procedures for ensuring that the RDM is in good working order and accurately dispenses the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards. (5-8-09)

f. An ongoing quality assurance program that monitors performance of the automated pharmacy system, including the RDM, and the personnel who access it. (5-8-09)

g. Such other terms and conditions of operations as the executive director deems are reasonably necessary to ensure the health, safety, and welfare of the public with respect to the operations of the pilot remote pharmacy. (5-8-09)

h. A description of the procedures detailing the security and accounting of returned, discarded, or unused medications with existing state and federal laws, rules, and regulations. (5-8-09)

03. Pilot Remote Pharmacy Operations. The operating memorandum shall govern (in conjunction with all applicable laws, rules, and regulations) the operations of the pilot remote pharmacy with respect to all aspects of the practice of pharmacy at the pilot remote pharmacy. The operating memorandum may identify specific rules of the Board which are not applicable to the operation of the pilot remote pharmacy or for which particular applications are modified due to the specific nature of the operations at the pilot remote pharmacy; however, the operating memorandum may not waive or modify application of federal laws or regulations, or state statutes governing the practice of pharmacy. (5-8-09)

04. Dispute Resolution. In the event of a dispute between the pharmacist-in-charge and the executive director with respect to specific terms or conditions of the operating memorandum, either may petition the Board for a determination, which determination by the Board shall be final. The operating memorandum may be amended by

agreement between the pharmacist-in-charge and the executive director. Any such amendment shall be in writing and shall be appended to the original operating memorandum. In addition, the operating memorandum may be amended by order of the Board upon the petition of either the pharmacist-in-charge or the executive director to the Board, or upon the Board's own motion. Any such Board order shall be appended to the original operating memorandum. (5-8-09)

268. PHARMACIST-IN-CHARGE.

01. Responsibilities. The pharmacist-in-charge shall be responsible for all aspects of the operation of the pilot remote pharmacy including safety, accuracy, security, and patient confidentiality. (5-8-09)

02. Product Supply. The pharmacist-in-charge shall ensure that the RDM is stocked accurately and in accordance with the established, written policies and procedures. A pharmacist must check the accuracy of the product supplied for stocking the machine. (5-8-09)

269. DRUG DELIVERY AND CONTROL.

01. Licensed Pharmacist Present. At all times the automated pharmacy system is being operated, there shall be a pharmacist licensed in the state of Idaho, or a technician registered in the state of Idaho, present at the pilot remote pharmacy and attending to such operations. (5-8-09)

02. Communication. At all times the automated pharmacy system is being operated, there shall be a pharmacist licensed in the state of Idaho available at the responsible pharmacy for immediate communication through a two-way audio and video hookup between the responsible pharmacy and the pilot remote pharmacy. (5-8-09)

03. Electronic Recording. All events involving the contents of the RDM must be recorded electronically. Records must be maintained by the responsible pharmacy for a minimum of three (3) years and must be readily available to the Board. The records are in addition to any records required under other statutes, regulations, or rules, and shall be available for inspection by the Board in the same fashion as other required pharmacy records, and shall include: (5-8-09)

a. Identity of RDM accessed; (5-8-09)

b. Identification of the individual accessing the RDM; (5-8-09)

c. Type of transaction; (5-8-09)

d. Date and time of transaction; (5-8-09)

e. Name, strength, dosage form, and quantity of the drug accessed; (5-8-09)

f. Name of the patient for whom the drug was ordered; (5-8-09)

g. Name of the prescribing practitioner; and (5-8-09)

h. Any additional information as the pharmacist-in-charge may deem necessary. (5-8-09)

04. Access to RDM. Only an Idaho licensed pharmacist may have access to the RDM, unless specifically detailed in the approved operating memorandum. (5-8-09)

05. Stocking Medications. Only an Idaho licensed pharmacist may stock medications in the RDM unless specifically detailed in the approved operating memorandum. (5-8-09)

06. Packaging and Labeling. All containers of medications stored in the RDM shall be packaged and labeled in accordance with state and federal laws, rules, and regulations. (5-8-09)

07. Handling Controlled Substances. All aspects of handling controlled substances shall meet the

requirements of all state and federal laws, rules, and regulations. (5-8-09)

08. Counseling. Oral counseling shall be provided by a pharmacist licensed in Idaho at the time of dispensing by a two-way audio and video hookup between the responsible pharmacy and the pilot remote pharmacy. (5-8-09)

09. RDM Identification. The RDM must be clearly marked with the name, address, and phone number of the responsible pharmacy and pharmacist-in-charge. (5-8-09)

270. TECHNICIAN-CHECKING-TECHNICIAN PILOT PROGRAM.

01. Nature of Pilot Program. The Board, through its Executive Director, may authorize institutional pharmacies located within acute care hospitals to participate in a Technician-Checking-Technician Pilot Program. The purpose of the Technician-Checking-Technician Pilot Program is to allow pharmacy technicians to review the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for hospital patients whose orders have previously been reviewed and approved by a licensed pharmacist. During the pilot project phase of the Technician-Checking-Technician Pilot Program, designation to participate in the program shall be at the discretion of the Board and the executive director. (4-2-08)

02. Qualifying Institutional Pharmacies. Only an institutional pharmacy located within an acute care hospital, which for purposes of these rules is defined as a facility that is primarily engaged in providing, by or under the supervision of physicians, concentrated medical and nursing care on a twenty-four (24) hour basis to inpatients experiencing acute illness, shall be eligible to receive authorization to conduct a pilot technician-checking-technician program. (4-2-08)

03. Written Program Filing. Each institutional pharmacy authorized to conduct a pilot technician-checking-technician program shall have on file with the Board, prior to initiating its technician-checking-technician program, a written description of its program that shall contain, at a minimum: (4-2-08)

a. The name of the institutional pharmacy's pharmacist-in-charge; (4-2-08)

b. The name of the pharmacist, if different from the pharmacist-in-charge, assigned by the institutional pharmacy as the coordinator of its technician-checking-technician program; (4-2-08)

c. A description of the duties of the pharmacist assigned by the institutional pharmacy as coordinator of the technician-checking-technician program; (4-2-08)

d. A description of the duties of the pharmacy technician designated by the institutional pharmacy to perform the function of checking the work of other technicians; (4-2-08)

e. Identification of the types of medications with respect to which the designated pharmacy technician will perform the function of checking the work of other technicians; (4-2-08)

f. A description of the specialized and advanced training that shall be provided by the institutional pharmacy to each pharmacy technician designated by it to perform the function of checking the work of other technicians; (4-2-08)

g. A description of the monitoring and evaluation process that the institutional pharmacy shall utilize to ensure the on-going competency of each pharmacy technician designated by it to perform the function of checking the work of other technicians; and (4-2-08)

h. A description of the means of identification the institutional pharmacy shall use to identify within the pharmacy those pharmacy technicians designated by it to perform the function of checking the work of other technicians. (4-2-08)

04. Program Requirements. Each institutional pharmacy authorized to conduct a pilot technician-checking-technician program shall comply with the following requirements: (4-2-08)

a. No pharmacy technician shall be designated by an institutional pharmacy to perform, nor shall such technician perform, the function of checking the work of other technicians without having received and competently completed the specialized and advanced training prescribed in the institutional pharmacy's written program description filed with the Board. (4-2-08)

b. A pharmacy technician designated by an institutional pharmacy to perform the function of checking the work of other technicians may check the work of other technicians concerning the filling of floor and ward stock and unit dose distribution systems regarding manufacturer prepared or robotically prepared unit dose medications for hospital patients whose prescription orders have previously been reviewed and approved by a licensed pharmacist. The checking function performed by the designated pharmacy technician shall be limited to those types of medications identified in the institutional pharmacy's written program description filed with the Board. If either the alteration of a unit dose or the combination of unit doses is required, a licensed pharmacist shall verify the resulting unit dose alteration or combination of unit doses. (4-2-08)

c. The institutional pharmacy shall conduct ongoing monitoring and evaluation of each pharmacy technician designated by it to perform the function of checking the work of other technicians in order to ensure the ongoing competency of each such designated technician and the safety of patients. (4-2-08)

d. Each institutional pharmacy authorized to conduct a technician-checking-technician program shall, for each pharmacy technician designated by the institutional pharmacy to perform the function of checking the work of other technicians, maintain on its premises records available for inspection by the Board containing: (4-2-08)

i. The date the pharmacy technician was so designated; (4-2-08)

ii. The date the technician completed the specialized and advancing training prescribed in the written program description on file with the Board; (4-2-08)

iii. The dates and results of all competency evaluations; and (4-2-08)

iv. The dates of and reasons for any suspension or revocation by the institutional pharmacy or hospital of the pharmacy technician's designation to perform the function of checking the work of other technicians, or other disciplinary action by the institutional pharmacy or hospital against the designated technician connected with the technician's performance of the technician's duties in the technician-checking-technician program. (4-2-08)

e. Each pharmacy technician designated by the institutional pharmacy to perform the function of checking the work of other technicians shall wear a form of identification identifying the individual as a pharmacy technician so designated. The manner of identification shall be as described in the institutional pharmacy's written program description filed with the Board. (4-2-08)

f. The institutional pharmacy shall designate a licensed pharmacist, who may be the institutional pharmacy's pharmacist-in-charge, as the technician-checking-technician program coordinator, whose duties as program coordinator shall include the direct supervision of pharmacy technicians designated by the institutional pharmacy to perform the function of checking the work of other technicians and such other duties as specified in the institutional pharmacy's written program description filed with the Board. (4-2-08)

g. The pharmacist-in-charge of the institutional pharmacy shall be responsible for the overall operation of the institutional pharmacy's technician-checking-technician program; for ensuring that the activities of pharmacy technicians in performing the function of checking the work of other technicians are performed completely, safely, and without risk of harm to patients; and for compliance by the institutional pharmacy and its staff with the Board's rules regarding the Pilot Technician-Checking-Technician Program. (4-2-08)

05. Duration of Authorization. Authorization for an institutional pharmacy to conduct a pilot technician-checking-technician program shall not exceed two (2) years and shall be subject to the right of the Board and its executive director to conduct an annual review of the institutional pharmacy's technician-checking-technician program. (4-2-08)

271. -- 290. (RESERVED).

291. FAILURE TO RENEW.

01. Renewal of Licenses and Registrations. All licenses and registrations must be renewed within thirty (30) days prior to the expiration of their same. (11-22-93)

a. Failure to make application for renewal prior to the expiration date will cause the license or registration to be cancelled. (11-22-93)

b. The Board may reinstate a cancelled license or registration on payment of fifty dollars ($50) together with all fees delinquent at the time of reinstatement. (7-1-93)

02. Pharmacist License Renewal. Pharmacists shall apply for renewal of their license annually not later than the first day of June (Section 54-1724, Idaho Code). (11-22-93)

03. Reinstatement. The Board may compel pharmacist applicants for reinstatement of license, who have not practiced as a licensed pharmacist within or without the state, for the year preceding the time of filing the application for reinstatement of license, to take a practical or a jurisprudence examination or both. (11-22-93)

292. REGISTRATION, DRUG OUTLET.

01. Annual Renewal of Registration of Drug Outlet. (7-1-93)

a. Annually each drug outlet shall renew its registration no later than July 1 on a form provided by the Board and accompanied by the required fee. (7-1-93)

b. Each facility may be inspected by an inspector of the Board to ascertain that proper procedures are being carried out in regard to distribution of drugs. (7-1-93)

02. Retail Drug Outlet. (7-1-93)

a. A Retail Pharmacy Drug Outlet is a community pharmacy or any other pharmacy managed by an Idaho licensed pharmacist. (7-1-93)

b. A Retail Non-Pharmacy Drug Outlet includes any grocery store, bar, hotel, department store, vending machine, etc., not registered as a pharmacy that sells non-legend drugs, devices, or medical supplies to be sold at retail. (7-1-93)

03. Registrations and Renewals of Retail Non-Pharmacy Drug Outlet. For the issuing of registrations and renewals required by Section 54-1729, Idaho Code, the fee for each retail non-pharmacy drug outlet registration shall be determined as follows: (7-1-93)

a. "B" registration for those stocking not more than fifty (50) drug items; (8-4-94)

b. "A" registration for those stocking more than fifty (50) drug items; and (7-1-93)

c. "V" registration for vending machines, annual fee of five dollars ($5). (8-4-94)

d. Reinstatement of a non-pharmacy registration shall be a minimum of five dollars ($5) or one-half (1/2) the annual fee. (7-1-93)

04. Institutional Pharmacy Outlet. A hospital pharmacy, nursing home pharmacy, state institution pharmacy, and any other institutional outlet having a pharmacy within the facility. (7-1-93)

05. Institutional Non-Pharmacy Drug Outlet. A hospital, nursing home, state institution, shelter home, convalescent home, extended care facility, drug abuse treatment center, family planning clinic, and any other

outlet not having a pharmacy within the facility. (7-1-93)

06. Manufacturing Drug Outlet. A manufacturer manufacturing pharmaceuticals within the state, or a manufacturer located outside the state but doing business within the state of Idaho. (7-1-93)

07. Wholesale Drug Outlet. A company located within the state or outside the state but doing business within the state of Idaho. (7-1-93)

08. Vending Machines. Machines used for non-prescription drugs not otherwise restricted for over-the-counter sale will be considered a separate drug outlet and must be registered with the Board. (7-1-93)

a. Application for registration must be made on forms provided by the Board, accompanied by a reasonable registration fee for each machine that shall have a registration number issued by the Board. (7-1-93)

b. Registration must be renewed annually on or before June 30. (7-1-93)

c. Drugs and medical supplies stored in vending machines are subject to inspection by the Board upon reasonable notice. (7-1-93)

09. Durable Medical Equipment (DME) Outlet. (7-1-98)

a. All entities holding for sale legend or non-legend devices to be sold at retail or wholesale must be registered with the Board. Said legend devices may only be sold or delivered at retail upon the lawful order of a practitioner. DME outlets may hold non-legend drugs for sale. (7-1-98)

b. Registered DME outlets may hold for sale at retail only upon the order of a practitioner the following legend drugs: (7-1-98)

i. Pure oxygen for human application; (7-1-98)

ii. Nitrous oxide; (7-1-98)

iii. Sterile sodium chloride; and (7-1-98)

iv. Sterile water for injection. (7-1-98)

10. Telepharmacy Drug Outlet Across State Lines. (3-29-10)

a. "Institution engaged in the practice of telepharmacy across state lines" means an out-of-state hospital with an institutional pharmacy licensed or registered in another state, or a central order entry pharmacy licensed or registered in another state and that is part of a hospital system. (3-29-10)

b. "Central order entry pharmacy" means an out-of-state pharmacy that processes information related to the practice of pharmacy, that engages solely in centralized prescription processing but from which drugs are not dispensed, and that is physically located outside the institutional pharmacy of a hospital. (3-29-10)

c. "Hospital system" means one (1) or more hospitals under common ownership, where at least one (1) of the hospitals has within it a licensed or registered institutional pharmacy. A hospital system may also include, under the same common ownership, one (1) or more licensed or registered central order entry pharmacies. (3-29-10)

d. For registration as a telepharmacy drug outlet across state lines, an institution engaged in the practice of telepharmacy across state lines must satisfy the requirements of Section 54-1729, Idaho Code. (3-29-10)

11. Registration Issued at Specific Location. A registration will be issued to an applicant at a specific location and is not transferable as to person or place. (7-1-93)

293. REGISTRATION POSTING.

Registrations issued under the provisions of the Idaho Pharmacy Act must be conspicuously posted in the place for which registration is granted, are not transferable, and shall expire on the date indicated on the registration. (7-1-93)

294. REGISTRATION OF PHARMACISTS TO ENGAGE IN THE PRACTICE OF TELEPHARMACY ACROSS STATE LINES.

01. Registration. To engage in the practice of telepharmacy across state lines, a pharmacist who is not licensed to practice pharmacy within the state of Idaho must be registered by the Board. (3-29-10)

02. Requirements and Registration Fee. In order to be registered to engage in the practice of telepharmacy across state lines, the pharmacist must satisfy all the requirements of Section 54-1723A, Idaho Code, and pay a registration fee of two hundred fifty dollars ($250). (3-29-10)

03. Renewal and Renewal Fee. The renewal of registration to engage in the practice of telepharmacy across state lines will be as specified in Section 54-1723A(5), Idaho Code, and the annual renewal fee shall be two hundred fifty dollars ($250). (3-29-10)

295. -- 320. (RESERVED).

321. DEFINITIONS.

01. Authentication. To affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred. (4-2-08)

02. Authorized Distributor of Record. A wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following: (4-2-08)

a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (4-2-08)

b. The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis. (4-2-08)

03. Chain Pharmacy Warehouse. A physical location for prescription drugs that acts as a central warehouse and performs intra-company sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control. (4-2-08)

04. Co-Licensed Partner or Product. An instance where two (2) or more parties have the right to engage in the manufacturing or marketing, or both, of a prescription drug consistent with the federal Food and Drug Administration's implementation of the Prescription Drug Marketing Act. (4-2-08)

05. Components. Articles intended for use as a component of any articles specified in Subsections 321.01, 321.02, or 321.03 of these rules. (4-2-08)

06. Drop Shipment. The sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug. The wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor. (4-2-08)

07. Drug. Articles recognized as drugs in the official United States Pharmacopoeia, official National

Formulary, official Homeopathic Pharmacopoeia, other drug compendia or their supplement. (7-1-93)

08. Facility. Facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale. (4-2-08)

09. Manufacturer. A person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices consistent with the federal Food and Drug Administration definition of "manufacturer" under its regulations and guidance implementing the Prescription Drug Marketing Act. (4-2-08)

10. Manufacturer's Exclusive Distributor. A person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be considered part of the normal distribution channel. (4-2-08)

11. Normal Distribution Channel. A chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its co-licensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States Food and Drug Administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States Food and Drug Administration, either directly or by drop shipment to: (3-29-10)

a. A pharmacy to a patient; (4-2-08)

b. A designated person authorized by law to dispense or administer such drug to a patient; (4-2-08)

c. A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; (4-2-08)

d. A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or (4-2-08)

e. A chain pharmacy warehouse to the chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient. (4-2-08)

12. Pedigree. A document or electronic file containing information that records each wholesale distribution of a prescription drug. (4-2-08)

13. Prescription Drug. Any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by prescription, including finished dosage forms and bulk substances, subject to Section 503(b) of the federal Food, Drug and Cosmetic Act. (4-2-08)

14. Repackage. Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding any repackaging completed by the pharmacist responsible for the purpose of dispensing the drug to the patient. (4-2-08)

15. Repackager. A person who repackages. (4-2-08)

16. Sample. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (4-2-08)

17. Third Party Logistics Provider. A person who contracts with a prescription drug manufacturer to

provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but who does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third party logistics provider must be licensed as a wholesale distributor, pursuant to Section 54-1753, Idaho Code, and must also be an authorized distributor of record to be considered part of the normal distribution channel. (4-2-08)

18. Wholesale Distribution. Distribution of prescription drugs to persons other than a consumer or patient, but excluding the following: (4-2-08)

a. Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity or any transaction or transfer between co-licensees of a co-licensed product. (4-2-08)

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or the offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons. (4-2-08)

c. The distribution of prescription drug samples by manufacturers' representatives. (4-2-08)

d. Drug returns when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23. (4-2-08)

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use. (4-2-08)

f. The sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription. (4-2-08)

g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy from or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets. (4-2-08)

h. The sale, purchase, distribution, trade, or transfer of a prescription drug from one (1) authorized distributor of record to one (1) additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had, to date, been exclusively in the normal distribution channel. (4-2-08)

i. The delivery of, or the offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs if the common carrier does not store, warehouse, or take legal ownership of the prescription drug. (4-2-08)

j. The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or third party returns processor, including a reverse distributor. (4-2-08)

19. Wholesale Distributor. A person engaged in wholesale distribution of drugs including, but not limited to: manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturer's and distributor's warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel, a wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record. (4-2-08)

322. WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENT.

01. License Required. Every wholesale distributor who engages in wholesale distribution of prescription drugs must be licensed by the Board in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs, and every nonresident wholesale distributor, if it ships prescription

drugs into this state, must be licensed by the Board in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs. (4-2-08)

02. Exemption. Manufacturers distributing their own federal Food and Drug Administration approved drugs and devices are exempt from the wholesale distributor licensing requirement unless federal law or regulation requires the manufacturers to be licensed in this state as wholesale distributors. (4-2-08)

323. MINIMUM REQUIREMENTS FOR LICENSURE.

01. Information Under Oath. The following information shall be provided under oath from each wholesale drug distributor as part of the initial licensing procedure and for license renewal: (4-2-08)

a. The name, full business address, and telephone number of the licensee. (7-1-93)

b. All trade or business names used by the licensee. (7-1-93)

c. Addresses, telephone numbers, and names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs. (4-2-08)

d. The type of ownership or operation (such as, partnership, corporation, or sole proprietorship). (7-1-93)

e. The name of the owner or operator, or both, of the licensee, including: (7-1-93)

i. If a person, the name of the person; (7-1-93)

ii. If a partnership, the name of each partner, and the name of the partnership; (7-1-93)

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any; or (7-1-93)

iv. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. (7-1-93)

f. A list of all licenses, permits, and registrations issued to the applicant/licensee by any other state that authorizes the applicant/licensee to purchase or possess prescription drugs. (4-2-08)

g. Any convictions of the applicant/licensee under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (4-2-08)

h. Any felony convictions of the applicant/licensee under federal, state, or local law. (4-2-08)

i. Any discipline of the applicant/licensee by a regulatory agency in any state for violating any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (4-2-08)

j. The name of the licensee's designated representative for the facility together with the personal information statement and fingerprints required for such individual pursuant to Paragraph 323.01.k. of these rules. (4-2-08)

k. For each individual identified by the licensee as a designated representative pursuant to Paragraph 323.01.g. of these rules, the licensee shall provide the following information: (4-2-08)

i. The individual's places of residence for the past seven (7) years; (4-2-08)

ii. The individual's date and place of birth; (4-2-08)

iii. The individual's occupations, positions of employment, and offices held during the past seven (7) years; (4-2-08)

iv. The principal business and address of any business, corporation, or other organization in which each such office of the individual was held or in which each such occupation or position of employments was carried on; (4-2-08)

v. Whether the individual, during the past seven (7) years, has been the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and its disposition. (4-2-08)

vi. Whether the individual, during the past seven (7) years, has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from the possession, control, or distribution of prescription drugs for violating any federal or state law or regulation or other criminal violation and provide explanatory details concerning any such event; (4-2-08)

vii. A description of any involvement by the individual, during the past seven (7) years, with any business, including any investment other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party and in which the individual was also a named party or, regardless of whether the individual was a named party, in which the individual testified in a deposition or testified as a witness at trial; (5-8-09)

viii. A description of any felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or *nolo contendere*. If the individual has a criminal conviction under appeal and a copy of the notice of appeal of that criminal offense is submitted to the Board, the licensee must submit to the Board within fifteen (15) days after disposition of the appeal a copy of the final written order of disposition; and (4-2-08)

ix. A photograph of the individual taken in the previous year. (4-2-08)

02. License Required for Each Facility. If a wholesale distributor distributes prescription drugs from more than one (1) facility, the wholesale distributor shall obtain a license for each facility. (4-2-08)

03. Changes in Information Must Be Submitted to Board. Changes in, or corrections to, any information provided pursuant to Subsection 323.01 of these rules shall be submitted under oath to the Board at the time of license renewal. (4-2-08)

04. Accreditation by VAWD. The Board will recognize inspection and accreditation of wholesale distributors by the National Association of Boards of Pharmacy's (NABP) Verified-Accredited Wholesale Distributors (VAWD) program. (4-2-08)

05. License by Reciprocity. The Board may license by reciprocity a wholesale distributor that is licensed under the laws of another state if: (4-2-08)

a. The wholesale distributor has obtained VAWD accreditation through NABP; or (4-2-08)

b. The wholesale distributor is licensed under the laws of another state pursuant to standards comparable to those in Idaho and acceptable to the Board and the other state extends reciprocal treatment to distributors of this state. (4-2-08)

324. MINIMUM QUALIFICATIONS.

01. Mandatory Denial of Licensure for Wholesale Distribution of Drugs. The Board shall not issue a wholesale distributor license to an applicant if the designated representative does not meet all of the following qualifications: (4-2-08)

a. Is at least twenty-one (21) years of age; (4-2-08)

b. Has been employed full time for at least three (3) years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs; (4-2-08)

c. Is employed by the applicant full time in a managerial position; (4-2-08)

d. Is actively involved in the daily operation of the wholesale distributor; (4-2-08)

e. Is physically present at the applicant facility during regular business hours except when the absence of the designated representative is authorized including, but not limited to, sick leave and vacation leave; (4-2-08)

f. Is serving in the capacity of a designated representative for only one (1) applicant at a time, except where more than one (1) licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code; (4-2-08)

g. Does not have any convictions under a federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and (4-2-08)

h. Does not have any felony convictions under federal, state, or local law. (4-2-08)

02. Other Eligibility Factors. Besides the qualifications of the applicant's designated representative, the Board will consider the following factors in determining the applicant's eligibility for licensure as a wholesale distributor: (4-2-08)

a. Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances; (7-1-93)

b. Any felony convictions of the applicant under federal, state, or local laws; (7-1-93)

c. The applicant's past experience in the manufacture or distribution of drugs, including controlled substances; (7-1-93)

d. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution; (7-1-93)

e. Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances; (7-1-93)

f. Compliance with licensing requirements under previously granted licenses, if any; (7-1-93)

g. Compliance with the requirements to maintain and make available to the state licensing authority or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and (4-2-08)

h. Any other factors or qualifications the Board considers relevant to, and consistent with, the public health and safety. (7-1-93)

03. Denial of License to Applicant. The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the interest of the public health, safety, and welfare. (4-2-08)

325. PERSONNEL.

01. Employment of Adequate Personnel. The licensed wholesale distributor shall employ adequate

personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs. (4-2-08)

02. Continuing Training for Designated Representative. A licensed wholesale distributor's designated representative must receive and complete: (4-2-08)

a. Continuing training specified by the Board regarding federal and state laws regarding wholesale distribution of prescription drugs; or (4-2-08)

b. If no formal continuing training is specified by the Board, training programs that address applicable federal and state laws regarding wholesale distribution of prescription drugs provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. (4-2-08)

326. MINIMUM REQUIREMENTS.

01. Requirements for Storage and Handling of Drugs. The following are required for the storage and handling of drugs and for the establishment and maintenance of drug distribution records by wholesale drug distributors and their officers, designated representative, agents, and employees. (4-2-08)

02. Drug Facility Requirements. All facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall: (7-1-93)

a. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations; (7-1-93)

b. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; (7-1-93)

c. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in medicate or sealed secondary containers that have been opened; (7-1-93)

d. Be maintained in a clean and orderly condition; and (7-1-93)

e. Be free from infestation by insects, rodents, birds, or vermin of any kind. (7-1-93)

03. Security of Wholesale Drug Distribution Facilities. All facilities used for wholesale drug distribution shall be secure from unauthorized entry. (7-1-93)

a. Access from outside the premises shall be kept to a minimum and well controlled. (7-1-93)

b. The outside perimeter of the premises shall be well lighted. (7-1-93)

c. Entry into areas where drugs are held shall be limited to authorized personnel. (7-1-93)

d. All facilities shall be equipped with an alarm system to detect entry after hours. (7-1-93)

e. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. (7-1-93)

f. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. (7-1-93)

04. Proper Storage of Drugs. All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with requirements in the current edition of an official compendium. (7-1-93)

a. If no storage requirements are established for a drug, the drug may be held at "controlled" room

temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected. (7-1-93)

b. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs shall be utilized to document proper storage of drugs. (7-1-93)

c. The recordkeeping requirements in Subsection 326.07 of these rules shall be followed for all stored drugs. (7-1-93)

05. Examination of Materials. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or drugs that are otherwise unfit for distribution. (7-1-93)

a. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. (7-1-93)

b. Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions. (7-1-93)

c. The recordkeeping requirements in Subsection 326.07 of these rules shall be followed for all incoming and outgoing drugs. (7-1-93)

06. Returned, Damaged, and Outdated Drugs. Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed or returned to the original manufacturer or third party returns processor. (4-2-08)

a. Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be considered adulterated and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the original manufacturer or third party returns processor. (4-2-08)

b. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug shall be 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. (7-1-93)

c. In determining whether the conditions 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. (7-1-93)

d. The recordkeeping requirements in Subsection 326.07 of these rules shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs. (7-1-93)

07. Recordkeeping by Wholesale Drug Distributors. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. (7-1-93)

a. The records shall include: (7-1-93)

i. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped; (7-1-93)

ii. The identity and quantity of the drugs received and distributed or disposed of; and (7-1-93)

iii. The dates of receipt and distribution or other disposition of the drugs. (7-1-93)

b. Inventories and records shall be made available for inspection and photocopying by any authorized

official of any governmental agency charged with enforcement of these rules for a period of two (2) years following disposition of the drugs. (7-1-93)

c. 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. (7-1-93)

d. 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 these rules. (7-1-93)

327. WRITTEN POLICIES AND PROCEDURES.
Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures that shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories, and as required by this Section: (7-1-93)

01. Distribution of Oldest Approved Stock First. A procedure shall be established whereby the oldest approved stock of a drug product is distributed first but may permit deviation from this requirement if such deviation is temporary and appropriate. (7-1-93)

02. Procedure for Recalls and Withdrawals. A procedure shall be established for handling recalls and withdrawals of drugs that adequately addresses recalls and withdrawals due to: (7-1-93)

a. 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; (7-1-93)

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or. (7-1-93)

c. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design. (7-1-93)

03. Procedure for Crisis Situations. A procedure shall be established to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or other situations of local, state, or national emergency. (7-1-93)

04. Segregation and Disposal of Outdated Drugs. A procedure shall be established to ensure that any outdated drugs shall be segregated from other drugs and either returned to the original manufacturer or third party returns processor, including a reverse distributor, or destroyed and which shall provide for the written documentation of the disposition of outdated drugs to be maintained for two (2) years following the disposition of the outdated drugs. (4-2-08)

328. RESPONSIBLE PERSONS.
Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, the designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling and shall include a description of each individual's duties and a summary of their qualifications. (4-2-08)

329. COMPLIANCE.
Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations. (7-1-93)

01. Inspections of Wholesale Drug Distributors. Wholesale drug distributors shall permit the Board 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, at reasonable times and in a reasonable manner upon presentation of appropriate identification, to the extent authorized by law. (7-1-93)

02. Registration of Wholesale Drug Distributors Dealing in Controlled Substances. Wholesale drug distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and the DEA and shall comply with all applicable state, local and DEA laws, rules and regulations. (7-1-93)

330. SALVAGING AND REPROCESSING.
Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws, rules, or regulations that relate to drug product salvaging or reprocessing including, but not limited to, 21 CFR 297, 210, and 211. (7-1-93)

331. PEDIGREE.

01. Pedigree Contents. A pedigree for each prescription drug shall contain the following information: (4-2-08)

a. The proprietary and established name of the prescription drug; (4-2-08)

b. The container size of the prescription drug; (4-2-08)

c. The number of containers; (4-2-08)

d. The dosage form; (4-2-08)

e. The dosage strength; (4-2-08)

f. The lot number with expiration dates and the national drug code (NDC) of the prescription drug; (4-2-08)

g. The name of the manufacturer and repackager, if applicable, of the finished prescription drug product; (4-2-08)

h. The name, address, telephone number, and, if available, the e-mail address, of each owner of the prescription drug and each wholesale distributor of the prescription drug; (4-2-08)

i. The name and address of each location from which the prescription drug was shipped, if different from the owner's; (4-2-08)

j. The dates of each transaction; (4-2-08)

k. A certification that each recipient has authenticated the pedigree; and (4-2-08)

l. The name and address of each recipient of the prescription drug. (4-2-08)

02. Pedigree Format. The pedigree format shall include the contents described in Subsection 331.01 of these rules and may be subject to the approval of the Board. (4-2-08)

03. Requirement of a Pedigree. Each person engaged in wholesale distribution of prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, that leave or have ever left the normal distribution channel shall, before each wholesale distribution of a drug, provide a pedigree to the person who receives the drug. A retail pharmacy or chain pharmacy warehouse shall comply with the pedigree requirement only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution. (4-2-08)

04. Authentication. Each person who is engaged in the wholesale distribution of a prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify that each transaction listed on the pedigree has occurred before any wholesale distribution of a prescription

drug occurs. (4-2-08)

05. Maintenance of Pedigree. The purchaser and the wholesale distributor of a prescription drug shall maintain the pedigree for not less than three (3) years from the date of sale or transfer. (4-2-08)

06. Availability of Records for Inspection. Pedigrees shall be made available to the Board for inspection within five (5) business days of a request from the Board. (4-2-08)

332. FAILURE TO COMPLY.
A wholesale distributor's violation of, or failure to comply with, these rules may result in imposition by the Board of any one (1) or more of the penalties provided in Section 54-1728, Idaho Code. (4-2-08)

333. -- 350. (RESERVED).

351. DEFINITIONS.

01. Anesthetics, General. Any drug or substance capable of rendering an animal unconscious. (7-1-93)

02. Anesthetics, Local. Any drug or substance capable of blocking impulses by affecting sensory nerves or their endings. (7-1-93)

03. Distribution. The act of receiving orders, preparing drugs and associated recordkeeping relevant to legend veterinary drug delivery. (7-1-93)

04. Controlled Substances. A controlled substance, also referred to as "basic class" or "class drugs," is any substance classified by the federal Food and Drug Administration or the Board in Schedule I through V of the state or federal Controlled Substances Act. (7-1-93)

05. Legend Drug. A drug that, prior to being distributed, is required by federal law to be labeled with the following statement: "Caution: Federal law restricts this drug to be used by or on the order of a licensed veterinarian" or a drug that is required by any state or federal law or regulation to be distributed pursuant to a prescription or used by practitioners only. (7-1-93)

06. Non-Legend Drug. Any drug that is properly labeled and established as safe and effective by the FDA for sale and use by consumers and approved for sale without a prescription or a practitioner's order. (7-1-93)

07. Formulary. A negative or exclusive list of drug types or therapeutic categories not available for distribution by retail veterinary drug outlets. (7-1-93)

08. Roster or Official Veterinary Drug Technician Roster. The list of names of qualified veterinary drug technicians (VDT) kept in the Board office. (7-1-93)

09. Retail Veterinary Drug Outlet. An establishment registered by the Board employing a qualified VDT authorized to distribute legend veterinary drugs pursuant to bona fide orders of practitioners. (7-1-93)

10. Veterinary Drug Order (VDO). A lawful order of a veterinary practitioner issued pursuant to the establishment of a bona fide veterinarian, patient, client relationship as recognized by the American Veterinary Medical Association. (7-1-93)

11. Veterinary Drug Technician (VDT). A non-pharmacist licensed by the Board to distribute legend veterinary drugs in a retail veterinary drug outlet. (7-1-93)

12. Veterinarian or Veterinary Practitioner. A veterinarian licensed in this or any contiguous state to practice veterinary medicine. (7-1-93)

352. PURPOSE.

These rules are to accomplish the purposes of Section 54-1729(2)(a)5, Idaho Code, and Section 54-1734(3)(a) through (c), Idaho Code, relevant to registration of retail veterinary drug outlets and the procedures relevant to distributing veterinary drug orders. (7-1-93)

353. APPLICABILITY.
The following rules are applicable to all retail establishments and individuals distributing legend veterinary drug products pursuant to orders of a practitioner. (7-1-93)

354. REGISTRATION.
All retail establishments distributing legend veterinary drug products pursuant to orders of a practitioner shall register annually with the Board by completing the appropriate application and submitting the established fee, after which certificates of registration will be issued to satisfy the requirements of Section 54-1729(2)(a)5, Idaho Code. (7-1-93)

355. PERSONNEL.

01. Veterinary Drug Technicians. Only a qualified veterinary drug technician (VDT) will be authorized to process veterinary drug orders for distribution to the clients of licensed practitioners. A high school graduate who is at least eighteen (18) years of age and who has scored at least seventy-five percent (75%) on a Board examination designed to measure knowledge of these rules will be listed on the official VDT roster. (7-1-93)

02. Sufficient Staffing. Registered retail veterinary drug outlets must employ sufficient VDTs to ensure that one (1) such person will be on duty at all times when the establishment is open to the public for business. (7-1-93)

03. Registration of Veterinary Drug Technicians. VDTs will register annually and pay the established fee. (7-1-93)

356. VETERINARY DRUG ORDERS.

01. Veterinary Orders for Legend Drugs. All veterinary orders for legend drugs issued to clients to be distributed by a retail veterinary drug outlet will be written on an official numbered three (3) part order form available through the Idaho Department of Agriculture. Such orders will be processed as follows: (5-8-09)

a. The practitioner (veterinarian) will retain the second copy in his records; (5-8-09)

b. Original and third copy will be sent to the retail veterinary drug outlet; and (5-8-09)

c. The VDT will file the original copy in a readily retrievable manner and will attach the first copy to the order for delivery to the client. (5-8-09)

02. Distribution of Veterinary Drugs. At no time will legend veterinary drugs be distributed to clients (customers) unless the first copy of the practitioner order is attached in some manner. (7-1-93)

03. Retention of Drug Orders for Inspection. Original copies of drug orders will be retained by the establishment and made available for Board inspection for at least two (2) years from the date of processing. (7-1-93)

357. DRUG ORDERS.

01. Processing Veterinary Drug Orders. Veterinary drug orders are to be processed for no more than the quantity indicated by the practitioner. (7-1-93)

a. No refilling or reprocessing of veterinary drug orders is allowed. (7-1-93)

b. In the event of a split shipment, the VDT must indicate on the reverse of the original order the date, quantity and initials of the person supplying the partial order. Delivery of the remaining quantity must be made within ninety (90) days. (7-1-93)

02. Processing Orders as Written. Veterinary drug orders must be processed exactly as written by the practitioner. (7-1-93)

a. Supplying a different brand or product will be *prima facie* evidence of rule violation and will subject both the VDT and the establishment to disciplinary proceedings by the Board. (7-1-93)

b. Only original manufacturers' containers bearing the entire label intact may be delivered (and no partial containers), and no compounding is permitted by VDTs. (7-1-93)

03. Telephone Orders. To ensure proper processing and distribution of drug orders, telephone orders must be received directly by a VDT from a licensed practitioner. If the practitioner is not known to the VDT, he must make a reasonable effort to determine that the oral authorization comes from a licensed practitioner, which may include a call back to the individual practitioner for verification. (7-1-93)

04. Oral Orders. All oral prescription orders are subject to the following: (5-8-09)

a. Upon receiving an oral prescription order, the establishment shall promptly reduce the oral order to writing on an unnumbered telephone drug order form available through the Idaho Department of Agriculture. The establishment shall keep the original of the completed form on file at the place of distribution. (5-8-09)

b. Following reduction of the oral order to writing, processing of the order shall be identical to the procedure for written orders. (5-8-09)

c. Within seventy-two (72) hours after receiving an oral prescription order, the establishment shall have on file at the place of distribution written confirmation of the oral order from the practitioner. Written confirmation must be copy one (1) of an official numbered three-part order form available through the Idaho Department of Agriculture, signed by the practitioner. The written confirmation may be hand delivered, mailed, faxed, attached to an e-mail, or otherwise properly delivered to the Veterinary Drug Outlets (VDO). The VDO shall attach to the written confirmation the form completed by the VDO pursuant to Paragraph 357.04.a. of these rules. (5-8-09)

358. (RESERVED).

359. SECURITY AND STORAGE.
All products must be stored in compliance with United States Pharmacopoeia/National Formulary specifications for temperature and light. (7-1-93)

01. Separation of Legend and Non-Legend Drugs. All legend drugs must be separated from the non-legend drugs and stored in an area that is lockable for security purposes, and only VDTs and authorized regulatory personnel shall have access to legend drug areas. (7-1-93)

02. Written Policy for Inventory Review. A written policy will be established to review inventory at least semi-annually for the purpose of identifying and removing outdated products. (7-1-93)

360. FORMULARY.
Retail veterinary drug outlets are authorized to stock and VDTs are authorized to prepare and deliver all legend veterinary drugs except the following: (7-1-93)

01. Controlled Substances. Controlled substances listed in Schedules I through V of either the state or federal Controlled Substances Act. (7-1-93)

02. Euthanasia Drugs. Euthanasia drugs or products. (7-1-93)

03. Tranquilizers. Tranquilizer drugs or products. (7-1-93)

04. Neuromuscular Paralyzing Drugs. Curare, succinylcholine, or other neuromuscular paralyzing drugs. (7-1-93)

05. General Anesthetics. General anesthesia drugs or products. (7-1-93)

361. RESPONSIBILITIES.

01. Understanding of Rules. Owners or manager of registered veterinary drug outlets must have sufficient understanding of the rules pertaining to this business to detect improper activities. (7-1-93)

02. Unauthorized Drug Distribution. Owners or managers are jointly responsible for unauthorized drug distribution from the establishment they own or manage. (7-1-93)

03. Compliance with Recordkeeping and Reporting. Owners or managers are ultimately responsible for establishing compliance with recordkeeping and report filing requirements imposed by these rules. (7-1-93)

362. RECORDKEEPING REQUIREMENTS.

01. Invoices and Orders. All purchase invoices and practitioner orders will be maintained in a readily retrievable manner for a minimum of two (2) years. (7-1-93)

02. Policy and Procedure Manual. An establishment policy and procedure manual will be maintained in an up-to-date form at all times and will include current Board rules and company policy for handling practitioner orders. (7-1-93)

03. Notification of Personnel Changes. Notification relevant to VDT personnel changes will be forwarded in writing to the Board within five (5) days of any such change, including names and addresses of resigning and newly hired VDTs. (7-1-93)

04. Drug Order Numbering. Drug orders will be assigned a serially arranged number for identification purposes. This same number is to appear on the client copy accompanying the order. (7-1-93)

363. AUTHORITY.
Pursuant to Section 54-1720, Idaho Code, the Board is granted the authority to control registrants covered under Title 54, Chapter 17, Idaho Code. (7-1-93)

364. PENALTIES.

01. Violation of These Rules. Pursuant to Section 54-1728, Idaho Code, the Board shall have authority to suspend, revoke or restrict the registration of any establishment or VDT found by the Board to have violated the provisions of these rules or may impose a monetary penalty, not to exceed two thousand dollars ($2000), for violations. (7-1-93)

02. Board Finds Unauthorized Items or Products. In the event that unauthorized items, including misbranded, adulterated, or mislabeled products, are observed by Board compliance officers, the items may be embargoed or impounded until proper disposal of such items can be arranged. (7-1-93)

03. Activities of Compliance Officers. All activities of compliance officers will be in accordance with the Idaho Administrative Procedure Act and Board parameters, and disciplinary decisions will be in accordance with these rules. (7-1-93)

04. Removal of Name from Official Roster. The Board shall have the authority to remove for cause the name of a VDT from the official roster. (7-1-93)

365. INSPECTIONS.

01. Compliance Inspection. No less than once a year, the Board will conduct a compliance inspection of veterinary drug outlets and will review all aspects of management and distribution with particular attention to practices affecting public health. (7-1-93)

02. Request for Records and Reports. Upon request, the establishment will furnish to the reviewer all records, invoices, inventories, orders, and other records and reports as may be required to conduct an in depth audit of drug distribution and receipts. (7-1-93)

03. Inspection Reports. Inspection reports will be signed by the owner or manager at completion of the exit interview with the compliance officer, and these reports will be posted in a conspicuous area within the establishment. (7-1-93)

04. Noted Deficiencies. Deficiencies noted by inspectors will be promptly remedied at the owner's expense, and the Board office will be promptly notified of corrective measures. (7-1-93)

05. Failure to Correct Deficiency. Failure to correct a deficiency within ninety (90) days will subject parties to receiving a Board citation or reinspection, or both, at the owner's expense. (7-1-93)

366. -- 379. (RESERVED).

380. LEGEND DRUG DONATION – STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. In order to be eligible for donation, drugs must meet the following criteria: (3-29-10)

a. The drug name, strength, lot number, and expiration date must appear on the drug package or label. (3-29-10)

b. Donated drugs must be approved by the federal Food and Drug Administration and: (3-29-10)

i. Be in the original unit dose packaging; or (3-29-10)

ii. Be oral or parenteral drugs in sealed single-dose containers approved by the federal Food and Drug Administration; or (3-29-10)

iii. Be topical or inhalant drugs in sealed units-of-use containers approved by the federal Food and Drug Administration; or (3-29-10)

iv. Be parenteral drugs in sealed multiple-dose containers approved by the federal Food and Drug Administration from which no doses have been withdrawn. (3-29-10)

c. Donated drugs must not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug wholesaler or manufacturer. (3-29-10)

d. Donated drugs must not require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia. (3-29-10)

e. Donated drugs must not be the subject of federal Food and Drug Administration restricted drug distribution programs including, but not limited to, thalidomide and lenalidomide. (3-29-10)

02. Donation Standards. (3-29-10)

a. A licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority at the qualifying charitable clinic or center will be responsible for defining a specified set of drugs that will be included in their formulary. (3-29-10)

b. Donating nursing homes may only donate drugs that appear on the qualifying charitable clinic or center's formulary. (3-29-10)

c. A licensed pharmacist, nurse, physician, or physician assistant from the donating nursing home

must sign and date a manifest before delivery of the donated drugs to the qualifying charitable clinic or center that: (3-29-10)

i. Certifies that the donated drugs have been maintained in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and the United States Pharmacopoeia standards; (3-29-10)

ii. Certifies that the donated drugs have been continuously under control of a health care professional and have never been in the custody of a patient or other individual; (3-29-10)

iii. Certifies that the donating nursing home has only donated drugs on the qualifying charitable clinic or center's formulary; (3-29-10)

iv. Certifies that the donating nursing home has complied with the provisions of these rules; (3-29-10)

v. Certifies that the patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the donating nursing home; (3-29-10)

vi. Lists the name of the donating nursing home and the name of the receiving qualifying charitable clinic or center; and (3-29-10)

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug to be donated. (3-29-10)

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. (3-29-10)

03. Receipt of Donated Drugs. Donated drugs may be received at a qualifying charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel. (3-29-10)

04. Verification of Received Drugs. (3-29-10)

a. Receipt of each donated drug must be verified against each manifest by a pharmacist, physician, physician assistant, advanced practice professional nurse with prescriptive authority, dentist, optometrist, or authorized clinic personnel. (3-29-10)

b. In the event that the identifying patient information is not removed by the donating entity, the information must be removed or redacted at the charitable clinic or center. (3-29-10)

c. Before donated drugs are placed with a qualified charitable clinic or center's regular stock, a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must: (3-29-10)

i. Verify utilizing a current drug identification book, a computer program, or an online service for the same that the donated drugs meet the criteria in Subsection 380.01 of these rules; (3-29-10)

ii. Verify that the name and strength noted on the label of each unit of the donated drug is correct; and (3-29-10)

iii. Determine that the donated drugs are not adulterated or misbranded and that they are safe to dispense. (3-29-10)

d. Improperly donated drugs that do not meet criteria in Subsections 380.01 through 380.03 of these rules must be destroyed, and documentation of such destruction must be maintained within a destruction record. (3-29-10)

05. Storage of Donated Drugs. (3-29-10)

a. Drug storage must have proper environmental controls to assure the integrity of the drug in accordance with the drug manufacturer's recommendations and United States Pharmacopoeia standards. (3-29-10)

b. Donated drugs may be commingled with the qualifying charitable clinic or center's regular stock of drugs only if the packaging on the donated drugs has been labeled to show that the drugs were obtained through a nursing home. (3-29-10)

c. Donated drugs with packaging that has not been labeled to show that the drugs were obtained through a nursing home must be kept in an area that is separately designated from the qualifying charitable clinic or center's regular stock of drugs. (3-29-10)

d. The space in which drugs are stored must be secured at all times and accessible only to pharmacists, physicians, physician assistants, dentists, optometrists, advanced practice professional nurses with prescriptive authority, and authorized clinic personnel. (3-29-10)

06. Dispensing Donated Drugs to Medically Indigent Patients. (3-29-10)

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions must not be re-dispensed to indigent patients and must be destroyed. Documentation of such destruction must be maintained within a destruction record. (3-29-10)

b. A licensed pharmacist, physician, physician assistant, dentist, optometrist, or an advanced practice professional nurse with prescriptive authority working at a qualifying charitable clinic or center who re-dispenses donated drugs to any patient must: (3-29-10)

i. Utilize a proper and appropriate container; (3-29-10)

ii. Place a label on the container that conforms to provisions of these rules; and (3-29-10)

iii. Initial the prescription label. (3-29-10)

c. The re-dispensed drug must be assigned the same expiration date as is on the original package. (3-29-10)

d. A charitable clinic or center must maintain dispensing records for each donated drug dispensed. (3-29-10)

e. Licensed pharmacists, physicians, physician assistants, dentists, optometrists, and advanced practice professional nurses with prescriptive authority dispensing donated drugs are required to provide patient counseling. (3-29-10)

07. Miscellaneous. (3-29-10)

a. Authorized clinic personnel means an individual who is: (3-29-10)

i. Under the general supervision of a licensed pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority; and (3-29-10)

ii. Named in writing by the qualifying charitable clinic or center's medical director or consultant pharmacist. (3-29-10)

b. The qualifying charitable clinic or center must maintain a list of the names of authorized clinic personnel, their individual duties, and a summary of their qualifications. (3-29-10)

c. Physician assistant has the same definition as in Section 54-1803, Idaho Code. (3-29-10)

d. Qualifying charitable clinics or centers receiving donated drugs must develop policies and procedures to assure that authorized clinic personnel will comply with applicable federal, state, and local laws. (3-29-10)

e. Drugs donated under these rules must not be sold, resold, offered for sale, traded, or transferred to another charitable clinic or center. (3-29-10)

f. Nothing in these rules precludes a qualifying charitable clinic or center from charging an indigent patient a dispensing fee. (3-29-10)

08. Record Keeping Requirements. (3-29-10)

a. Donating nursing homes must maintain all manifests in a readily retrievable fashion for at least two (2) years. (3-29-10)

b. Qualifying charitable clinics or centers must maintain destruction records, dispensing records, and manifests in a readily retrievable fashion for at least two (2) years. (3-29-10)

381. -- 400. (RESERVED).

401. FEES.
Pursuant to 54-1720(5)(a), Idaho Code, the Board will collect fees, such fees to remain in effect until changed by the Board. All fees set by the Board shall be annual, or for any portion of the year, and shall not be prorated. (7-1-98)

402. ORIGINAL PHARMACIST LICENSE.

01. Certification for NAPLEX Examination. One hundred dollars ($100). (3-13-02)

02. Reciprocity. Two-hundred and fifty dollars ($250). (7-1-93)

03. State Jurisprudence Exam. Fifty dollars ($50). (3-13-02)

403. DUE DECEMBER 31, ANNUALLY.

01. Controlled Substance Registration. Sixty dollars ($60). (3-13-02)

404. DUE JUNE 30, ANNUALLY -- TABLE.

01. Pharmacist License. (12-7-94)

a. Active: ninety dollars ($90). (3-13-02)

b. Inactive: fifty dollars ($50). (3-13-02)

02. Pharmacy. (6-1-94)

a. Pharmacy license: one hundred dollars ($100). (12-7-94)

b. Parenteral admixture license: one hundred dollars ($100). (12-7-94)

03. Out-of-State Mail Service. (7-1-93)

a. Pharmacy, initial license: five hundred dollars ($500). (12-7-94)

b. Renewal license: two hundred fifty dollars ($250). (12-7-94)

04. **Clinics and Nursing Homes**. Thirty-five dollars ($35). (3-13-02)

05. **Non-Pharmacy**. (11-1-93)

a. "A": sixty dollars ($60). (3-13-02)

b. "B": twenty-five dollars ($25). (3-13-02)

c. "V" (Vending machines): ten dollars ($10). (3-13-02)

d. "DME": fifty dollars ($50). (7-1-98)

06. **Hospitals without Pharmacy**. Thirty-five dollars ($35). (3-13-02)

07. **Wholesaler (Distributor)**. One hundred thirty dollars ($130). (4-9-09)

08. **Controlled Substance for Wholesalers and Distributors**. One hundred dollars ($100). (3-13-02)

09. **Researcher, Analytical Lab**. Forty dollars ($40). (3-13-02)

10. **Retail Veterinary Drug Outlet - Retail or Retail/Wholesale**. One hundred dollars ($100). (3-13-02)

11. **Veterinary Drug Technician**. Thirty-five dollars ($35). (12-7-94)

12. **Pharmacy Technician**. Thirty-five dollars ($35). (3-13-02)

13. **Preceptor Site**. Twenty-five dollars ($25). (5-8-09)

405. STUDENT PHARMACIST REGISTRATION.

01. **Intern**. Fifty dollars ($50). (5-8-09)

02. **Extern**. Fifty dollars ($50) at acceptance to accredited college of pharmacy, to last until July 15 following graduation. (5-8-09)

406. MISCELLANEOUS.

01. **Test Score Certification**. Twenty-five dollars ($25). (3-13-02)

02. **Hour Certification**. Twenty-five dollars ($25). (3-13-02)

03. **Controlled Substance Inventory Book**. Fifteen dollars ($15). (3-13-02)

04. **Duplicate Pharmacist Certificate**. Thirty-five dollars ($35). (3-13-02)

05. **Commercial Lists**. (12-24-93)

a. Pharmacy list: fifty dollars ($50). (3-13-02)

b. Pharmacist list: fifty dollars ($50). (3-13-02)

c. CSA Practitioner list: fifty dollars ($50). (3-13-02)

i. Complete CSA Practitioner list: one hundred fifty dollars ($150). (3-13-02)

ii. Each profession CSA list: fifty dollars ($50). (3-13-02)

06. **Official Idaho Register**. Fifteen dollars ($15). (3-13-02)

07. **Pharmacy Law**. Includes two (2) year updates: thirty-five dollars ($35). (7-1-93)

08. **Reinstatement Fee**. All licenses: seventy-five dollars ($75). (3-13-02)

09. **Transcript of Hearing**. Per page: five dollars ($5). (3-13-02)

407. -- 431. (RESERVED).

432. DEFINITIONS - (A -- G).

01. **Act**. The term "Act" means the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code. (7-1-93)

02. **Addict**. The term "addict" means any individual who habitually uses any narcotic drug so as to endanger the public morals, health, safety, or welfare, or who is so far addicted to the use of narcotic drugs as to have lost the power of self-control with reference to his addiction. (7-1-93)

03. **Basic Class**. The term "basic class" means controlled substances listed in Schedules I and II, including: (7-1-93)

a. 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 37-2705(b), Idaho Code. (7-1-93)

b. 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 37-2705(c), Idaho Code. (7-1-93)

c. 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 37-2705(d), Idaho Code. (7-1-93)

d. 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: (7-1-93)

i. Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium, and tincture of opium; (7-1-93)

ii. Apomorphine; (7-1-93)

iii. Codeine; (7-1-93)

iv. Ethylmorphine; (7-1-93)

v. Hydrocodone; (7-1-93)

vi. Hydromorphone; (7-1-93)

vii. Metopon; (7-1-93)

viii. Morphine; (7-1-93)

ix. Oxycodone; (7-1-93)

x. Oxymorphone; (7-1-93)

xi. Thebaine; (7-1-93)

xii. Mixed alkaloids of opium listed in Section 37-2707(b)(2), Idaho Code; (7-1-93)

xiii. Cocaine; and (7-1-93)

xiv. Ecgonine. (7-1-93)

e. Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, ethers, and salts is possible within the specific chemical designation, listed in Section 37-2702(c), Idaho Code. (7-1-93)

f. Methamphetamine, including its salts, isomers, and salts of isomers when contained in any injectable liquid. (7-1-93)

04. Board of Medicine. The term "Board of Medicine" means the Idaho State Board of Medicine created by Title 54, Chapter 18, Idaho Code. (7-1-93)

05. Board of Health. The term "Board of Health" means the Idaho State Board of Health as created by Title 39, Chapter 1, Idaho Code. (7-1-93)

06. Department. The term "Department" means the Idaho State Police. (7-1-93)

07. Executive Director. The term "executive director" means the Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (7-1-93)

08. Distributor. The term "distributor" means a person who supplies drugs that he himself has not produced or prepared and who sells to persons other than the ultimate consumer. (7-1-93)

09. Drug Dependent Person. The term "drug dependent person" means a person who is using a controlled substance (as defined in Section 37-2720, Idaho Code) and who is in a state of psychic or physical dependence, or both, arising from the use of that substance on a continuous basis. (7-1-93)

10. Drug Dependence. The term "drug dependence" is defined and characterized by behavioral and other responses that include a strong compulsion to take the substance on a continuous basis in order to experience its psychic effects or to avoid the discomfort caused by its absence. (7-1-93)

433. DEFINITIONS -- (H - Z).

01. Hospital. The term "hospital" means an institution for the care and treatment of the sick and injured approved by the Idaho Department of Health and Welfare and entrusted with the custody of controlled substances and the professional use of controlled substances under the direction of a practitioner. (7-1-93)

02. Individual Practitioner. The term "individual practitioner" means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted by the state in which he practices to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner. (7-1-93)

03. Institutional Practitioner. The term "institutional practitioner" means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices to dispense a controlled substance in the course of professional practice, but does not include a pharmacy. (7-1-93)

04. Laboratory. The term "laboratory" means a laboratory approved by the Board and entrusted with

the custody and use of controlled substances for scientific and medical purposes and for purposes of instruction and administered by a person licensed by the state of Idaho to possess such substances. (7-1-93)

05. Name. The term "name" means the official name, common or usual name, chemical name, or brand name of a substance. (7-1-93)

06. Official Idaho Register. The term "Official Idaho Register" is defined as the official register issued by the Board that contains the required information to record the sales or disposition of Schedule V substances. The book shall be in duplicate bearing the notice to the public on the reverse side of the original sheet which is permanently bound in the book, and shall be retained for a period of two (2) years after the last dated entry. (7-1-93)

07. Owner. The term "owner" means any person having any right, title, or interest in a referenced vehicle. (7-1-93)

08. Pharmacist. The term "pharmacist" means any pharmacist licensed by a state to dispense controlled substances and includes any other person (for example, student pharmacist) authorized by a state to dispense controlled substances under the supervision of a licensed pharmacist. (7-1-93)

09. Pharmacy. The term "pharmacy" means every store or other place of business where prescriptions are compounded, dispensed, or sold by a pharmacist and where prescription drug orders for controlled substances are received or processed in accordance with federal law and the pharmacy laws and rules of this state. (4-7-11)

10. Register, Registration. The terms "register" and "registration" refer only to registration required and permitted by Section 37-2717, Idaho Code. (7-1-93)

11. Registrant. The term "registrant" means any person who is registered. (7-1-93)

12. Readily Retrievable. The term "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records, or both. (7-1-93)

13. Sale. The term "sale" as used herein includes barter, exchange, gift, or offer thereof, and each such transaction made by any person, whether as principal, proprietor, agent, servant, or employee. (7-1-93)

14. Transport. The term "transport" with reference to controlled substances, includes "conceal," "convey," and "carry." (7-1-93)

15. Vehicle. The term "vehicle" means any vehicle or equipment used for the transportation of persons or things. (7-1-93)

16. Physician, Veterinarian, Dentist, Podiatrist, Osteopath, Optometrist, Pharmacist. These titles or any similar designation, refer to persons who hold valid, unrevoked licenses to practice their respective professions in this state, issued by their respective examining boards. (12-7-94)

17. Physician. The term "physician" includes only persons licensed under Title 54, Chapter 18, Idaho Code. (7-1-93)

434. ARTICLE II, SCHEDULE II.

Unless specifically excepted or unless listed in another schedule, any injectable liquid that contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers, shall be listed in Schedule II, under Article II, Title 37, Chapter 27, Idaho Code. (7-1-93)

435. PREREQUISITES FOR REGISTRATION.

An applicant for an Idaho controlled substances registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances. Applicants for an Idaho controlled substances registration (excepting

pharmacists and certified euthanasia technicians) must hold a valid federal DEA registration. (7-1-99)

436. ISSUANCE OF REGISTRATION.
The Board shall issue an Idaho controlled substance registration to persons who have qualified therefore in accordance with the provisions of Title 37, Chapter 27, Idaho Code. The registration shall be issued for a period of one (1) year, shall bear on its face the Seal of the Board, and the signature of the executive director, and will be effective until the first day of January following its issuance. (7-1-93)

437. FEES.
Pursuant to Section 37-2715, Idaho Code, the Board shall collect a fee for each annual registration and a fee for each annual renewal of the registration and shall deposit all registration fees in the state treasury to the credit of the "Pharmacy Fund." (7-1-93)

01. Fee for Manufacture of Controlled Substance. For each registration or re-registration to manufacture controlled substances, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

02. Fee for Distribution of Controlled Substances. For each registration or re-registration to distribute controlled substances, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

03. Fee for Dispensing or Conducting Research or Instructional Activities with Controlled Substances. For each registration or re-registration to dispense or to conduct research or instructional activities with controlled substances listed in Schedule II through V, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

04. Fee for Research or Instructional Activities. For each registration or re-registration to conduct research or instructional activities with a controlled substance listed in Schedule I, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

05. Fee for Conducting Chemical Analysis With Controlled Substances. For each registration or re-registration to conduct chemical analysis with controlled substances listed in any schedule, the registrant shall pay a fee as determined by the Board and published in the fee schedule. (7-1-93)

438. TIME AND METHOD OF PAYMENT.
Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing in the form of a personal, certified, or cashier's check or money order made payable to the "Idaho State Board of Pharmacy." In the event that the application is not accepted for filing or is denied, the payment shall be refunded to the applicant. (7-1-93)

439. DISPOSITION OF FEES.
All fees of any kind collected under these provisions shall be deposited in the state treasury to the credit of a separate fund to be known as the "Pharmacy Fund," including fees collected under the "Duplicate Prescription Program," and all such money as may hereafter come into such fund is hereby appropriated to the Board to carry out its defined purposes and objectives. The moneys shall be paid out on warrants drawn by the state auditor upon presentation of proper vouchers approved by the Board, and all claims and vouchers shall be examined by the State Board of Examiners as are other claims against the state. (7-1-98)

440. SEPARATE REGISTRATION FOR INDEPENDENT ACTIVITIES.

01. Independent Activities. The following six (6) groups of activities are deemed to be independent of each other: (7-1-93)

a. Manufacturing controlled substances; (7-1-93)

b. Distributing controlled substances; (7-1-93)

c. Dispensing narcotic and non-narcotic, and conducting research with non-narcotic, and conducting instructional activities with narcotic and non-narcotic controlled substances listed in Schedules II through V; (7-1-93)

d. Conducting research with narcotic controlled substances listed in Schedules II through V; (7-1-93)

e. Conducting research and instructional activities with controlled substances listed in Schedule I; and (7-1-93)

f. Conducting chemical analysis with controlled substances listed in any schedule. (7-1-93)

02. Separate Registration for Each Independent Activity. Every person who engages in more than one (1) group of independent activities shall obtain a separate registration for each group of activities. (7-1-93)

441. TIME FOR APPLICATION FOR REGISTRATION.
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 registration is granted by the Board. (7-1-93)

442. EMERGENCY PRESCRIPTION DRUG ORDER - SCHEDULE II.
An emergency, as referenced in Section 37-2722(b), Idaho Code, is one in which the prescriber determines: immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; and that no appropriate alternative treatment is available, including administration of a drug which is not a Schedule II controlled substance; and that it is not reasonably possible for the prescriber to provide a written prescription drug order to be presented to the person dispensing the substance prior to the dispensing. (4-7-11)

01. Quantity Limited. The quantity prescribed and dispensed must be 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 drug order signed by the prescriber). (4-7-11)

02. Prescription Drug Order Reduced to Writing. The prescription drug order must be immediately reduced to writing by the pharmacist and must contain all of the information required in Section 37-2723, Idaho Code, except for the signature of the prescriber. (4-7-11)

03. Written Prescription Drug Order. Within seven (7) days after issuing verbal authorization for the dispensing of an emergency prescription for a Schedule II controlled substance, the prescriber must provide a written prescription drug order for the emergency quantity dispensed. In addition to conforming to the requirement of Section 37-2723, Idaho Code, the prescription drug order must have written on its face "Authorization for Emergency Dispensing" and the date the verbal prescription drug order was issued. (4-7-11)

04. Delivery of Paper Prescription Drug Order The paper prescription drug order may be delivered by mail if postmarked within the seven (7)-day period. (4-7-11)

05. Attachment of Paper Prescription Drug Order. A paper prescription drug order must be attached to the verbal emergency prescription drug order that was previously reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the verbal order. (4-7-11)

06. Notification to the Board. The pharmacist must notify the Board if the prescriber fails to provide a written prescription drug order within the seven (7)-day period. (4-7-11)

443. REFILLING PRESCRIPTIONS.
The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. (7-1-93)

444. PARTIAL-FILL DISPENSING OF SCHEDULE II PRESCRIPTIONS.

01. Conditions for Partial-Fill Dispensing. A Schedule II controlled substance prescription may be partially filled and dispensed when the pharmacist is unable to supply the full quantity ordered. (4-7-11)

a. The remaining portion of the prescription may only be filled within seventy-two (72) hours of the first partial filling; however, if the remaining portion is not or cannot be filled within seventy-two (72) hours, the pharmacist must so notify the prescriber. (4-7-11)

b. Additional quantities must not be dispensed after seventy-two (72) hours from the time the initial quantity was dispensed without a new prescription drug order. (4-7-11)

02. Partial-Fill Dispensing to LTCF and Terminal Illness Patients. A Schedule II controlled substance prescription for a patient in a Long Term Care Facility (LTCF) or for a patient with a documented terminal illness may be filled in partial quantities and individual dosage units. (4-7-11)

a. If there is any question as to whether a patient may be classified as having a terminal illness, the pharmacist must contact the prescriber prior to partially filling the prescription. Both the pharmacist and the prescriber have a corresponding responsibility to ensure that the controlled substance is for a terminally ill patient. (4-7-11)

b. The pharmacist must record that the patient is either "terminally ill" or an "LTCF patient." (4-7-11)

03. Partial-Fill Documentation. For each partially filled prescription dispensed, the following information must be recorded: (4-7-11)

a. The date; (4-7-11)

b. The quantity dispensed; (4-7-11)

c. The remaining quantity authorized for dispensing; and (4-7-11)

d. The identification of the dispensing pharmacist. (4-7-11)

445. FILING OF PRESCRIPTIONS.

01. Records of Written and Oral Prescriptions. All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of Section 37-2720, Idaho Code.(7-1-93)

02. Emergency Room Drug Administration. A written record of every emergency room Schedule II drug administration will be submitted by the institutional pharmacy (pharmacist) to the Board office on a monthly basis, with administration records of the previous month mailed on the first day of the month following, and will (at a minimum) include: (7-1-93)

a. Date of use; (7-1-93)

b. Name of patient; (7-1-93)

c. Name and amount of Schedule II drug; (7-1-93)

d. Name of practitioner; and (7-1-93)

e. Name of pharmacy. (7-1-93)

446. PRESCRIBER ADMINISTRATION AND DELIVERY OF CONTROLLED SUBSTANCES.
An authorized prescriber may administer or deliver a controlled substance listed in Schedules II, III, IV, or V in the course of the prescriber's professional practice, pursuant to the inventory and recordkeeping requirements of federal law; Section 37-2720, Idaho Code; and these rules. (4-7-11)

447. REFILLING OF PRESCRIPTION.
No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six (6)

months after the date on which the prescription was issued, and no such prescription authorized to be refilled may be refilled more than five (5) times. (7-1-93)

01. Refilling a Prescription for a Controlled Substance. Each refilling of a prescription shall be entered on the back of the prescription (or on another appropriate, uniformly-maintained record, such as medication record that indicates prescription refills), initialed and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed. (7-1-93)

02. Initialing and Dating Prescription. If the pharmacist merely initials and dates the back of the prescription, the full face amount of the prescription will be deemed to have dispensed. (7-1-93)

03. New Prescription Required for Additional Quantities. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new and separate prescription, as provided in Section 37-2722, Idaho Code. (7-1-93)

448. LABELING OF SUBSTANCES.
The pharmacist filling a prescription for a controlled substance listed in Schedule III or IV shall affix to the package a label showing: (7-1-93)

01. Pharmacy. The pharmacy name and address; (7-1-93)

02. Serial Number. The serial number; (7-1-93)

03. Date. The date of initial filling; (7-1-93)

04. Patient. The name of the patient; (7-1-93)

05. Practitioner. The name of the practitioner issuing the prescription; (7-1-93)

06. Directions. Directions for use; and (7-1-93)

07. Cautions. Any cautionary statements required by law. (7-1-93)

449. FILING PRESCRIPTIONS.
All prescriptions for controlled substances listed in Schedule III and IV shall be kept in accordance with Section 37-2720, Idaho Code. (7-1-93)

450. (RESERVED).

451. DISPENSING WITHOUT A PRESCRIPTION.
A controlled substance listed in Schedule V and any controlled substance listed in Schedules II, III, or IV that is not a prescription drug, as determined under the federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist or student pharmacist without a prescription to a purchaser at retail. (7-1-93)

01. Distribution of Schedule V Controlled Substances by Pharmacist or Student Pharmacist. Such distribution shall be made only by a pharmacist or a student 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 this Section, the actual cash or credit transaction or delivery may be completed by a non-pharmacist). (7-1-93)

02. Restricted Quantity. Not more than two hundred forty (240) cc (eight (8) ounces) of any Schedule V substance containing opium, or more than one hundred twenty (120) cc (four (4) ounces) of any other Schedule V substance may be distributed at retail to the same purchaser in any given forty-eight (48) hour period. (7-1-93)

03. Purchaser's Age. The purchaser must be at least eighteen (18) years of age. (7-1-93)

04. Identification Required for Purchase. The pharmacist shall require every purchaser of a

controlled substance listed in Schedule V not known to him to furnish suitable identification (including proof of age where appropriate) and require every purchaser of a controlled substance listed in Schedule V to sign the Official Idaho Register upon receipt of the controlled substance. (7-1-93)

05. Official Idaho Register. A bound record book, to be known as the "Official Idaho Register" provided by the Board at a reasonable fee for recording distributions of controlled substances listed in Schedule V (other than by prescription), shall be maintained by the pharmacist in accordance with the recordkeeping requirements of Section 37-2720, Idaho Code, and shall contain: (7-1-93)

a. The name and address of the purchaser; (7-1-93)

b. The name and quantity of controlled substances purchased; (7-1-93)

c. The date of each purchase; and (7-1-93)

d. The name or initials of the pharmacist who distributed the substance to the purchaser. (7-1-93)

06. Prescription. A prescription is not required for distribution or dispensing of the substance pursuant to any other federal, state or local law. (7-1-93)

452. EMERGENCY DISTRIBUTION OF A DISPENSER.
In an emergency, a dispenser may distribute (without being registered to distribute) a controlled substance to a second dispenser in order for the second dispenser to dispense the substance. (7-1-93)

01. Allowable Amount. The amount distributed shall not exceed the amount required by the second dispenser for immediate dispensing. (7-1-93)

02. Records of the Distribution. The distribution must be recorded as a dispensing by the first dispenser and the receipt as a distribution received by the second dispenser. Each dispenser must retain a signed receipt of the distribution. (7-1-93)

03. Registration. The second dispenser must be registered to dispense the controlled substance to be distributed to him. (7-1-93)

04. Required Order Form. If the substance is listed in Schedule I or II, an order form must be used as required in Section 37-2721, Idaho Code. (7-1-93)

05. Emergency. For purposes of this Section, an emergency means a situation where a quantity of controlled substance must be dispensed to a person who does not have an alternative source for such substance reasonably available to him and the dispenser cannot obtain such substance through a normal distribution channel within the time required to meet the need of the person for the substance. (7-1-93)

453. ACQUISITION OF SCHEDULE I AND II SUBSTANCES - PROCEDURE REQUIRED.
Persons authorized to manufacture, distribute, or dispense controlled substances in Schedule I or II, hospitals, and approved state institutions shall acquire these substances for sale, manufacture, administration, distribution or prescription only by executing the official written order required by Section 37-2721, Idaho Code. (7-1-93)

454. PRESCRIBING FOR SELF PROHIBITED.
No person shall prescribe, administer, or furnish a controlled substance for himself. (7-1-93)

455. ANTEDATING OR POSTDATING PRESCRIPTION PROHIBITED.
No person shall antedate or postdate a prescription. (7-1-93)

456. FALSE NAME OR ADDRESS PROHIBITED.
No person shall, in connection with the prescribing, furnishing, administering or dispensing of a controlled substance, give a false name or false address. (7-1-93)

457. ALTERATION OR ERASURE - FILLING PROHIBITED.
No person shall fill a prescription if it shows evidence of alteration, erasure, or addition by any person other than the person writing it. (7-1-93)

458. EXPIRATION DATE: SCHEDULE II PRESCRIPTION DRUG ORDER.
No Schedule II prescription drug order shall be filled more than ninety (90) days after the date the order was written. (5-8-09)

459. PRESCRIPTION FILE OPEN TO INSPECTION.
A controlled substance prescription on file shall at all times be open to inspection by the prescriber and properly authorized agents and inspectors of the Board. (7-1-93)

460. REBUTTAL PRESUMPTION OF VIOLATION.
In a proceeding to suspend or revoke the controlled substance registration of a registrant for violation of Section 37-2720, Idaho Code, and in which there is evidence of an amount of a controlled substance that is different from the amount reflected on any record or by any inventory required by federal law and additional rules, if any, issued by the Board, there shall be a rebuttable presumption that the registrant has failed to keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of federal law and additional rules, if any, issued by the Board and is in violation of Section 37-2720, Idaho Code. (5-8-09)

461. RECORDS OPEN TO INSPECTION.
Any record required by these rules shall be open at all times to inspection by inspectors of the Board. It is unlawful to refuse to permit or to obstruct such inspection. (7-1-93)

462. RECEIPT FOR REMOVED CONTROLLED SUBSTANCE PRESCRIPTION.
Whenever the pharmacist's copy of a controlled substance prescription is removed by an inspector of the Board for evidentiary purposes, the inspector shall give the pharmacist a receipt. (7-1-93)

463. CONTENTS OF PRESCRIPTION FILE RECORD.
The prescription file shall constitute a record of transactions that shall include the following: (4-11-06)

01. Patient Information. The name and address of patient; (4-11-06)

02. Indentification. A description of the means of positive identification obtained by the pharmacy when so required under Section 464 of these rules; (4-11-06)

03. Date. The date; (4-11-06)

04. Controlled Substance Information. The character and quantity of the controlled substance involved; and (4-11-06)

05. Prescriber Information. The name, address, and state registry number of the prescriber. (4-11-06)

464. FILLING A CONTROLLED SUBSTANCE PRESCRIPTION AND POSITIVE IDENTIFICATION.

01. Filling and Dispensing. No person other than a registered pharmacist under the laws of this state shall be responsible for the filling and dispensing of a prescription for a controlled substance. (4-2-08)

02. Identification. Persons receiving controlled substances shall be positively identified by staff at the pharmacy at the time any controlled substance is dispensed directly to an individual at the pharmacy. (4-2-08)

a. Positive identification shall consist of either a valid, current state or military driver's license or identification card or a valid, current passport, each of which must contain a photo of the individual and the individual's signature. For each controlled substance prescription dispensed directly to an individual at the pharmacy, the pharmacy shall: (4-2-08)

i. Make and maintain a photocopy of the identification presented; or (4-2-08)

ii. Maintain a record of the name of the person receiving the prescribed controlled substance that contains a notation of the type of positive identification presented by such person; the state, military branch, or other government entity issuing the identification; and the specific identification number of the driver's license, identification card, or passport. (4-2-08)

b. In lieu of these means of positive identification, an individual whose identity is personally and positively known to a staff member of the pharmacy who is present and who identifies the individual at the time of delivery of the prescribed controlled substance may be so identified by the staff member. In such instances, the pharmacy shall maintain a record of: (4-2-08)

i. The name of the person receiving the prescribed controlled substance (if other than the patient); (4-2-08)

ii. A notation indicating that the patient or other person receiving the prescribed controlled substance was known to the pharmacy staff; and (4-2-08)

iii. The name of the pharmacy staff person making the identification. (4-2-08)

c. The provisions in Paragraphs 464.02.a. and 464.02.b. of these rules do not apply to a prescription dispensed directly to the patient at the pharmacy if: (4-2-08)

i. The prescription is to be paid for, in whole or in part, by an insurer; or (4-2-08)

ii. The pharmacy is part of the health care facility where the patient is being treated. (4-2-08)

03. Retrieval of Identification Records. The identification records required under Subsection 464.02 of these rules may be maintained by the pharmacy in any manner provided that the pharmacy must be able to produce such records upon any lawful request and match the prescription filled with the positive identification records for the person receiving the prescribed controlled substances, as required in Paragraphs 464.02.a. and 464.02.b. of these rules, within no more than two (2) business days from the date of the request. (4-2-08)

465. VETERINARIANS PROHIBITED FROM PRESCRIBING FOR PERSONS.
No veterinarian shall prescribe, administer, or furnish controlled substances for himself or any other human being. (7-1-93)

466. CONTENTS OF VETERINARIANS' PRESCRIPTIONS.
A prescription written by a veterinarian shall state the kind of animal for which it is ordered, the name and address of the owner or person having custody of the animal, and shall conform to Section 37-2723, Idaho Code. (7-1-93)

467. DUTY OF PROSECUTING ATTORNEY -- REPORT NOT REQUIRED.
It shall be the duty of each prosecuting attorney, to whom the Board reports a violation of these rules, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Nothing in these rules shall be construed as requiring the executive director to report, for the institution of proceedings under these rules, minor violations if the executive director believes that the public interest will be adequately served under the circumstances by a suitable written notice or warning. (7-1-93)

468. PROHIBITION ON ADVERTISING CONTROLLED SUBSTANCES.
No person shall advertise to the public controlled substances, Schedules I through V, in any manner and no pharmacy shall display these products to their patrons or members of the public. (7-1-93)

469. PRESCRIPTION DRUG ORDER REPORTING.
Certain data on all controlled substances must be reported weekly or more often as required by the Board by all pharmacies holding a DEA retail pharmacy registration that dispense controlled substances, and by practitioners that deliver controlled substances. Data on controlled substance prescription drug samples does not need to be reported. (4-7-11)

470. REQUIREMENTS FOR PRESCRIPTION FORM -- DISCIPLINE OF PRACTITIONERS.

01. Prescription Form. A prescription for a controlled substance, including a prescription blank used for a controlled substance prescription, shall conform to the requirements of Section 37-2725, Idaho Code. (3-20-04)

02. Discipline of Practitioners. A practitioner who issues a prescription for a controlled substance that does not comply with the requirements of Section 37-2725, Idaho Code, shall be subject to discipline by the Board as follows: (3-20-04)

a. Definition of "offense." For purposes of this Subsection the term "offense" shall mean clear evidence of a pattern of prescription writing by a practitioner in violation of the requirements of Section 37-2725, Idaho Code. (3-20-04)

b. First offense. A letter with a representative copy or copies of prescriptions giving rise to the letter shall be sent by certified mail, with a return receipt requested, to the practitioner at the practitioner's registration address. The letter shall describe the offense and the basis for required action and a copy of the letter and prescription shall be sent to the practitioner's respective licensing board. The practitioner shall thereafter have thirty (30) days from the date of mailing to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the practitioner's licensing board shall be notified of such failure, allowed thirty (30) days from receipt of notice from the Board to take appropriate action and shall be requested to immediately notify the Board when action is taken. If the Board is not notified of an action taken by the licensing board within the thirty-day period, the Board shall take disciplinary action under Paragraph 470.02.c. of these rules. (3-20-04)

c. Second offense. The practitioner's controlled substance registration shall be suspended for a period of one (1) week, pursuant to Section 37-2718, Idaho Code, and an administrative fine assessed, pursuant to Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the suspension action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension of registration. The notice shall be sent by certified mail, return receipt requested, to the practitioner at the practitioner's registration address. To avoid the suspension, practitioners may send to the Board a written explanation for the offense, a written plan of action setting forth how the practitioner will avoid offenses in the future, and a payment of one hundred dollars ($100) within thirty (30) days of the date postmarked on the notice of the offense. The practitioner shall have thirty (30) days from the date postmarked on the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the Board shall take disciplinary action under Paragraph 470.02.d. of these rules. (3-20-04)

d. Third offense. The practitioner's controlled substance registration shall be suspended for a period of thirty (30) days, pursuant to Section 37-2718, Idaho Code, and an administrative fine assessed, pursuant to Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension of registration. The notice shall be sent by certified mail, return receipt requested, to the practitioner at the practitioner's registration address. To avoid the suspension action, practitioners may send to the Board a written explanation for the offense, a written plan of action setting forth how the practitioner will avoid offenses in the future, and a payment of five hundred dollars ($500) within thirty (30) days of the date postmarked on the notice of the offense. The practitioner shall have thirty (30) days from the date postmarked on the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after the thirty-day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the Board shall take disciplinary action under Paragraph 470.02.e. of these rules. (3-20-04)

e. Fourth offense. The practitioner's controlled substance registration shall be suspended or revoked, pursuant to Section 37-2718, Idaho Code, for such period as the Board, in its discretion, may determine based on the circumstances, and an administrative fine assessed, pursuant to Section 37-2719, Idaho Code, equal to the costs of prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. The practitioner shall be mailed notice of the offense and notice that the Board will commence the action for suspension or revocation of the registration. The notice shall be sent by certified mail, return

receipt requested, to the practitioner at the practitioner's registration address. (3-20-04)

f. Offenses subject to discipline under Subsection 470.02 of these rules shall accumulate for each subsequent offense that occurs within six (6) months of the date the practitioner is sent notice of the prior offense. An offense occurring more than six (6) months after the date the practitioner receives notice of any immediately prior offense shall be deemed a first offense. (3-20-04)

g. Prescribing or dispensing controlled substances by a practitioner whose registration has been suspended or revoked hereunder shall be deemed a separate offense of the Board's rules and applicable statute and shall be subject to a separate action by the Board. (3-20-04)

471. THEFT LOSS REPORTS.
It is the duty of every registrant to report any theft or loss of controlled substances to the Board, even if the theft or loss has been accounted for and the employee disciplined internally. The report of the theft or loss required hereunder shall contain all of the information reported to the DEA, as required under 21 CFR 1301.74(c), and shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

472. -- 490. (RESERVED).

491. POWERS OF ENFORCEMENT PERSONNEL.
All duly constituted peace officers of political subdivisions and municipalities within the state and all prosecuting attorneys shall have the power and responsibility to enforce the Uniform Controlled Substances Act and these rules, including, but not limited to, Sections 37-2732, 37-2733, 37-2734, 37-2737, and 37-2744, Idaho Code. This rule is not meant, nor shall it be construed, to limit in any way the general police power of peace officers within the state of Idaho, but instead is meant to supplement the enforcement provisions as they are enumerated in the Uniform Controlled Substances Act. (7-1-93)

492. SEIZURES AND FORFEITURES.

01. Property Subject to Forfeiture. Property subject to forfeiture under the Uniform Controlled Substances Act may be seized by the Board or by any duly constituted peace officer in the state of Idaho upon process issued by any district court, or magistrate's division thereof, having jurisdiction over the property. Seizure without process may be made if: (7-1-93)

a. The seizure is incident to an arrest for a search under a search warrant or an inspection under an administrative inspection warrant; (7-1-93)

b. The property subject to seizure has been the subject of a prior judgment in favor of the state in a criminal injunction or forfeiture proceeding based upon the Uniform Controlled Substances Act; (7-1-93)

c. The Board or any duly constituted peace officer in this state has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or (7-1-93)

d. The Board or any duly constituted peace officer in this state has probable cause to believe that the property was used or is intended to be used in violation of the Uniform Controlled Substances Act. (7-1-93)

02. Conveyances Used to Transport Controlled Substances. When conveyances used to transport controlled substances have been seized pursuant to the Uniform Controlled Substances Act, immediate notice of such seizure shall be given to the Board by the law enforcement agency making the seizure on forms provided by the Board. (7-1-93)

03. Assuming a False Identify. No person shall, for the purpose of falsely obtaining controlled substances assume the title of or represent himself to be a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, or agents of any of these or other authorized person. (7-1-93)

04. False or Forged Labels. No person shall affix any false or forged label to a package or receptacle containing a controlled substance. (7-1-93)

493. SAMPLE, COMPLIMENTARY.
No manufacturer's sales representative shall distribute a controlled substance as a complimentary sample without the written request of an individual practitioner. Such requests shall include the names and addresses of the supplier and the requester and the name and quantity of the specific controlled substance desired and shall be preserved by the supplier with the records required by Section 37-2720, Idaho Code. (7-1-93)

494. OVER THE COUNTER SALES, CONTROLLED SUBSTANCES.
Drugs in unit dosage form and other drug of the quantitative composition for one (1) of the following drugs or that are the same except that they contain a lesser quantity of controlled substances and that may be lawfully sold over-the-counter without a prescription are exempt from the recordkeeping requirements of Section 37-2720, Idaho Code. (7-1-93)

01. Exempt Trade Names. The following trade names are exempt from recordkeeping requirements: Bronkaid, Bronkotabs, and Primatene. (8-4-94)

02. Exemptions. Drugs in unit dosage form and other drug of the quantitative composition that are the same except that they contain a lesser quantity of controlled substances that are restricted by law to dispensing on prescription and that are exempt from the requirements of Section 511(d)(1) of the federal act are also exempt from the recordkeeping requirements of Section 37-2720, Idaho Code. (7-1-93)

495. CONTROLLED SUBSTANCE DISPOSAL.
Any person in possession of a controlled substance and desiring or required to dispose of the substance may request the assistance of the executive director of the Board in disposing of such substances. (7-1-93)

01. If Reports Required by Registrant for Disposal of Controlled Substance. If the person is a registrant required to make reports, pursuant to Section 37-2720, Idaho Code, he shall list the controlled substance or substances that he desires to dispose of on IBP Form 15 in quadruplicate and submit three copies to the Board. (7-1-93)

02. Non-Registrant Request. If the person is not a registrant, he shall submit to the executive director of the Board a written statement that includes: (7-1-93)

a. The name and address of the person; (7-1-93)

b. The name and quantity of each controlled substance to be disposed of; (7-1-93)

c. How the applicant obtained the substance, if known; and (7-1-93)

d. The name, address, and registration number of the person who possessed the controlled substance prior to the applicant, if known. (7-1-93)

03. Authorization to Dispose Controlled Substance. The executive director shall authorize and instruct the applicant to dispose of the controlled substance in one (1) of the following manners: (7-1-93)

a. By transfer to a person registered under the act and authorized to possess the substance; (7-1-93)

b. By delivery to an agent of the Board at the office of the Board; or (7-1-93)

c. By destruction in the presence of an agent of the Board or other authorized person or by such other means as the executive director may determine to assure that the substance does not become available to unauthorized persons. (7-1-93)

04. Procedures Provided for in Law. This rule shall not be construed as affecting or altering, in any way, the disposal of controlled substances through procedures provided in laws and regulations of the federal government. (7-1-93)

496. CONTROLLED SUBSTANCE INVENTORIES, PRESCRIPTION DRUG ORDERS, AND RECORDS.
Each controlled substance registrant must maintain the prescription drug orders, inventories, and records of controlled substances as follows: (4-7-11)

01. Inventories and Records for Schedules I and II. Prescription drug orders, inventories, and records of controlled substances listed in Schedules I and II must be maintained separately from other prescription drug orders and records of the pharmacy. (4-7-11)

02. Inventories and Records for Schedules III, IV, and V. Prescription drug orders, inventories, and records of controlled substances listed in Schedules III, IV, and V must be maintained separately from other prescription drug orders and records or in such manner that the information required is readily retrievable. (4-7-11)

03. Readily Retrievable Paper Prescription Drug Orders. Controlled substance prescription drug orders, inventories, and records are considered readily retrievable if they are stored in an electronic recordkeeping or an alternative system in such a manner that they can be separated from all other records in a reasonable time or if they are made in some manner visually identifiable and distinguished from other records or from other items appearing on the records. Electronic prescription drug order records must be maintained in compliance with applicable federal law. (4-7-11)

04. Annual Inventory of Stocks of Controlled Substances. Each controlled substance registrant must conduct an inventory of all stocks of controlled substances at least annually in a form and manner that satisfies the inventory requirements of federal law, regulations, and these rules. (4-7-11)

a. Inventories of controlled substances required by these rules must result from a physical (or actual) count of stock on hand or in the control of the registrant. (4-7-11)

b. An electronic recordkeeping system may be used to record receipts and distributions of controlled substances and to record the annual inventory if the inventory is also maintained in a written, typewritten, or printed form at the registered location. (4-7-11)

c. Upon completion, the inventory must be dated as of the day conducted, noted as to whether it was conducted at the opening or closing of business, and signed by the party that completed the inventory. (4-7-11)

d. Complete inventories conducted as otherwise required by these rules may also be considered in complying with the annual inventory requirement. (4-7-11)

05. Separate Inventories for Each Location. A separate inventory must be conducted and maintained at each registered location. (4-7-11)

06. Inventory on Change of Pharmacist-in-Charge (PIC). A complete controlled substance inventory must be conducted in the event of a PIC change. The inventory must be conducted following the close of business on the last day of employment of the outgoing PIC and prior to opening for business on the first day of employment of the incoming PIC. However, a single inventory is sufficient if there is no lapse of employment between the outgoing and the incoming PICs. (4-7-11)

07. Inventory on Discovery of Theft or Loss of Controlled Substances. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. (4-7-11)

08. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, every registrant who possesses that substance must conduct an inventory of all stocks of the substance on hand, and thereafter, include the substance in each inventory conducted by the registrant. (4-7-11)

09. Maintaining Record of Each Substance. Each controlled substance registrant must maintain a current, complete, and accurate record of each substance manufactured, imported, received, ordered, sold, delivered,

exported, or otherwise disposed of by the registrant in a readily retrievable manner, except that a registrant is not required by this rule to maintain a perpetual inventory. (4-7-11)

10. Maintaining Inventories. Inventories must be maintained on the registered premises for a minimum of three (3) years. (4-7-11)

497. INFORMATION FROM THE CONTROLLED SUBSTANCES PRESCRIPTION DATABASE.

01. Authority. These rules are adopted pursuant to the authority of Section 37-2726(4), Idaho Code. (4-2-08)

02. Definitions. The definitions set forth in Section 37-2701, Idaho Code, shall apply to these rules. (4-2-08)

03. Access to Online Prescription Monitoring Program. Access to the Board's online Prescription Monitoring Program shall be limited to licensed practitioners and licensed pharmacists who have registered with the Board. (4-2-08)

04. Registration and Access Requirements. In order to register with the Board and obtain access to the online Prescription Monitoring Program, a licensed practitioner or licensed pharmacist must: (4-2-08)

a. Complete the registration form available from the Board; (4-2-08)

b. Obtain a user account, login name, and password from the Board; and (4-2-08)

c. Agree in writing that: (4-2-08)

i. No information shall be accessed from the Prescription Monitoring Program by a licensed practitioner having authority to prescribe controlled substances unless it relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance; (4-2-08)

ii. No information shall be accessed by a licensed pharmacist having authority to dispense controlled substances from the Prescription Monitoring Program unless it relates specifically to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance; (4-2-08)

iii. Information accessed from the Prescription Monitoring Program shall be kept confidential; (4-2-08)

iv. Information accessed from the Prescription Monitoring Program shall not be disclosed to any unauthorized person; and (4-2-08)

v. User account information, login names, and passwords shall not be shared with any person, regardless of whether or not that person is also an authorized user of the online Prescription Monitoring Program. (4-2-08)

05. Conditions of Access and Use. Each of the following conditions applies to access to the online Prescription Monitoring Program and to use of information obtained from it. (4-2-08)

a. No licensed practitioner or licensed pharmacist authorized by the Board to access the online Prescription Monitoring Program shall share user account information, login names, or passwords with any person, regardless of whether or not that person is also an authorized user of the online Prescription Monitoring Program. (4-2-08)

b. A licensed practitioner having authority to prescribe controlled substances shall access the online Prescription Monitoring Program only to obtain information specifically related to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing any controlled substance. (4-2-08)

c. A licensed pharmacist having authority to dispense controlled substances shall access the Prescription Monitoring Program only to obtain information specifically related to a current patient to whom that pharmacist is dispensing or considering dispensing any controlled substance. (4-2-08)

d. Information obtained from the Prescription Monitoring Program shall be kept confidential. (4-2-08)

e. No information obtained from the Prescription Monitoring Program shall be disclosed to any unauthorized person. (4-2-08)

f. No information obtained from the Prescription Monitoring Program shall be used for a purpose outside the licensed practitioner's or licensed pharmacist's scope of professional practice. (4-2-08)

g. No licensed practitioner or licensed pharmacist shall permit an unauthorized person to utilize the practitioner's or pharmacist's user account, account name, or password in order to access the online Prescription Monitoring Program regarding any person or for any purpose. (4-2-08)

06. Termination of Access and Discipline. Violation of these rules shall be grounds for suspension, revocation, or restriction of the licensed practitioner's or licensed pharmacist's authorization to access the online Prescription Monitoring Program and shall be grounds for discipline of the licensed practitioner or licensed pharmacist and the imposition of penalties pursuant to Sections 54-1726 and 54-1728, Idaho Code. (4-2-08)

07. Other Profile Requests. Profiles from the Prescription Monitoring Program may be obtained by those persons authorized by Section 37-2726(2), Idaho Code, to obtain such information, but who are not registered and authorized by the Board for online access or are not eligible under these rules for registration and online access, by: (4-2-08)

a. Completing the form provided by the Board and mailing or faxing the completed form, along with any proof of identification and authorization required by the Board, to the Board's office; or (4-2-08)

b. By serving upon the Board a lawful order of a court of competent jurisdiction directing the Board to produce the profile to that court or to such person designated by the court in its order. (4-2-08)

08. Additional Grounds for Discipline. A licensed practitioner or licensed pharmacist who obtains an individual's profile pursuant to Subsection 497.07 of these rules shall be subject to discipline and sanctions, pursuant to Sections 54-1726 and 54-1728, Idaho Code, if: (4-2-08)

a. The profile was obtained for an individual with whom the practitioner or pharmacist did not have a current practitioner/patient or pharmacist/patient relationship at the time the profile was requested; (4-2-08)

b. The profile was requested for an unlawful purpose; (4-2-08)

c. The information in the profile was used for an unlawful purpose; or (4-2-08)

d. The profile or information from the profile was disclosed by the practitioner or pharmacist to an unauthorized person. (4-2-08)

09. Duties, Powers, and Immunities. Nothing in these rules shall affect the Board's duties and powers under Sections 37-2730a(2) and 37-2730a(3), Idaho Code, or the immunities granted by Section 37-2730a(4), Idaho Code. (4-2-08)

498. -- 999. (RESERVED).

Subject Index

M

N

O

P

Q

R

S

T

U

V

W