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IDAPA 27
TITLE 01
CHAPTER 01

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

000. -- 009. (RESERVED).

010. DEFINITIONS.

01. Board. Idaho Board of Pharmacy. (6-16-06)T

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 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 in supervising the training of a pharmacist extern or intern. The preceptor shall be responsible for: (6-30-95)

a. Personally providing the extern or intern with training experience which in his judgment will increase the extern or intern's proficiency; and (6-30-95)

b. Reporting to the Board upon request, the progress of any pharmacy extern or intern under his supervision; and (6-30-95)

c. Certifying the extern or intern's experience affidavits when the extern or intern leaves his supervision. (6-30-95)

05. Ratios. A ratio of one (1) pharmacist preceptor to one (1) extern or intern will be required for dispensing functions. (6-30-95)

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 of Pharmacy at the office of the Board of Pharmacy 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
P.O. 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, provided, 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 a facsimile machine process (FAX), provided such FAX transmission must be received legibly, and in its entirety, during the office hours set forth

in Subsection 011.01. 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. Interns shall, prior to obtaining practical experience, make application for registration to the Idaho Board of Pharmacy, 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 on May 15, annually. (3-15-02)

02. Externs. Externs shall, prior to obtaining practical experience, be enrolled in an accredited college of pharmacy and make application for registration to the Idaho Board of Pharmacy, 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. Registration. The training site shall make application to the Idaho Board of Pharmacy for registration on forms provided by the Board along with the appropriate fee. This registration expires on June 30, annually. (6-30-95)

04. Credit. Credit for practical experience will not be accepted unless the extern or intern and the training site have been registered. (6-30-95)

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

102. PRACTICAL EXPERIENCE TIME REQUIRED.
The extern or intern must acquire one thousand five hundred (1,500) hours of practical pharmacy experience under a licensed pharmacist, at a registered training site, said one thousand five hundred (1,500) hours to be acquired after the individual is enrolled in a college of pharmacy. Practical experience may be acquired concurrently with college attendance. (6-30-95)

103. CERTIFICATION OF EXPERIENCE.

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

a. For externs or interns at the termination of any specific training period or training site; (6-30-95)

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 these affidavits are submitted by the extern or intern. The affidavit must be submitted to the Board within thirty (30) days of the ending date of the training period. The extern or intern will be notified of the acceptance or denial of the experience submitted. (6-30-95)

104. APPROVED TRAINING SITE REQUIREMENTS.
An approved training site shall be registered by the Board as a place providing practical and professional training deemed applicable for preparing the extern or intern for licensure. One-half (1/2) the experience must be gained at a community or hospital pharmacy. Approved training site may include: (6-30-95)

01. Community Pharmacy, Registered by the Board. It shall provide adequate experience in recognized and accepted pharmaceutical procedures normally encountered in a community pharmacy only while under the direct, personal supervision of a licensed pharmacist. (6-30-95)

02. Hospital Pharmacy, Registered by the Board. It shall provide adequate experience in recognized and accepted pharmaceutical procedures normally encountered in an accredited and licensed hospital pharmacy and only while under the direct, personal supervision of a licensed pharmacist. (6-30-95)

03. Pharmaceutical Manufacturing Company or Lab. A pharmaceutical manufacturing company or laboratory may provide experience in testing, analysis, manufacturing, packaging, labeling, the development and research of pharmaceutical products, and the applicable laws relative to training. One-half (1/2) of the experience may be gained with a pharmaceutical manufacturing company or laboratory. The balance shall be in other approved training areas. (7-1-93)

04. Pharmaceutically Related Research Programs. Extern or interns participating in pharmaceutically related research programs supervised by instructors who are licensed pharmacists, may gain one-fourth (1/4) of the experience required in this area. The extern or intern shall outline the research experience in a manner that will assure the Board that such experience has contributed to his fitness for licensure. (6-30-95)

05. Instructorship and Teaching Assistant. Pharmacy interns employed as instructors and pharmacy externs or interns employed as teaching assistants in an accredited college or school of pharmacy and teaching required pharmacy courses, may gain experience equivalent to one-fourth (1/4) of the required training.This experience must be gained under the supervision of a licensed pharmacist instructor on the staff where the extern or intern is teaching. The extern or intern shall outline the scope of the teaching experience in a manner that will assure the Board that such experience has contributed to his fitness for licensure. The intern instructor shall be deemed eligible to participate in this area of experience only after he has obtained the first professional degree in pharmacy. (6-30-95)

06. Other. Experience may be gained in other areas related to pharmacy with prior approval by the Board. (6-30-95)

105. PRACTICE LIMITATION OF EXTERN OR INTERN.

01. Activities. The extern or intern shall be allowed to engage in any of the practice activities of a licensed pharmacist provided that: (7-1-93)

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; (7-1-93)

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

02. Violation. Violation of the above practice limitations will result in the cancellation of the registration of the training site, disciplinary action against the pharmacist or pharmacists and an evaluation for acceptance or rejection of the hours the extern or intern has obtained while under the supervision of a preceptor at this training site. (6-30-95)

106. LICENSURE EXAMINATIONS.

The examination of candidates for licensure as a pharmacist will be administered at least two (2) times during each fiscal year of the state. 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 Board examinations. The applicant, if examined after June 1, 1986, must pass the National Association of Boards of Pharmacy standard examination for licensure, or equivalent examination, jurisprudence and practical pharmacy. Applicant must obtain a score of not less than seventy-five (75) to pass the examination. NABPLEX, jurisprudence and practical examinations are not averaged to obtain a final score. Failure will subject the applicant to re-examination and payment of the original fee. All NABPLEX failures must wait until a regularly scheduled uniform testing date to retake examinations. State jurisprudence and practical examinations may be arranged through the Board office, providing at least thirty (30) days from the date of the failed examination have elapsed. After candidate

has successfully passed the examination, licensure will be completed when certification of the required extern/ internship has been filed with the Board office. After an applicant for examination has completed and filed the official application, he will be notified by the Board as to the time and place of the examination and, should the applicant fail to appear for an examination, the applicant may apply for a refund. Upon application for a refund, the Board will refund thirty dollars ($30) of the original fee. Only under these circumstances will a refund be made to applicant. (7-1-93)

107. FORMS.
Registration forms issued to externs/interns will provide a personal registration-receipt copy that shall be carried by the registrant whenever engaged in extern/intern training. (7-1-93)

108. APPLICANT FOR LICENSURE BY EXAMINATION.

01. General Requirements. The applicant, if examined after June 1, 1986, must pass the National Association of Boards of Pharmacy standard examination for licensure, or equivalent examination, jurisprudence and practical pharmacy. Applicant must obtain a score of not less than seventy-five (75) to pass the examination. NABPLEX, jurisprudence and practical examinations are not averaged to obtain a final score. (7-1-93)

02. Failure of Examinations. Failure will subject the applicant to re-examination and payment of the original fee. All NABPLEX failures must wait until a regularly scheduled uniform testing date to retake examinations. State jurisprudence and practical examinations may be arranged through the Board office, providing at least thirty (30) days from the date of the failed examination have elapsed. (7-1-93)

03. Upon Completion of Application. After an applicant for examination has completed and filed the official application he will be notified by the board as to the time and place of the examination and should the applicant fail to appear for an examination, the applicant may apply for a refund. Upon application for a refund, the Board will refund thirty dollars ($30) of the original fee. Only under these circumstances will a refund be made to applicant. (7-1-93)

109. EXAMINATION APPLICATION.
All applications for examination as provided for in Section 54-1722, Idaho Code, must be filed with the Board together with all fees, at least thirty (30) days prior to the date of the examination. (7-1-93)

110. FOREIGN PHARMACY GRADUATES.
Only those schools or colleges of pharmacy which have demonstrated that the standards of their respective undergraduate degree programs are at least equivalent to the minimum standards of accreditation established by the American Council on Pharmaceutical Education shall be deemed "approved" by the Board of Pharmacy for the purposes of Section 54-1722(1)(d), Idaho Code. However, graduates of schools or colleges of pharmacy located outside the United States which have not demonstrated that the standards of their respective undergraduate degree programs are at least equivalent to the minimum standards for accreditation established by the ACPE shall have satisfied the requirements of Section 54-1722(1)(d), Idaho Code, by providing evidence satisfactory to the Board of Pharmacy of graduation from such school, by successfully passing an equivalency examination, and tests of both spoken and written English, recognized by the Board of Pharmacy. (7-1-93)

111. ACCREDITED PHARMACY COLLEGE.
For the purposes of Section 54-1722, Idaho Code, a college recognized by the Idaho State Board of Pharmacy is an institution which meets the minimum standards of the American Council on Pharmaceutical Education and appears on its list of accredited colleges of pharmacy as published by the Council as of July 1 of each year. The Board also approves the accreditation standards of the American Council on Pharmaceutical Education as they appear in Section IV, pages 11 through 17 of the Accreditation Manual, Seventh Edition, January 1, 1974, a copy of which is kept on file at the Board office. (7-1-93)

112. RECIPROCITY.

01. Applicant for Reciprocity. After an applicant for reciprocity has completed and filed the official application he will be notified by the Board as to the time and place the application will be acted upon, at which time and place the applicant must be present. Applicants may be required to take an examination in jurisprudence. 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 compelled to take the practical examination. (7-1-93)

02. Compliance with Instructions. If the instructions accompanying the application are not fully complied with, if application is filed and withdrawn, if applicant does not present himself to the Board and make it possible for the Board to act upon the application, the applicant will not be entitled to any refund. (7-1-93)

03. Denial of Reciprocal Licensure by Board. If the applicant completes and files the official application as instructions require, and personally appears before the Board of Pharmacy but is denied reciprocal licensure, he may then apply for a refund. When the Board office receives the application for refund a refund of fifty dollars ($50) will be made. Only under these circumstances will a refund be made to applicants. (7-1-93)

113. FAILURE.
Failure to pass the jurisprudence examination will result in a re-examination fee as set by IDAPA 27.01.01, "Rules of the Idaho State Board of Pharmacy." (7-1-93)

114. -- 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 of Pharmacy 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 post graduate 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 and other self-instructed units and such other methods which 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. Programs shall provide for examinations or other evaluation methods to assure satisfactory completion by participants. (7-1-93)

c. The person or persons who are to instruct or who are 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 of Pharmacy. (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, 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 of Pharmacy. (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 unit (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 of Pharmacy. (7-1-93)

01. ACPE or CME. At a minimum, eight clock hours (0.8 CEU) will be all or a combination of American Council of Pharmaceutical Education (ACPE) or Continuing Medical Education (CME) approved programs. (12-7-94)

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

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

04. Live Attendance. Three 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, by reciprocity, has been licensed one (1) year in Idaho. (7-1-93)

136. CONTINUING EDUCATION-DUAL LICENSEES.

01. Idaho Licensee. Any Idaho licensed pharmacist residing in another state shall, in order to receive Idaho license renewal, 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 Idaho Board of Pharmacy 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. (7-1-93)

140. LICENSE REINSTATEMENT.
Any applicant for a restored license as provided within 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. STANDARDS OF CONDUCT.

01. Duty to Cooperate in Investigation. It is the duty of every licensee to cooperate with a disciplinary investigation and any failure or refusal to do so is grounds for disciplinary action. (4-6-05)

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), which information shall be reported to the Board at the same time it is reported to the DEA. (3-30-07)

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 material which has exceeded its expiration date shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

c. All stock and material that appears 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, the container of which is defective shall be removed from stock and returned to the source of supply or destroyed. (7-1-93)

152. REFERENCE LIBRARY.
Required Books. The latest edition and supplement(s) of the following: Idaho Pharmacy Law and Rules; one (1) of the following current pharmacy references - Facts and Comparisons, Clinical Pharmacology, Micromedex; and one (1) other current pharmacy reference of your choice (book or computer diskette). (3-20-04)

153. TECHNICAL EQUIPMENT.
The necessary equipment for compounding and dispensing should include: (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) assorted sizes steel spatulas. (7-1-93)

05. Funnels. Two (2) funnels, 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 temperature maintained within the comfort zone, with clean and sanitary surroundings devoted primarily to the compounding of prescriptions, the manufacture of pharmaceutical preparations, and the operations necessary to assure 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, and storage cabinets; a sink with hot and cold water, refuse disposal, proper sewerage outlet, and refrigeration storage equipment of a 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 for pharmacy staff adjoining or in the pharmacy. (7-1-93)

04. New or Remodeled Pharmacy. Any new pharmacy or any existing pharmacy which 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, 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 handicap 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(s) 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 Report of Pharmacy Employer. Annually, on the date of renewal of registration, the pharmacy employer must notify the Board of the registered pharmacist-manager of the pharmacy and each registered employee-pharmacist and each extern/intern training in the pharmacy, on the place provided on the application. Any change in pharmacist or extern/intern employment must be reported to the Board within five (5) days. (7-1-93)

03. Responsible Pharmacist Manager. A non-registered proprietor of a pharmacy shall place in charge of such pharmacy a pharmacist licensed in the state of Idaho who shall be known as "responsible pharmacist manager" and the non-registered proprietor shall immediately report to the state Board of Pharmacy the name of the pharmacist manager. (7-1-93)

04. Responsibility of Pharmacist Manager. Responsible pharmacist managers of pharmacies owned by non-registered proprietors are responsible for the management of such stores so far as they are affected by the pharmacy laws. Every part of the establishment coming under the regulation of the pharmacy laws shall be under the full and complete control of such responsible pharmacist manager. (7-1-93)

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 provided 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 Subsection 156.05.b. must be satisfied: (3-20-04)

a. Unit Dose is defined as medications packaged in individually sealed doses with tamper-evident packaging (e.g., 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 repackaged by the pharmacy, each repackage 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 repackaging): (3-20-04)

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

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

(3) The date the medication was repackaged; (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 repackaging. (3-20-04)

c. If the information required under Subparagraphs 156.05.b.vi.(4) and 156.05.b.vi.(5) 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. shall apply in addition to the labeling requirements under Section 159. (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. In order 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 any 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. Such medications that are released for self-administration by the patient, or for administration outside the hospital or facility premises or that are 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" provided 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 provided the hospital or facility does not allow any such medication to be returned to the same medication storage area as medications eligible for return. (3-20-04)

ii. Such 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 the pharmacist-in-charge shall be responsible for consulting with each hospital or facility from which the pharmacy will accept returns under Section 156 to ensure that the hospital or facility has an employee or employees who are 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 the same for Board inspectors upon request. (3-20-04)

g. Each pharmacy and the pharmacist-in-charge that will be accepting returns under Section 156 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 the same for Board inspectors upon request. (3-20-04)

06. Damaged Drugs. To sell, offer for sale, barter or give away any drugs damaged by fire or water or by 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, 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 facia 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; (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, the knowledge of which 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 those drugs designated as prescription or legend drugs as defined in Section 54-1705(23), Idaho Code, the Idaho Board of Pharmacy 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 Subsection 158.02.a. is exempt from the designation as prescription drugs under Subsection 158.01 and exempt 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; and 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. Provided, however, that hemorrhoidal ointments containing not more than two tenths percent (.2%) Ephedrine Sulfate and suppositories not exceeding four (4) milligrams Ephedrine Sulfate per suppository are also exempt pursuant to Subsection 158.02. (7-1-98)

159. PRESCRIPTION REQUIREMENTS.

01. Prescription Requirements. All prescriptions shall at a minimum indicate the following: the name of the patient; the date written; the directions for use; the name, strength, and amount of the medication; the name of the prescriber; and, if written, the pre-printed, stamped or hand-printed name of the prescriber and the handwritten signature of the prescriber. No prescription is refillable unless specifically indicated by the prescriber. Further requirements for controlled substance prescriptions are contained in Subsection 433.10. (7-1-98)

02. Prescription Labels. Any drug dispensed shall bear a label containing the following: the name, address and telephone number of the dispenser (person or business), the serial number and date of the prescription or its filling, the name of the prescriber and the name of the patient, the directions for use, name (generic or brand) of the medication (including manufacturer's name if a generic), and any cautionary statements required to protect the consumer, including when advisable the manufacturer's original expiration date, the quantity of item dispensed and the initials of the person dispensing and the statement: "Warning: Federal or State law prohibits the transfer of this prescription to any person other than the person for whom it was prescribed." When appropriate, the prescriber may request "Do Not Label", in such cases the medication name will not appear. (7-1-98)

160. PRESCRIPTION TRANSFER.

A pharmacist may transfer prescription order information for the purpose of refilling a prescription only if the information is communicated orally directly by one (1) pharmacist to another pharmacist. Such oral information can be communicated by an extern/intern 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 and the order is not for a controlled substance. In the alternative, the transferring pharmacist may transfer the prescription order information by facsimile transmission

to the receiving pharmacist. In the case of a facsimile transmission, the transmission shall be signed by the transferring pharmacist. (3-30-01)

01. Prescriptions for Controlled Substances. Prescriptions for controlled substances may be transferred only from the pharmacy where it was originally filled, and never from the pharmacy that received the transfer. (7-1-93)

a. In addition to the information required below, the pharmacist transferring the prescription shall record on the back of the original order, the DEA number and address of the pharmacy to which the transfer was made. (7-1-93)

b. The receiving pharmacist must record the DEA number and address of the pharmacy transferring the order. (7-1-93)

02. Transferring a Prescription. The pharmacist (extern/intern) who transfers the prescription shall: (7-1-93)

a. Invalidate the original prescription by writing the word "void" across the face of the form. (7-1-93)

b. On the reverse side of the form shall record the following information: his name; name of the receiving individual; name of the receiving pharmacy; date of the transfer and the number of authorized refills available. (7-1-93)

03. Receiving Transferred Prescription. The pharmacist (extern/intern) who receives the transferred prescription shall: (7-1-93)

a. Reduce the transferred information to writing including a notation that the prescription is a "transfer" and include all information required by law or rule. (7-1-93)

b. On the reverse side of the form he shall record the following information: his name; the name of the transferring individual; the name of the transferring pharmacy; the date of the original dispensing and transfer and the number of refills authorized; the number of valid refills remaining and the date of the last refill; the serial number of the prescription transferred. (7-1-93)

04. Computer. Transferring pharmacies that utilize a computer prescription database which contains all of the prescription information required by law or rule may enter the information required under Section 160 into the pharmacy's prescription database (including de-activation of the transferred prescription in the database of the transferring pharmacy), in lieu of entry of the required information on the original written prescription. The receiving pharmacy must generate a hard copy to be treated as a new prescription, which hard copy shall also contain all of the information required under Section 160. (3-30-01)

05. Refills. Prescriptions for non-controlled drugs may be transferred more than one (1) time as long as there are refills remaining and all of the provisions as listed above are followed. (7-1-93)

06. Common Electronic Files. (7-1-98)

a. For drugs other than controlled substances: Two (2) or more pharmacies may establish and use a common shared electronic prescription file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file. (7-1-98)

b. For controlled substances: Pharmacies must satisfy all information requirements of a manual mode for prescription transferal. (7-1-98)

c. All common electronic files must contain complete and accurate records of each prescription and refill dispensed. Hard copies must be generated and treated as a new prescription by the receiving pharmacy.(7-1-98)

161. FACSIMILE PRESCRIPTION TRANSMISSION.
The receipt of prescriptions through facsimile (FAX) transmission for dispensing purposes will be allowed from an authorized prescribing practitioner to a pharmacy only under the following provisions: (7-1-98)

01. Actual Transmittal. Actual transmittal of the signed prescription is done 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 medication order. If voice verification is refused, the prescription may not be filled. (6-30-95)

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

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

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

06. Schedule II Facsimile Prescriptions. A prescription for a Schedule II substance may be transmitted 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. The following prescriptions for Schedule II substances may be dispensed upon receipt of the 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 Idaho Board of Pharmacy office. (6-30-95)

07. Facsimile Prescriptions of Schedules III, IV, and V. For drugs in Schedules III, IV, and V, a facsimile 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 drugs apply to facsimile transmitted prescriptions. (6-30-95)

08. Responsibility of Pharmacist. The pharmacist receiving a facsimile prescription will be responsible for the authenticity of the prescription and for ensuring that prescriptions for controlled substances have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice pursuant to 21 CFR 1306.04(a). Orders purporting to be prescriptions, which 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. That responsibility applies equally to an order transmitted by facsimile. (6-30-95)

162. PRESCRIPTION EXPIRATION.
All prescription orders that are legally refillable must have the refill instructions indicated on the face of the prescription order. All prescription orders expire fifteen (15) months after date of issue. For long term medication orders a new prescription must be obtained and a new file number issued. (4-6-05)

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. PHARMACOTHERAPY.
Collaborative practice between pharmacists and prescribing practitioners is allowed as provided in this rule. (7-1-99)

01. Definitions. (7-1-99)

a. Agreement. Means a written and signed agreement between a pharmacist or group of pharmacists and a prescribing practitioner or group of prescribing practitioners that provides for collaborative practice for the purpose of drug therapy management of patients. (7-1-99)

b. Collaborative practice. Means a practice in which the prescribing practitioner makes a diagnosis, maintains ongoing supervision of patient care and refers the patient to a pharmacist, who may initiate and modify drug therapy management within the protocol established by the prescribing practitioner and the pharmacist.(7-1-99)

c. Drug therapy management. Means the review of drug therapy regimen(s) of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Drug therapy management" includes: (7-1-99)

i. Implementing, modifying, and managing drug therapy according to the terms of the agreement; (7-1-99)

ii. Collecting and reviewing patient drug histories; (7-1-99)

iii. Obtaining and checking vital signs, including pulse, temperature, blood pressure, and respiration; and (7-1-99)

iv. Ordering and evaluating the results of laboratory tests directly relating to drug therapy, when performed in accordance with approved protocols applicable to the practice setting. (7-1-99)

d. Prescribing practitioner. Means a practitioner in active practice duly authorized and recognized by law in Idaho to prescribe legend drugs and controlled substances. (7-1-99)

e. Pharmacist's scope of practice. Means those duties and limitations of duties placed upon a pharmacist by the collaborating practitioner, the Board, and applicable law, and includes the limitations implied by the specialty practiced by the collaborating practitioner. (7-1-99)

02. Collaborative Practice Agreement. A pharmacist planning to engage in collaborative practice shall have on file at his or her place of practice a written agreement. The agreement may allow the pharmacist, within the pharmacist's scope of practice, to conduct a drug therapy management which must be approved by a prescribing practitioner. The collaboration that the prescribing practitioner agrees to conduct with the pharmacist must be within the scope of the prescribing practitioner's current practice. (7-1-99)

03. Contents of Agreement. The agreement shall include: (7-1-99)

a. A statement identifying the prescribing practitioners and the pharmacists who are a party to the agreement; (7-1-99)

b. A statement of the types of drug therapy management decisions that the pharmacist is allowed to make, which may include: (7-1-99)

i. A detailed statement of the types of diseases, drugs, or drug categories involved, and the type of

drug therapy management allowed in each case; (7-1-99)

ii. A detailed statement of the methods, procedures, decision criteria, and plan the pharmacist is to follow when conducting drug therapy management; and (7-1-99)

iii. A statement of the activities the pharmacist is to follow in the course of conducting drug therapy management, including documentation of decisions made and a plan or appropriate mechanism for communication, feedback, and reporting to the prescribing practitioner concerning specific decisions made. In addition to the agreement, documentation shall occur in the prescribing practitioners patient medical chart and may occur on the prescription record, patient profile, a separate log book, or in some other appropriate system; (7-1-99)

c. A method for the prescribing practitioner to monitor compliance with the agreement and clinical outcomes where drug therapy management by the pharmacist has occurred and to intercede where necessary; (7-1-99)

d. A provision that allows the prescribing practitioner to override the agreement whenever he or she deems it necessary or appropriate; and (7-1-99)

e. The agreement must be coupled with specific orders from the prescribing practitioner to apply such agreement as drug therapy management to any particular patient. The order must constitute a valid drug order or a valid prescription and contain all information necessary to conform to such requirements. (7-1-99)

04. Review, Renewal, and Revision of Agreement. At a minimum, the written agreement shall be reviewed and renewed, and if necessary, revised every year. (7-1-99)

166. -- 175. (RESERVED).

176. POISONS.

01. Definition -- Poison. A poison is any substance which, upon being 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 U. S. Food Drug and Cosmetic Act of 1938, the U. S. Poison Prevention Packaging Act of 1970 and the Idaho Food Drug and Cosmetic Act relevant to repackaging and/or distributing items included by definition or listing as poisons, the pharmacist must comply with the following rules. (7-1-93)

a. Sale of poison. 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, name of distributor) manufacturer's or distributor's containers. Such sales are permitted without record keeping requirements. (7-1-93)

b. Sale of repackaged items defined as poisons require the following: may be sold only to persons at least eighteen (18) years of age; placed in a suitable container with a safety closure; labeled as to name and strength of contents, antidote and 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, a bound book containing at least the following information: signature and age of purchaser; time and date of sale; item sold and quantity; intended use of item; signature (initials) of pharmacist. The Poison Register must be maintained in the pharmacy during its use and for three (3) years after date of 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. (7-1-93)

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

177. LIMITED SERVICE PHARMACIES.
Pharmacists proposing to operate retail drug outlets which are not community pharmacies but limit the types of drug orders which 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 Idaho Board of Pharmacy must be notified prior to construction of such pharmacies to allow approval of floor plans per Section 156. (7-1-93)

c. A permit separate from the regular pharmacy permit is required of all such pharmacies prior to opening 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. Sink with hot and cold water in close proximity to the hood(s). (7-1-93)

b. 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. 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 plus the most recent copy of “Handbook of Injectable

Drugs" by Trissel. (7-1-93)

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

f. All supplies necessary for handling 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. Labels shall contain, in addition to the requirements for other prescriptions, 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. Hood(s) shall be certified as recommended by the manufacturer or annually at a minimum. (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 shall apply to the prescription order blank and to 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 mercantile establishment which is open to the public for business at times when a pharmacist is not present, then the pharmacy must be totally and completely enclosed by a partition such as glass or metal mesh screen or a security fence, which is sufficient to provide adequate security for the pharmacy as approved by the Board or its representatives. In the absence of a pharmacist such pharmacies must be locked. Employees of the mercantile establishment may not be authorized to enter the closed pharmacy during those hours that the mercantile establishment is open to the public for business. (7-1-93)

02. Equipment, Records, Drugs and Other Items. All equipment and records referred to and all drugs, devices, poisons and other items or products which 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. But, if no pharmacist is present then the prescription orders must be deposited by the patient or his agent delivering the prescription order or refill request to the establishment into a "mail slot" or "drop box" such that the prescription order is stored in the pharmacy area. The times that the pharmacy is open for business must be so displayed that they are 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 and other times or products which are restricted to sale either by or under the personal supervision of a pharmacist can 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 an establishment shall have a separate and distinct telephone number from that of the business establishment. The phone shall not be answerable in the remainder of the establishment unless all conversations when the pharmacist is absent are recorded and played back by the pharmacist. (7-1-93)

07. Oral Prescriptions. Oral prescriptions cannot be taken if the pharmacist is not present unless it is taken on a recording which must inform the caller as to the times the pharmacy is open. (7-1-93)

08. Hours of Operation. A pharmacy must prominently display in a permanent manner on or adjacent to its entrance the times that it is open for business. If a pharmacy is located within a larger mercantile establishment having hours of operation different from the pharmacy then the pharmacy times of being 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. (7-1-93)

09. Advertising. Any advertising by the mercantile establishment which makes reference to the pharmacy or those products which are sold only in the pharmacy, which in such advertising sets forth the days and hours that the mercantile establishment is open to the public for business, must also indicate the days and hours that the pharmacy is open to the public for business. (7-1-93)

10. Notification to 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 of Pharmacy at least thirty (30) days prior to commencing such differential hours. In order to constitute notification the applicant must complete the file form provided by the Board providing the required information. Board inspection and approval must be completed prior to the commencing of such differential hours Such inspection and approval or disapproval shall be 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 pharmacy standards under Section 151. (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 Board Section 162, 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 (e.g., 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 State Board of Pharmacy inspector of 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 (e.g., 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 Subsection 108.01 or 181.02. (7-1-93)

07. Application for Permit. Any registrant who intends to use a system provided by Subsection 181.06 must first apply for a permit from the Drug Enforcement Administration to maintain central records as required by 21 CFR Section 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 IDAPA 27.01.01, "Rules of the Board of Pharmacy." (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 registered 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 duly registered and licensed 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. PRACTITIONER, CHANGE OF STATUS.
Upon any of the following events; death of prescriber; surrender or termination of the prescriber or permanent relocation of the prescriber that precludes a continued patient-practitioner relationship, a valid prescription or drug order of record in Idaho shall remain valid only to the extent necessary to insure 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 shall become aware of any of the preceding events shall advise the patient concerning the status of the prescription, advise the patient to engage a physician and only provide that amount of medication necessary to insure the short-term continuity of care that will best serve the needs of the patient. (7-1-93)

02. Knowledge of Change of Status. The pharmacist shall not dispense, refill or provide medication under this Rule in violation of state or federal law restricting dispensing or refills of controlled substances or legend drugs and, in no event shall the pharmacist provide medication here under after ninety (90) days following knowledge of the occurrence of any of the above events. (7-1-93)

03. Prescription Order Becomes Null and Void. After the expiration of the period necessary to insure 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. CONDUCT, UNPROFESSIONAL.
The following acts or practices by a registered pharmacist or the owner of a pharmacy are 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, 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. Allowing a Commission or Rebate. Allowing a commission or rebate to a person writing or making or otherwise ordering a prescription, or providing consultant services at no charge to receive prescription business. (7-1-93)

04. Failure to Follow Instructions. Failing to strictly follow the instructions of the person writing or making or ordering a prescription as to refilling, content 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." (7-1-93)

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

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

08. Supplying to Unqualified Persons. Supplying or diverting drugs, biological, medicines, substances or devices which are legally sold in pharmacies, so that unqualified persons can 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. Competency. Performing any duties as a pharmacist or pharmacy owner in an incompetent, unskilled or negligent manner. (7-1-93)

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

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

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

14. Discipline in Other States. Conduct which 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. Failure to Report 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 any prescription drug to the Board even if the theft, loss, or adulteration has been accounted for and the employee disciplined internally. (4-6-05)

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

185. PRODUCT SELECTION DEFINITIONS.

01. Substitution of Drugs. As used in this section means the dispensing or causing to be dispensed a different drug other than ordered or prescribed without the express permission of the orderer, or in the case of a prescription, the practitioner. (8-4-94)

02. Drug Product Selection. The act of selecting the brand or supplier of therapeutically equivalent generic drug products. (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. Describes the situation where pharmaceutical equivalent or pharmaceutical alternative drug products display comparable bioavailability when studied under similar experimental conditions. That is, 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 are considered to be pharmaceutical equivalents if they contain the same active ingredients and are identical in strength or concentration, and route of administration (e.g., chlordiazepoxide hydrochloride, five (5) mg. oral capsules). Pharmaceutically equivalent drug products, sometimes called chemical equivalents, are formulated to contain the same amount of active ingredient to meet the same or comparable standards (i.e., identity, strength, purity, and quality), but they 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 are considered to be pharmaceutical alternatives if

they contain the same therapeutic moiety but differ in the salt or ester of that moiety or in the dosage form or strength (e.g., tetracycline hydrochloride, two hundred and fifty (250) (two thousand five hundred (2,500) mg. capsules; tetracycline phosphate complex, two hundred and fifty (250) mg. capsules; quinidine sulfate, two hundred (200) mg. tablets, or 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. The concept of 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 (e.g., propoxyphene hydrochloride vs. pentazocine hydrochloride for the treatment of pain). (7-1-93)

b. Idaho Board of Pharmacy 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. (7-1-93)

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

02. Criteria Used for Therapeutically Equivalent Drug Products. Idaho Board of Pharmacy considers drug products to be therapeutically equivalent if they meet the criteria outlined above, even though they may differ in certain other characteristics, e.g., 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, Idaho Board of Pharmacy 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 Formulations. (7-1-93)

a. These dosage forms are subject to bioavailability and bioequivalence differences, primarily because different firms developing controlled release products for the same active ingredient rarely employ the same approach to formulating their controlled release products. (7-1-93)

b. Idaho Board of Pharmacy, therefore, does not evaluate different controlled release dosage forms containing the same active ingredient in equal strength as bioequivalent unless equivalence between individual products has been specifically demonstrated through appropriate bioequivalence studies. (7-1-93)

187. PROHIBITED ACTS.

01. Substitution. Substitution is prohibited and shall be deemed grounds for revocation of a license of a pharmacist pursuant to Section 54-1726, Idaho Code, and registration pursuant to Section 54-1732, Idaho Code.

(6-1-94)

02. Exception. The use of a formulary or drug list prepared by the Pharmacy and Therapeutics Committee of a hospital and agreed to by the staff physicians of the hospital. (8-4-94)

188. DRUG PRODUCT SELECTION.
Drug product selection is allowed only when bioequivalence has been shown. (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. The pharmacist shall label the prescription, unless the practitioner indicates "do not label", with the brand name dispensed or, if a generic is used, the name of the drug and the manufacturer. In addition, he must indicate, on the face of the prescription, the same information. (7-1-93)

05. Definition of Drug Product Selection. Drug product selection means the act of selecting the brand or supplier of therapeutically equivalent generic drug products and will be permitted in the state of Idaho. (7-1-93)

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

189. ADVERTISING.

01. Legality. It is unlawful for any person licensed, or drug outlet 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, directly or indirectly, the rendering of professional services or furnishing products in connection with the professional practice or business for which license or registration is issued. (7-1-93)

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

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

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

c. Is intended or is likely to create unjustified expectations of favorable results. (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 which

requires a prescription shall be limited to quantities of the drug which 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 and a relative strength can be assigned without listing all ingredients. (7-1-93)

d. Products with multiple active ingredients without special identification may be listed by brand name without strength for any ingredients. (7-1-93)

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

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

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

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

190. INSPECTION REPORTS AND CITATIONS.
Any 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 at a fee set by the Board. (8-4-94)

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

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

b. Must be at least sixty-five (65) years of age or unable to practice pharmacy because of a physical disability and complete the required application. (7-1-97)

02. Conditions for Inactive Status License. The following conditions will apply to an Inactive Status License: (7-1-97)

a. Will be exempt from the requirement of continuing education; (8-4-94)

b. Must not engage in the practice of pharmacy while on inactive status. (8-4-94)

03. Return to Active Status. If the applicant wishes to return to active status the applicant 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 of Pharmacy 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; (8-4-94)

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

192. -- 250. (RESERVED).

251. PHARMACY TECHNICIANS.

01. Definition -- Pharmacy Technician. Means an individual, registered with the Board who is employed or otherwise authorized by a pharmacy registered with the Board to perform routine functions, that do not require the use of a licensed pharmacist's professional judgment, in connection with the preparing, compounding, distribution or dispensing of medications at such pharmacy, and who has been adequately trained therefor according to the written standards of such pharmacy. Such written standards shall be available to the Board and its designated personnel for inspection and/or approval. (5-3-03)

02. Responsibility of Pharmacy and Pharmacist -- Assignment of Functions. (4-5-00)

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 may allow assignment to, or permit performance by, any individual, other than a registered pharmacy technician, a registered pharmacist extern/ intern, or a licensed pharmacist, of any functions connected to the preparing, compounding, distribution or dispensing of medications at the pharmacy. (5-3-03)

b. The pharmacy or the pharmacist-in-charge may assign to, or allow performance by, a registered pharmacy technician, only of those functions connected with the preparing, compounding, distribution or dispensing of medications, which meet all of the following criteria: (5-3-03)

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

ii. The function is one for which the pharmacy technician is adequately trained and supervised; and (4-5-00)

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 (e.g., 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 to insure that all such activities are performed completely, safely and without risk or harm to patients. (4-5-00)

d. A violation of the rules on pharmacy technicians by a pharmacist or a pharmacy is unprofessional conduct, and is grounds for revocation or suspension of the pharmacist's license and/or the pharmacy registration issued under Sections 54-1722, 54-1723, 54-1724 or 54-1729, Idaho Code, or other appropriate disciplinary action. (4-5-00)

03. Supervision. Where a pharmacy technician performs one (1) or more functions in connection with the preparing, compounding, distribution or dispensing of, the pharmacy technician 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: (4-5-00)

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. Pharmacy Technician Ratio. The ratio of pharmacists to pharmacy technicians shall be not less than one (1) pharmacist for every three (3) pharmacy technicians in any practice setting. (4-6-05)

05. Responsibility of Pharmacy Technicians. (4-5-00)

a. Pharmacy technicians shall perform all functions properly assigned to them with all necessary care. No pharmacy technician shall accept assignment of, or perform, any functions connected with the preparing, compounding, distribution or dispensing of medications unless such pharmacy technician is employed or otherwise authorized by the assigning pharmacy and such function meets all of the criteria set forth in Subsection 251.02.b. (5-3-03)

b. The Board of Pharmacy may initiate proceedings against pharmacy technicians who perform such tasks or functions connected with the preparing, compounding, distribution or dispensing of medications: (4-5-00)

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

ii. That the pharmacy technician is not adequately trained and supervised for; or (4-5-00)

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 of Pharmacy may initiate proceedings against pharmacy technicians who perform such tasks or functions connected with the preparing, compounding, distribution or dispensing of medications in a negligent or improper manner or otherwise violate the rules on pharmacy technicians. Such violations shall be grounds for revocation or suspension of the pharmacy technician's registration, or other appropriate disciplinary action. (4-5-00)

06. Identification of Pharmacy Technicians. (7-1-99)

a. All pharmacy technicians working as such in community pharmacies must be identified by a name badge designating that person as a pharmacy technician. 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. The identification badge must be clearly visible at all times. Pharmacy technicians 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. (4-5-00)

b. All pharmacy technicians must identify themselves as a pharmacy technician on any phone calls initiated or received by them while performing pharmacy functions. (7-1-99)

07. Registration of Pharmacy Technician. (4-5-00)

a. Annual Registration. All pharmacy technicians shall register annually with the Board. The Board will develop an appropriate annual registration notice and annual registration form to be mailed to all registered pharmacy technicians prior to June 1 of each year. The notice will state the annual pharmacy technician registration renewal fee. (4-5-00)

b. Initial Registration. Before commencing duties at a pharmacy as a pharmacy technician (including previously registered pharmacy technicians who are changing pharmacies), an individual must register with the Board, pay the registration fee, and have received a certificate of registration from the Board, provided however, an individual who has not previously had his registration as a pharmacy technician revoked or suspended may commence performing duties as a pharmacy technician immediately upon the completion and mailing of the registration form and applicable fee to the Board. The initial registration period shall be from the date of initial registration to the next annual registration date. (5-3-03)

c. Contents of Registration Form. The annual registration form and the initial registration form shall be prepared by the Board, and shall require such information regarding the individual and the employing or authorizing pharmacy as the Board may reasonably require. In addition, registration shall include the statement of the pharmacy owner (or an authorized agent of the pharmacy owner), and of the pharmacist-in-charge that either: (5-3-03)

i. The individual has been adequately trained by the pharmacist-in-charge, or by the pharmacy, to perform those routine functions in connection with the preparing, compounding, distribution or dispensing of medications as are, or will be, assigned to such individual; (4-5-00)

ii. The pharmacist-in-charge or the pharmacy owner has verified that such individual possesses adequate training to perform those routine functions in connection with the preparing, compounding, distribution or dispensing of medications as are, or will be, assigned to such individual; or (4-5-00)

iii. Such individual will be adequately so trained prior to the assignment of any routine functions in connection with the preparing, compounding, distribution or dispensing of medications. (4-5-00)

08. Discipline and Appeal. Any proceedings by the Board against any pharmacy technician shall comply in all respects with the Administrative Procedures Act, Chapter 52, Title 67, Idaho Code. (4-5-00)

252. PHARMACY PRACTICE IN INSTITUTIONS.

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

a. Institutional Facility is defined as: Hospital, Skilled Nursing Care Facility, Intermediate Care Facility, Extended Care Facility, and any other such organization, 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 practitioners of the healing arts who are duly licensed, engage in private practice. (7-1-93)

b. Institutional Pharmacy is defined as that portion of an Institutional Facility which is engaged in the distribution and/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 which shall be registered with the State Board of Pharmacy pursuant Chapter 17, Title 54, Idaho Code. (7-1-93)

02. Purpose. The purpose of the following rules is to accomplish the purposes of the Idaho Pharmacy

Act as specified in Section 54-1703, Idaho Code, by implementing the provisions of that portion of the Act concerning Registration of Facilities as specified in Section 54-1729, Idaho Code. (7-1-93)

03. Applicability. The following rules are applicable to all institutions and institutional pharmacies as defined in Subsection 252.01.a. (7-1-93)

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

05. Director of Institutional Pharmacy. Each institutional pharmacy shall be directed by a pharmacist, hereinafter referred to as the Director, who is licensed to engage in the practice of pharmacy in this state and who is knowledgeable in, and thoroughly familiar with the specialized functions of institutional pharmacies. He shall be responsible for all activities of the institutional pharmacy, and for meeting the requirements of the Idaho Pharmacy Act and these Rules. (7-1-93)

06. Supportive Personnel. The Director of an institutional pharmacy shall be assisted by a sufficient number of additional registered pharmacists and ancillary personnel as may be required to operate such 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 such technical personnel. (7-1-93)

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

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

07. Supervision by Director. All of the activities and operations of each 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 registered pharmacists to insure that all such functions and activities are performed competently, safely and without risk of harm to patients. (7-1-93)

09. Pharmacist Absence. During such times as an institutional pharmacy may be unattended by a registered pharmacist, arrangements shall be made in advance by the Director for provision of drugs to the medical staff and other authorized personnel of the institutional facility. (7-1-93)

10. Access to Pharmacy. One (1) supervisory registered professional nurse and only one (1), in any given eight (8) hour shift, may have access to the pharmacy and may remove drugs there from. (7-1-93)

11. Designated Nurse. Such 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 records and procedures required. 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 name of drug, strength, amount, date, time and signature of nurse. (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 which does not have an institutional pharmacy, drugs may be provided for use by authorized personnel by emergency kits located at such facility, provided, however, such kits meet the following requirements. (7-1-93)

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

03. Supplying Pharmacy. All emergency kit drugs shall be provided by one (1) pharmacy licensed by the Board of Pharmacy, retained for such purpose; upon retaining each such pharmacy, the institutional facility shall notify the Board in writing. Such pharmacy shall meet the requirements of Subsection 257. 01. (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 to prevent unauthorized access, and to insure a proper environment for 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 it is for use in emergencies only; and in addition, such label shall also contain a listing of the drugs contained therein, including name, strength, quantity and expiration of contents, and the name, address(es) and telephone number(s) 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 and shall also be labeled with such other and further 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 only pursuant to a valid physician's order by authorized personnel, or by the supplying pharmacist. (7-1-93)

09. Notifying Pharmacist When Kit Is Opened. Whenever an emergency kit is opened, the supplying pharmacist shall be notified within a reasonable time, and the pharmacist or pharmacist designee shall restock the kit. (7-1-97)

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

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

a. All Subsections of Section 253 shall apply to home health agency emergency kits except as modified in this Subsection 253.12. (7-1-97)

b. Home health agency emergency kit drugs may only contain such drugs as specifically approved by rule of the Board. Such drugs 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. (7-1-97)

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

c. Storage. Home health agency emergency kits shall be stored in locked areas, suitable to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs within that period. (7-1-97)

i. Provided, however, that 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 actually on duty and within the course and scope of their employment, the nurses must return the home health agency emergency kits to the storage area identified in Subsection 253.12.c. (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 licensed supplying pharmacy. (7-1-97)

254. PHYSICAL REQUIREMENTS.

01. Sufficient Space. An institutional pharmacy shall have within the facility, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of the section. (7-1-93)

02. Equipment and Materials. Each institutional pharmacy shall have equipment and physical facilities for proper compounding, dispensing and storage of drugs, including parenteral preparation, and, as a minimum, 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. (7-1-93)

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

03. Storage of Drugs. All drugs shall be stored in designated areas within the institutional pharmacy which are sufficient to insure 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 storage, compounding or dispensing of other pharmaceuticals. (7-1-93)

b. Such areas shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or rules as may apply. (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, such 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 under written procedures established by the director for the distribution of pharmaceutical materials so as to achieve this goal. (7-1-93)

02. Responsibility of Director. The director shall be responsible for the safe and efficient distribution of, control of and accountability for drugs. The other professional staff of the institutional facility shall cooperate with the director in meeting this responsibility and in ordering, administering and accounting for pharmaceutical materials so as to achieve this purpose. (7-1-93)

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

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

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

c. Manufacture of drugs, if applicable. (7-1-93)

d. 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 development of a formulary or drug list for the facility. (7-1-93)

f. Dispensing of all drugs within the facility only upon receipt of an original or a direct copy of a physician's order. (7-1-93)

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

h. Maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in 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 may be deemed necessary by the appropriate committee of the institutional facility. (7-1-93)

i. Records of all transactions of the pharmacy as may be required by applicable law, and/or 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 which relate to pharmaceutical utilization and effectiveness. (7-1-93)

k. Fullest cooperation with teaching and/or research programs in the institutional facility. (7-1-93)

l. Implementation of the policies and decisions of the appropriate committee(s) of the institutional facility. (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. For use inside the facility all drugs dispensed by the pharmacy intended for use within the facility shall be dispensed in appropriate containers and adequately labeled according to current acceptable professional standards. (7-1-93)

b. For use outside the facility all drugs dispensed to patients about 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. (7-1-93)

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

ix. Such other and further accessory cautionary information as may be required or desirable for proper use and absolute safety to the patient. (7-1-93)

c. Whenever any drugs are added to parenteral admixtures, whether within or outside 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 insure 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 make proper disposition or dispose 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. (7-1-93)

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 minimal contain the patient name and room number, drug name, strength, directions for use, date and physician’s signature or that of his authorized representative. (7-1-93)

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 Drug Enforcement Administration identification number, if applicable, and patient’s address, if applicable. (7-1-93)

11. Proofs of Use. Proofs of use of such 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 such drug. The forms shall specify, at a minimum, name of drug, dose, name of ordering physician, name of patient, date and time of administration to patient, and name of 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. Any and all suspected adverse drug reactions shall be reported in writing and orally immediately 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, such records and reports as are required to insure patient health, safety and welfare, and at a minimum 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. (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 of those members of the medical staff who have been granted clinical privileges or who are authorized members of the house staff and 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 by usual and customary standards of good medical practice. (7-1-93)

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, provided however, 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. DRUGS FROM OUTSIDE SOURCES.

01. Outside Pharmacies. Whenever drugs or pharmaceutical services are obtained from outside of the institutional facility arrangements shall be made to insure 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. Such arrangements shall be made in writing and shall, at a minimum, specify that: (7-1-93)

a. The outside pharmacist is to act in the capacity of a part-time Director and therefore, 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 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 Idaho Board of Pharmacy Rule Subsection 156.05. (3-20-04)

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

f. All drugs housed in long term care facilities will be labeled according to Idaho Board of Pharmacy Rule 159. (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. (7-01-94)

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

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

a. Whenever patients bring drugs into an institutional facility such drugs shall not be administered unless they can be precisely identified; administration shall be pursuant to a physician's order only. (7-1-93)

b. If such drugs are not to be administered, then the Director shall, according to procedures specified by him in writing, have them turned in to the pharmacy which shall package and seal them 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.
In an emergency, 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 record keeping pursuant to a licensed physician's order, 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 which 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 Pharmacist. Legend drugs identified on the approved list shall be prepackaged by a licensed pharmacist; and the number of doses in each package shall be limited to that 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 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 except that blank spaces may be left for the names of the patient and physician and the directions for use to the patient. (7-1-93)

05. Delivery of Legend Drugs by 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 to a person receiving emergency out-patient treatment, on 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 telephonic, 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. (7-1-93)

b. Complete a record of delivery which includes all of the information listed under Subsection 255.04.b. and the following: the expiration date of the drug if applicable, the lot number of the drug, the date of prepackaging, initials of the pharmacist who prepackaged the drug, a blank space for the name (initials) of the person delivering the drug to patient, and 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 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 Subsection 255.04.b. (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(s) with prior approval of the appropriate committee(s) 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 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(s). (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 insure 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 Subsection 260.01.f. herein above 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. (7-1-93)

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

03. Annual On-Site Review of Pharmacies. The Board of Pharmacy, shall, no less than once a year, conduct an announced on-site review by one of its members or by its qualified designee, 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 insure 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 will 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 and/or Deficiencies. Discrepancies and/or deficiencies shall be discussed at the exit interview, such shall be corrected within a reasonable time. (7-1-93)

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

261. TELEPHARMACY PILOT PROJECT.
The Board, through its Executive Director, may authorize specific Institutional Facilities and the Institutional Pharmacies located therein to participate in a Telepharmacy Program. The following rules shall apply to institutions so authorized by the Board for the telepharmacy practiced in the institution. The purpose of the Telepharmacy Program is to allow the provision of pharmaceutical care through the use of telecommunications and information

technologies to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care. During the pilot project phase of the Telepharmacy Program, designation to participate in the Telepharmacy Program shall be at the discretion of the Board and the Executive Director. (4-6-05)

262. DEFINITIONS.

01. Central Pharmacy. An institutional pharmacy authorized by the Board to participate in a Telepharmacy Program. (4-6-05)

02. Consulting Pharmacists. Pharmacists employed at a Central Pharmacy who provide pharmaceutical care to patients at a Rural Institutional Facility. (4-6-05)

03. Rural Institutional Facility. An Institutional Facility authorized by the Board to participate in a Telepharmacy Program. Rural Institutional Facilities will be those facilities such as federally designated critical access hospitals or other facilities operating in a health professional shortage area and who are unable to otherwise obtain pharmaceutical care on a timely basis twenty-four (24) hours per day. (4-6-05)

04. Rural Institutional Pharmacy. The institutional pharmacy located within a Rural Institutional Facility. (4-6-05)

05. Telepharmacy Program. The pilot project adopted by the Board to allow selected Central Pharmacies and selected Rural Institutional Facilities to engage in the provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance from the pharmacy and pharmacist providing the pharmaceutical care. (4-6-05)

263. CONTRACT FOR TELEPHARMACY PROGRAM.
A Central Pharmacy may contract with a Rural Institutional Facility for operation of a Telepharmacy Program as specified herein. (4-6-05)

01. Contract Matters. The contract shall address the following matters: (4-6-05)

a. Identify the director of pharmacy of the Central Pharmacy and the director of pharmacy of the Rural Institutional Pharmacy and provide for notice to the parties and to the Board in the event of a change in either director. (4-6-05)

b. Contain a description of the telepharmacy services to be performed by the Central Pharmacy for the Rural Institutional Pharmacy, including: (4-6-05)

i. Protocols for communication of orders for prescription drugs from the practitioners at the Rural Institutional Pharmacy to the pharmacists at the Central Pharmacy. (4-6-05)

ii. Protocols for the Central Pharmacy to accomplish dispensing of prescription drugs at the Rural Institutional Facility and to ensure that the Central Pharmacy has sufficient Consulting Pharmacists and support staff to meet the pharmacy needs of the Institutional Facility where the Central Pharmacy is located as well as performing the pharmacy functions for the Rural Institutional Pharmacy as are contemplated under the contract. (4-6-05)

iii. A description of the access to prescription drugs in the Rural Institutional Pharmacy under the program and protocol for maintaining the security of prescription drugs in the Rural Institutional Pharmacy. (4-6-05)

iv. Contain a provision for the orderly transition of pharmaceutical services for the Rural Institutional Pharmacy in the event the Central Pharmacy elects to terminate its participation in the Telepharmacy Program, such transition to include an adequate time for the Rural Institutional Pharmacy to locate appropriate pharmaceutical services from another source. (4-6-05)

v. The term of the contract 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 operations under the contract and of the Telepharmacy Program. (4-6-05)

02. Additional Contract Matters. The contract may address additional matters regarding the Telepharmacy Program between the Central Pharmacy and the Rural Institutional Facility. (4-6-05)

03. Contract Approval. The contract must be approved by the Executive Director of the Board of Pharmacy prior to the commencement of telepharmacy services between the Central Pharmacy and the Rural Institutional Facility. In reviewing the contract, the Executive Director shall evaluate the proposed terms in the light of: (4-6-05)

a. Promoting, preserving, and protecting the health, safety, and welfare of the public; (4-6-05)

b. Maintaining appropriate professional standards for the practice of pharmacy; and (4-6-05)

c. Maintaining appropriate safeguards for the protection of prescription drug inventories, especially controlled substance inventories, at the Rural Institutional Pharmacy. (4-6-05)

264. SPECIAL RULES FOR DIVISION OF RESPONSIBILITY FOR TELEPHARMACY.
Notwithstanding anything in these rules (IDAPA 27.01.01) to the contrary, for Rural Institutional Pharmacies and Central Pharmacies, and the pharmacists practicing under an approved contract for telepharmacy services, the following rules shall apply. (4-6-05)

01. Responsibility of Director of Central Pharmacy. The director of pharmacy of the Central Pharmacy shall be responsible for all telepharmacy services performed by the Central Pharmacy under the approved contract and for meeting the requirements of the Idaho Pharmacy Act and these rules with respect to such services. The telepharmacy activities and operations performed by the Central Pharmacy under the approved contract and the ancillary personnel of the Central Pharmacy engaged in such activities and operations shall be personally and directly supervised by the director of pharmacy in the same fashion as all other activities and operations at the Central Pharmacy. (4-6-05)

02. Responsibility of Director of Rural Institutional Pharmacy. The director of pharmacy of the Rural Institutional Pharmacy shall remain responsible for all other aspects of the Rural Institutional Pharmacy but shall not be responsible for the services performed by the Central Pharmacy under the approved contract. Where ancillary personnel are directed or supervised in telepharmacy activities by the Central Pharmacy, responsibility for such direction and supervision shall lie with the Central Pharmacy and the director thereof. (4-6-05)

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. (6-16-06)T

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. (6-16-06)T

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 which shall contain: (6-16-06)T

a. The operating protocols applicable to the Pilot Remote Pharmacy and which shall include written policies and procedures that: (6-16-06)T

i. Ensure safety, accuracy, security, and patient confidentiality; (6-16-06)T

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 (6-16-06)T

iii. Ensure that access to the medications complies with state and federal laws and regulations. (6-16-06)T

b. A complete description of the RDM including the operating specifications therefore. (6-16-06)T

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. (6-16-06)T

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. (6-16-06)T

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 record-keeping and security safeguards. (6-16-06)T

f. An ongoing quality assurance program that monitors performance of the Automated Pharmacy System, including the RDM, and the personnel who access it. (6-16-06)T

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. (6-16-06)T

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, provided however, the Operating Agreement may not waive or modify application of Federal laws or regulations, or state statutes governing the practice of pharmacy. (6-16-06)T

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 Responsible Pharmacist and the Executive Director. Any such amendment shall be in writing and shall be appended to the original Operating Memorandum. In addition, the Operating Agreement may be amended by order of the Board upon the petition of either the Responsible Pharmacist 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. (6-16-06)T

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. (6-16-06)T

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. (6-16-06)T

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. (6-16-06)T

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. (6-16-06)T

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. Such 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: (6-16-06)T

a. Identity of RDM accessed; (6-16-06)T

b. Identification of the individual accessing the RDM; (6-16-06)T

c. Type of transaction; (6-16-06)T

d. Date and time of transaction; (6-16-06)T

e. Name, strength, dosage form, and quantity of the drug accessed; (6-16-06)T

f. Name of the patient for whom the drug was ordered; (6-16-06)T

g. Name of the prescribing practitioner; and (6-16-06)T

h. Such additional information as the Pharmacist in Charge may deem necessary. (6-16-06)T

04. Access to RDM. Only an Idaho licensed pharmacist may have access to the RDM. (6-16-06)T

05. Stocking Medications. Only an Idaho licensed pharmacist may stock medications in the RDM. (6-16-06)T

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. (6-16-06)T

07. Handling Controlled Substances. All aspects of handling controlled substances shall meet the requirements of all state and federal laws, rules, and regulations. (6-16-06)T

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. (6-16-06)T

09. Wasted, Discarded, or Unused Medications. The Automated Pharmacy Systems shall provide a mechanism for securing and accounting for wasted, discarded, or unused medications in accordance with existing state and federal laws, rules, and regulations. (6-16-06)T

10. RDM Identification. The RDM must be clearly marked with the name, address, and phone number of the Responsible Pharmacy and Pharmacist in Charge. (6-16-06)T

270. -- 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 the 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 that 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 application for reinstatement of license, to take a practical and/or a jurisprudence examination. (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 first 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 of Pharmacy 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. Pharmacy Drug Outlet. Community pharmacy and any other pharmacy managed by an Idaho licensed pharmacist. (7-1-93)

b. Non-Pharmacy Drug Outlet. Grocery stores, bars, hotels, department stores, vending machines, etc. not registered as a pharmacy, holding for sale 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. (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 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 of Pharmacy (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 which 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 on 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. (7-1-98)

iv. Sterile water for injection. (7-1-98)

10. 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 and are not transferable, and shall expire on the date indicated on the registration. (7-1-93)

294. -- 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. (8-3-07)T

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: (8-3-07)T

a. The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and (8-3-07)T

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. (8-3-07)T

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. (8-3-07)T

04. Co-Licensed Partner or Product. An instance where two (2) or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the federal Food and Drug Administration's implementation of the Prescription Drug Marketing Act. (8-3-07)T

05. Components. Articles intended for use as a component of any articles specified in Subsection 321.01, 321.02, or 321.03 of these rules. (8-3-07)T

06. Drop Shipment. The sale of a prescription drug to a wholesale distributor or chain pharmacy warehouse by the manufacturer of the prescription drug, or 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 and the wholesale distributor invoices the pharmacy or 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, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor. (8-3-07)T

07. Drug. Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them. (7-1-93)

08. Facility. Facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale. (8-3-07)T

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. (8-3-07)T

10. Manufacturer's Exclusive Distributor. Anyone 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 under Section 54-1753, Idaho Code, and, to be considered part of the normal distribution channel, must also be an authorized distributor of record. (8-3-07)T

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, either directly or by drop shipment to: (8-3-07)T

a. A pharmacy to a patient; (8-3-07)T

b. Other designated persons authorized by law to dispense or administer such drug to a patient; (8-3-07)T

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; (8-3-07)T

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 (8-3-07)T

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. (8-3-07)T

12. Pedigree. A document or electronic file containing information that records each wholesale distribution of any given prescription drug. (8-3-07)T

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 a prescription, including finished dosage forms and bulk substances, subject to Section 503(b) of the federal Food, Drug and Cosmetic Act. (8-3-07)T

14. Repackage. Repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding that completed by the pharmacist responsible for dispensing product to the patient. (8-3-07)T

15. Repackager. A person who repackages. (8-3-07)T

16. Sample. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (8-3-07)T

17. Third Party Logistics Provider. Anyone who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. Such third party logistics provider must be licensed as a wholesale distributor under Section 54-1753, Idaho Code, and, to be considered part of the normal distribution channel, must also be an authorized distributor of record. (8-3-07)T

18. Wholesale Distribution. Distribution of prescription drugs to persons other than a consumer or patient, but does not include: (8-3-07)T

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. (8-3-07)T

b. The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons. (8-3-07)T

c. The distribution of prescription drug samples by manufacturers' representatives. (8-3-07)T

d. Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23. (8-3-07)T

e. The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use. (8-3-07)T

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. (8-3-07)T

g. The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stick or business assets. (8-3-07)T

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, until that time, been exclusively in the normal distribution channel. (8-3-07)T

i. The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug. (8-3-07)T

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. (8-3-07)T

19. Wholesale Distributor. Anyone 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 distributions. To be considered part of the normal distribution channel, such wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record. (8-3-07)T

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 Idaho Board of Pharmacy 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 Idaho Board of Pharmacy in accordance with the laws and rules of this state before engaging in wholesale distribution of prescription drugs. (8-3-07)T

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 such manufacturers to be licensed in this state as wholesale distributors. (8-3-07)T

323. MINIMUM REQUIREMENTS FOR LICENSURE.

01. Information Under Oath. The Idaho Board of Pharmacy requires the following information under oath from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license: (8-3-07)T

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 the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs. (8-3-07)T

d. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship). (7-1-93)

e. The name(s) of the owner and/or operator 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. (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 and permits issued to the applicant/licensee by any other state that authorizes the applicant/licensee to purchase or possess prescription drugs. (8-3-07)T

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. (8-3-07)T

h. Any felony convictions of the applicant/licensee under federal, state, or local law. (8-3-07)T

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. (8-3-07)T

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. (8-3-07)T

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: (8-3-07)T

i. The individual's places of residence for the past seven (7) years. (8-3-07)T

ii. The individual's date and place of birth. (8-3-07)T

iii. The individual's occupations, positions of employment, and offices held during the past seven (7) years. (8-3-07)T

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. (8-3-07)T

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 the disposition of the proceeding. (8-3-07)T

vi. Whether the individual during the past seven (7) years has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from either violating any federal or state law or regulation the possession, control, or distribution of prescription drugs or criminal violations, together with details concerning any such event. (8-3-07)T

vii. A description of any involvement by the individual during the past seven (7) years with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products, and any lawsuits in which such businesses were named as a party. (8-3-07)T

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. (8-3-07)T

ix. A photograph of the individual taken in the previous year. (8-3-07)T

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. (8-3-07)T

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 to the Idaho Board of Pharmacy under oath at the time of license renewal. (8-3-07)T

04. Requirement for Bond or Equivalent Security. Every wholesale distributor required to be licensed in this state shall submit to the Idaho Board of Pharmacy a bond of not less than one hundred thousand dollars ($100,000), or other equivalent means of security acceptable to the Board and payable to the Board, such as an irrevocable letter of credit issued by a third party acceptable to the Board or a deposit in a trust account or financial institution acceptable to the Board. Such bond or equivalent security shall secure payment of any administrative fines or penalties imposed by the Board and any fees or costs incurred by the Board regarding that licensee when those fines, penalties, fees, or costs are authorized under the laws of this state and the licensee fails to pay thirty (30) days after the fines, penalties, fees, or costs become final. The Board may make a claim against such bond or equivalent security until one (1) year after the licensee's license cease to be valid. A single bond may suffice to cover all facilities operated by the licensee in this state. (8-3-07)T

05. Separate Fund for Deposit of Bonds. The Board shall deposit the bonds required pursuant to Subsection 323.04 of these rules in a fund established by the Board separate from its other accounts. (8-3-07)T

06. Accreditation by VAWD. The Idaho Board of Pharmacy will recognize inspection and accreditation of wholesale distributors by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributors (VAWD) program. (8-3-07)T

07. License by Reciprocity. The Idaho Board of Pharmacy may license by reciprocity a wholesale distributor that is licensed under the laws of another state if the applicant is accredited by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributor's (VAWD) program. (8-3-07)T

324. MINIMUM QUALIFICATIONS.

01. Mandatory Denial of Licensure for Wholesale Distribution of Drugs. The Idaho Board of Pharmacy shall not issue a wholesale distributor license to an applicant if the designated representative does not meet all of the following qualifications: (8-3-07)T

a. Is at least twenty-one (21) years of age. (8-3-07)T

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. (8-3-07)T

c. Is employed by the applicant full-time in a managerial level position. (8-3-07)T

d. Is actively involved in and aware of the actual daily operation of the wholesale distributor. (8-3-07)T

e. Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized including, but not limited to, sick leave and vacation leave. (8-3-07)T

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. (8-3-07)T

g. Does not have any convictions under any federal, state, or local law relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (8-3-07)T

h. Does not have any felony convictions under federal, state, or local law. (8-3-07)T

02. Other Eligibility Factors. Besides the qualifications of the applicant's designated representative, the Idaho Board of Pharmacy will consider the following factors in determining the applicant's eligibility for licensure as a wholesale distributor. (8-3-07)T

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/or 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. (8-3-07)T

h. Any other factors or qualifications the Idaho Board of Pharmacy considers relevant to and consistent with the public health and safety. (7-1-93)

03. Denial of License to Applicant. The Idaho Board of Pharmacy 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. (8-3-07)T

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. (8-3-07)T

02. Continuing Training for Designated Representative. A licensed wholesale distributor's designated representative must receive and complete: (8-3-07)T

a. Continuing education programs specified by the Idaho Board of Pharmacy regarding federal and state laws regarding wholesale distribution of prescription drugs. (8-3-07)T

b. If no formal continuing education is specified by the Idaho Board of Pharmacy, training programs that address applicable federal and state laws regarding wholesale distribution of prescription drugs and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. (8-3-07)T

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. (8-3-07)T

02. Drug Facility Requirements. All facilities at which 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. (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 be 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/or logs shall be utilized to document proper storage of drugs. (7-1-93)

c. The record keeping requirements in Subsection 326.07 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 record keeping requirements in Subsection 326.07 of this section 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. (8-3-07)T

a. Any drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, 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. (8-3-07)T

b. If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then 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 record keeping requirements in Subsection 326.07 shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated drugs. (7-1-93)

07. Record Keeping 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. (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, which 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. (7-1-93)

01. Distribution of Oldest Approved Stock First. A procedure 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 to be followed for handling recalls and withdrawals of drugs that is adequate to deal with 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 Idaho Board of Pharmacy. (7-1-93)

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market. (7-1-93)

c. Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design. (7-1-93)

03. Procedure for Crisis Situations. A procedure 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 to ensure that any outdated drugs shall be segregated from other drugs and either returned to the original manufacturer or third party returns processor or destroyed which shall provide for written documentation of the disposition of outdated drugs and maintained for two (2) years after disposition of the outdated drugs. (8-3-07)T

328. RESPONSIBLE PERSONS.
Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, the designated representative, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. (8-3-07)T

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 Idaho Board of Pharmacy 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 with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA rules. (7-1-93)

330. SALVAGING AND REPROCESSING.
Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to drug product salvaging or reprocessing, including Chapter 21, parts 297, 210, 211 of the Code of Federal Regulations. (7-1-93)

331. PEDIGREE.

01. Pedigree Contents. A pedigree for each prescription drug shall contain the following information: (8-3-07)T

a. The proprietary and established name of the prescription drug. (8-3-07)T

b. The container size of the prescription drug. (8-3-07)T

c. The number of containers. (8-3-07)T

d. The dosage form. (8-3-07)T

e. The dosage strength. (8-3-07)T

f. The lot number with expiration dates and the national drug code number of the prescription drug. (8-3-07)T

g. The name of the manufacturer and repackager, if applicable, of the finished prescription drug product. (8-3-07)T

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. (8-3-07)T

i. The name and address of each location from which the prescription drug was shipped, if different from the owner's. (8-3-07)T

j. The sales invoice number. (8-3-07)T

k. The dates of each transaction. (8-3-07)T

l. A certification that each recipient has authenticated the pedigree, back to the manufacturer. (8-3-07)T

m. The name and address of each recipient of the prescription drug. (8-3-07)T

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 Idaho Board of Pharmacy. (8-3-07)T

03. Requirement of a Pedigree. Each person who is engaged in wholesale distribution of prescription drugs, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, that leaves or has ever left the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such 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. (8-3-07)T

04. Authentication. Each person who is engaged in the wholesale distribution of a prescription drug, 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 before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred. (8-3-07)T

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. (8-3-07)T

06. Availability of Records for Inspection. Pedigrees shall be made available to the Idaho Board of Pharmacy for inspection within five (5) business days of a request from the Board. (8-3-07)T

332. FAILURE TO COMPLY.
A wholesale distributor's violation of, or failure to comply with, these rules may result in imposition by the Idaho Board of Pharmacy of any one (1) or more of the penalties provided in Section 54-1728, Idaho Code. (8-3-07)T

333. -- 350. (RESERVED).

351. DEFINITIONS.

01. Anesthetics, General. Any drug or substances 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 pursuant record-keeping 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 of Pharmacy in Schedule I through V of the state or federal Controlled Substances Act. (7-1-93)

05. Legend Drug. A drug which under federal law is required, prior to being distributed 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 which 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 which 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 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 of Pharmacy office. (7-1-93)

09. Retail Veterinary Drug Outlet. An establishment registered by the Board of Pharmacy employing a qualified VDT authorized to distribute legend veterinary drugs pursuant to bonafide orders of practitioners. (7-1-93)

10. Veterinary Drug Order. 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. A non-pharmacist, licensed by the Idaho Board of Pharmacy, to distribute legend veterinary drugs in a Veterinary Legend 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.
The purpose of the following rules is to accomplish the purposes of Section 54-1729(2)(a)5, Idaho Code, and Section 54-1734(3)(a) through (c) 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 of Pharmacy by completing the necessary application and submitting the proper fee, at which

time 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 qualified veterinary drug technicians (VDT) will be authorized to process veterinary drug orders for distribution to the clients of licensed practitioners. A high school graduate, at least eighteen (18) years of age, that has scored at least seventy-five percent (75%) on a Board of Pharmacy 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 insure 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 three (3) part order form available through the Idaho Department of Agriculture. Such orders will be processed as follows: The practitioner (veterinarian) will retain the second copy in his records, original and one (1) copy will be sent to the retail veterinary drug outlet, 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. (7-1-93)

02. Distribution of Veterinary Drugs. At no time will legend veterinary drugs be distributed to clients (customers) without the first copy of the practitioner order being 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 Pharmacy 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 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 of Pharmacy. (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. Within seventy-two (72) hours after receiving an oral order the establishment will have on file at the place of distribution a written copy signed by the practitioner. (7-1-93)

a. Processing of oral orders will be identical to written orders in all other areas and will be promptly reduced to writing on Department of Agriculture telephone drug order blanks. (7-1-93)

b. Subsequent processing will be identical to written orders. (7-1-93)

358. DISTRIBUTION.
Wholesale distribution of legend drugs will be permitted only to Registered Veterinarians or other licensed Veterinarian Legend Drug Outlets. (7-1-93)

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 out-dated 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. (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 Record Keeping and Reporting. Owners or managers are ultimately responsible for establishing compliance with record keeping and report filing requirements imposed by these rules. (7-1-93)

362. RECORD KEEPING 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. Establishment policy and procedure manual will be maintained in an up-to-date form at all times and will include current Board of Pharmacy 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 of Pharmacy 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, the 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 of Pharmacy is vested with the authority to control registrants covered under Chapter 17, Title 54, Idaho Code. (7-1-93)

364. PENALTIES.

01. Violation of These Rules. Pursuant to Section 54-1728, Idaho Code, the Board of Pharmacy 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 of Pharmacy 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 follow the Idaho Administrative Procedures Act and Board of Pharmacy parameters and such disciplinary decisions will be arrived at as prescribed in these rules. (7-1-93)

04. Removal of Name From Official Roster. The Board of Pharmacy shall have the authority to remove the name of a VDT from the official roster for cause. (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 at which time all aspects of management and distribution will be reviewed with particular attention being directed toward practices that can affect the 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 such 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-manager at completion of the exit interview with the compliance officer and such 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 of Pharmacy 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 of Pharmacy citation and/or reinspection at the owner's expense. (7-1-93)

366. -- 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 NABPLEX Examination. Fee -- one hundred dollars ($100). (3-13-02)

02. Reciprocity. Fee -- two-hundred and fifty dollars ($250). (7-1-93)

03. State Jurisprudence Exam. Fee -- fifty dollars ($50). (3-13-02)

403. DUE DECEMBER 31, ANNUALLY.

01. Controlled Substance Registration. Fee -- 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 dollars ($100). (12-7-94)

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. Veterinary Legend Drug Outlet - Retail or Retail/Wholesale. One hundred dollars ($100).

(3-13-02)

11. **Veterinary Drug Technician**. Thirty dollars ($35). (12-7-94)

12. **Pharmacy Technician**. Thirty-five dollars ($35). (3-13-02)

405. DUE APRIL 1 ANNUALLY.

01. **Preceptor Site**. Fee --twenty-five dollars ($25). (7-1-97)

02. **Intern**. Fee -- fifty dollars ($50). (3-13-02)

03. **Extern**. Fee - fifty dollars ($50) at acceptance to accredited college of pharmacy, to last until July 31 following graduation. (3-13-02)

406. MISCELLANEOUS.

01. **Test Score Certification**. Fee -- twenty-five dollars ($25). (3-13-02)

02. **Hour Certification**. Fee -- twenty-five dollars ($25). (3-13-02)

03. **Controlled Substance Inventory**. Book Fee -- fifteen dollars ($15). (3-13-02)

04. **Duplicate Pharmacist Certificate**. Fee -- thirty-five dollars ($35). (3-13-02)

05. **Commercial Lists**. (12-24-93)

a. Pharmacy list. Fee -- fifty dollars ($50). (3-13-02)

b. Pharmacist list. Fee -- fifty dollars ($50). (3-13-02)

c. CSA Practitioner list. Fee -- fifty dollars ($50). (3-13-02)

i. Complete CSA Practitioner list. Fee -- one hundred fifty dollars ($150). (3-13-02)

ii. Each profession CSA list. Fee -- fifty dollars ($50). (3-13-02)

06. **Official Idaho Register**. Official Idaho Register -- fifteen dollars ($15). (3-13-02)

07. **Pharmacy Law**. Pharmacy law, includes two (2) year updates -- thirty-five dollars ($35). (7-1-93)

08. **Reinstatement Fee**. Reinstatement fee, all licenses -- seventy-five dollars ($75). (3-13-02)

09. **Transcript of Hearing**. 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:

(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; (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" as used in this act, means the Idaho State Board of Medicine created by Chapter 18, Title 54, Idaho Code. (7-1-93)

05. Board of Health. The term "Board of Health" as used in this act, means the Idaho State Board of Health as created by Chapter 1, Title 39, Idaho Code. (7-1-93)

06. Department. The term "Department" as used in this act means the Idaho State Police of the state of Idaho. (7-1-93)

07. Executive Secretary. The term "executive secretary" as used in this act refers to 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 nor 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. Drug dependence is defined as characterized by behavioral and other responses which 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 Department of Health as proper to be intrusted 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 Idaho Board of Pharmacy as proper to be entrusted with the custody of controlled substances and the 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 of Pharmacy and contains the required information to record the sales or disposition of Schedule V substances, which 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" as defined in this act, with reference to a vehicle, means any person having any right, title or interest in it. (7-1-93)

08. Pharmacist. The term "pharmacist" means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist-intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State. (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 prescriptions for controlled substances are received or processed in accordance with the federal law and the pharmacy laws and rules of this state. (7-1-93)

10. Prescription. The term "prescription" as used in this act, means a prescription for a controlled substance in Schedules III, IV, V, such prescription is an oral order given individually for the person for whom prescribed, directly from the prescriber or by the prescriber's employee or agent to the pharmacist or indirectly by means of an order written in ink, indelible pencil, typewritten, or a computer generated hard copy, signed by the prescriber, and shall contain the address of the prescriber, his federal registry number, the name and address of the patient, the name and quantity of the drug prescribed, directions for use, and shall be dated as of the date on which it is written. Written prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to federal and state laws, regulations and rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules. (4-11-06)

11. Register, Registration. The terms "register" and "registration" refer only to registration required and permitted by Section 37-2717, Idaho Code. (7-1-93)

12. Registrant. The term "registrant" means any person who is registered. (7-1-93)

13. Readily Retrievable. The term "readily retrievable" means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records. (7-1-93)

14. Sale. The term "sale" as used in this act, includes barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as principal, proprietor, agent, servant or employee. (7-1-93)

15. Transport. The term "transport" as used in this act, with reference to controlled substances, includes "conceal", "convey", and "carry." (7-1-93)

16. Vehicle. The term "vehicle" as used in this act, any vehicle or equipment used for the transportation of persons or things. (7-1-93)

17. Physician, Veterinarian, Dentist, Podiatrist, Osteopath, Optometrist, Pharmacist. As used in this act, these terms or any similar designation, means persons who hold valid, unrevoked licenses to practice their respective professions in this state, issued by their respective examining boards in this state. (12-7-94)

18. Physician. The term "physician" includes only persons licensed under Chapter 18 of Title 54, Idaho Code. (7-1-93)

434. ARTICLE II, SCHEDULE II.

Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts or 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 license in Idaho 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 therefor in accordance with the provisions of Chapter 27, Title 37, Idaho Code, which registration shall be issued for a period of one (1) year, and shall bear on its face the Seal of the Board of Pharmacy, the signature of the Executive Secretary thereof, and will be effective until the first day of January next after its issuance. (7-1-93)

437. FEES.
The said Board of Pharmacy shall collect a fee (pursuant to Section 37-2715, Idaho Code) for each annual registration, and a like fee for each annual renewal of such registration, and shall deposit each and both of the same 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 reregistration 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 reregistration 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 reregistration 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 reregistration 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 reregistration 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 reregistration fees shall be paid at the time when the application for registration or reregistration is submitted for filing in the form of a personal, certified or cashier's check or money order made payable to "The Idaho 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 the provisions of this act 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 of Pharmacy to carry out the purposes of the objectives of this act. Such moneys shall be paid out upon warrants drawn by the state auditor upon presentation of proper vouchers approved by the Board of Pharmacy and such 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 nonnarcotic, and conducting research with nonnarcotic, and conducting instructional activities with narcotic and nonnarcotic 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. (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 and, 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. REQUIREMENT OF PRESCRIPTION - SCHEDULE II.

01. Pharmacist. A pharmacist may dispense a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, and on delivery signed by the individual receiving such, except as provided in Subsection 442.04. (7-1-93)

02. Practitioner. An individual practitioner may administer or dispense a controlled substance listed in Schedule II in the course of his professional practice without a prescription, subject to Section 37-2701(d), Idaho Code. (7-1-93)

03. Institutional Practitioner. An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user. (7-1-93)

04. Emergency. In the case of an emergency situation, as defined by the secretary in Section 37-2722(b), Idaho Code, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner. (7-1-93)

a. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner). (7-1-93)

b. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner. (7-1-93)

c. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith effort to insure his identity. (7-1-93)

d. Within seven (7) days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist; in addition to conforming to the requirement of Section 37-2723, Idaho Code, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. (7-1-99)

e. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven (7) day period. (7-1-99)

f. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. (7-1-93)

g. The pharmacist shall notify the nearest office of the Bureau if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority

conferred by this subsection to dispense without a written prescription of a prescribing individual practitioner. (7-1-93)

443. REFILLING PRESCRIPTIONS.
The refilling of a prescription for a controlled substance listed in Schedule II is prohibited. (7-1-93)

444. PARTIAL FILLING OF PRESCRIPTIONS.
The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). (7-1-93)

01. Remaining Portion of Prescription. The remaining portion of the prescription may be filled within the seventy-two (72) hour period, the pharmacist shall so notify the prescribing individual practitioner. (7-1-93)

02. Supplying Further Quantity. No further quantity may be supplied beyond the seventy-two (72) hours without a new prescription. (7-1-93)

03. Partial Quantities. A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." (7-1-99)

a. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. (7-1-99)

b. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed sixty (60) days from the issue date unless sooner terminated by the discontinuance of medication. (7-1-99)

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 of Pharmacy office monthly, such record will (at a minimum) include: date of use, name of patient, name and amount of Schedule II drug, name of practitioner and name of pharmacy. Reports will be mailed the first of each month and will contain records of administrations for the previous month. (7-1-93)

446. REQUIREMENT OF PRESCRIPTION - SCHEDULE III OR IV.

01. Dispensing a Controlled Substance -- Pharmacist. A pharmacist may dispense a controlled substance listed in Schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 37-2722(c), Idaho Code except for the signature of the prescribing individual practitioner. (7-1-93)

02. Dispensing a Controlled Substance -- Individual Practitioner. An individual practitioner may administer or dispense a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code. (7-1-93)

03. Dispensing a Controlled Substance -- Institutional Practitioner. An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all of the information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 37-2720, Idaho Code. (7-1-93)

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 such 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 records, which 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 he shall be deemed to have dispensed for a full face amount of the prescription. (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 prescription as provided in Section 37-2722, Idaho Code, which shall be a new and separate prescription. (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 the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as 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. REQUIREMENT OF PRESCRIPTION - SCHEDULE V.

01. Dispensing Schedule V Controlled Substances. A pharmacist may dispense a controlled substance listed in Schedule V pursuant to a prescription as required for controlled substances listed in Schedule III and IV in Section 451. (7-1-93)

02. Refilling Schedule V Controlled Substances Requires Authorization. A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. (7-1-93)

03. Labeling Schedule V Controlled Substances for Dispensing. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with Section 448 and file the prescription in accordance with Section 449. (7-1-93)

04. Dispensing Schedule V Controlled Substances by Individual Practitioner. An individual practitioner may administer or dispense a controlled substance listed in Schedule V in the course of his professional practice without a prescription, subject to Section 37-2720, Idaho Code. (7-1-93)

05. Dispensing Schedule V Controlled Substances by Institutional Practitioner. An institutional practitioner may administer or dispense directly (but no prescribe) a controlled substance listed in Schedule V only pursuant to a written prescription signed by the prescribing individual practitioner, or pursuant to an oral prescription

made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in Section 37-2723, Idaho Code, except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to Section 37-2720, Idaho Code. (7-1-93)

451. DISPENSING WITHOUT A PRESCRIPTION.
A controlled substance listed in Schedule V, and a controlled substance listed in Schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, may be dispensed by a pharmacist or pharmacist-intern, without a prescription to a purchaser at retail. (7-1-93)

01. Distribution of Schedule V Controlled Substances by Pharmacist or Pharmacist-Intern. Such distribution is made only by a pharmacist or a pharmacist-intern, not by a nonpharmacist 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 credit transaction, or delivery may be completed by a nonpharmacist). (7-1-93)

02. Restricted Quantity. Not more than two hundred and forty (240) cc. (eight (8) ounces) of any such substances containing opium, nor more than one hundred and twenty (120) cc. (four (4) ounces) of any other controlled substances listed in Schedule V 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 is at least eighteen (18) years of age. (7-1-93)

04. Identification Required for Purchase. The pharmacist requires 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) is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substances purchased, the date of each purchase, and the name or initials of the pharmacist who distributed the substance to the purchaser and the book shall be maintained in accordance with the record-keeping requirement of Section 37-2720, Idaho Code. (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 the event of 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 does not exceed to the amount required by the second dispenser for immediate dispensing. (7-1-93)

02. Records of the Distribution. The distribution is recorded as a dispensing by the first dispenser, and the receipt as a distribution received by the second dispenser; and each dispenser retains a signed receipt of the distribution. (7-1-93)

03. Registration. The second dispenser is registered under the Act 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 and II, an order form is used as required in Section 37-2721, Idaho Code. (7-1-93)

05. Emergency. For purposes of this section, an emergency shall mean 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 normal distribution channels within the time required to meet the need of the person for such substance. (7-1-93)

453. ACQUISITION OF SCHEDULE I AND II SUBSTANCES - PROCEDURE REQUIRED.
Persons authorized under this act to manufacture, distribute or dispense controlled substances in Schedule I and II, and hospitals and approved state institutions may 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. TIME FOR FILLING PRESCRIPTION.
No person shall fill a prescription for a controlled substance listed in Schedule II unless the prescription is tendered to him on or before the thirtieth day following the date of issue. (5-3-03)

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 of Pharmacy. (7-1-93)

460. POSSESSION OF GREATER OR LESSER AMOUNT OF CONTROLLED SUBSTANCE THAN SHOWN BY RECORDS -- EVIDENCE OF GUILT.
In a prosecution under this act proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substance possessed by a defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of guilt. (7-1-93)

461. RECORDS OPEN TO INSPECTION.
Any record required by this act shall be open at all times to inspection by inspectors of the Board of Pharmacy and 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 of Pharmacy for the purpose of evidence, the inspector shall give to the pharmacist a receipt in lieu thereof. (7-1-93)

463. CONTENTS OF PRESCRIPTION FILE RECORD.
The prescription file shall constitute a record that as to the transactions shall show all of the following: name and address of patient; a description of the means of positive identification obtained by the pharmacy when so required under Section 464 of these rules; the date; the character and quantity of the controlled substance involved; the name, address and state registry number of the prescriber. (4-11-06)

464. FILLING OF A PRESCRIPTION FOR A CONTROLLED SUBSTANCE.
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. 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. Positive identification shall consist of either a valid, current state or military drivers license or

identification card, or a valid, current passport, each of which must contain a photo of the individual and the individual's signature. 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. (4-11-06)

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 ordered and the name and address of the owner or person having custody of the animal and must 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 any violation of this act, 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 this act shall be construed as requiring the secretary to report for the institution of proceedings under this act for minor violations, whenever the secretary believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning. (7-1-93)

468. PROHIBITION ON ADVERTISING CONTROLLED SUBSTANCES.
No person shall advertise controlled substances, Schedule I through V in any manner to the public, nor shall any pharmacy display these products to their patrons or members of the public. (7-1-93)

469. PRESCRIPTION REPORTING.

01. Prescription Reporting Requirements. All community and mail service pharmacies will report by the first of every month or more often as directed by the Board, certain data, as required by the Board, on all schedule II, III and IV controlled substance prescriptions filled. The data may be reported in the form of diskette, direct computer link, magnetic tape or other method as approved by the Board. (7-1-98)

02. Reporting Not Required. Prescriptions for controlled substances filled for patients in long term care facilities, are not required to be reported. (7-1-98)

470. REQUIREMENTS FOR PRESCRIPTION FORM -- DISCIPLINE OF PRACTITIONERS.

01. Prescription Form. Any prescription for a Controlled Substance, including any 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 which 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 470.02, 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 certified mail with a return receipt requested to the practitioner at the practitioner's registration address describing the offense and the basis for required action, with a copy of the letter and prescription 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 such thirty (30) 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 and given an opportunity to take appropriate action within thirty (30) days of receiving notice from the Board of Pharmacy and shall immediately notify the Board of Pharmacy when such action is taken. If the Board of Pharmacy is not notified of an action taken by the licensing board within such thirty

(30) day period, the Board of Pharmacy shall take disciplinary action under Subsection 470.02.c. (3-20-04)

c. Second offense -- suspension of the practitioner's controlled substance registration for a period of one (1) week pursuant to Section 37-2718, Idaho Code, along with an administrative fine 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, such notice to be sent certified mail with a return receipt requested to the practitioner at the practitioner's registration address. Practitioners who wish to avoid the suspension action may do so by sending to the Board a written explanation for the offense along with 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 mailing of notice of the offense. The practitioner shall have thirty (30) days from the date of mailing of the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after such thirty (30) day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho Code, the Board of Pharmacy shall take disciplinary action under Subsection 470.02.d. (3-20-04)

d. Third offense -- suspension of the practitioner's Controlled Substance registration for a period of thirty (30) days pursuant to Section 37-2718, Idaho Code, along with an administrative fine 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 registration, such notice to be sent certified mail with a return receipt requested to the practitioner at the practitioner's registration address. Practitioners who wish to avoid the suspension action may do so by sending to the Board a written explanation for the offense along with 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 mailing of notice of the offense. The practitioner shall thereafter have thirty (30) days from the date of mailing of the notice of offense to come into compliance with the requirements of Section 37-2725, Idaho Code. If, after such thirty (30) day period, the practitioner fails to comply with the requirements of Section 37-2725, Idaho, the Board of Pharmacy shall take disciplinary action under Subsection 470.02.e. (3-20-04)

e. Fourth offense -- suspension or revocation of the practitioner's Controlled Substance registration pursuant to Section 37-2718, Idaho Code, for such period as the Board, in its discretion, may determine based on the circumstances, along with an administrative fine 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, such notice to be sent certified mail with a return receipt requested to the practitioner at the practitioner's registration address. (3-20-04)

f. Offenses subject to discipline under this Subsection 470.02 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 rule and applicable statute and shall be subject to 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 Drug Enforcement Administration (DEA) as required under 21 CFR 1301.74(c), which information 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, including but not limited to the following: Sections 37-2732, 37-2733, 37-2734, 37-2737 and 37-2744, Idaho Code. This rule is not meant, nor shall the same be so 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 the same 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 of 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; (7-1-93)

d. The board of 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 to be provided by the board. (7-1-93)

03. Assuming a False Identify. No person shall, for the purpose of obtaining controlled substances falsely 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 controlled substances. (7-1-93)

493. SAMPLE, COMPLIMENTARY.
No manufacturer's sales representative shall distribute any controlled substances as a complimentary sample without the written request of an individual practitioner. Such requests shall contain the names and addresses of the supplier and the requester, 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 any other drug of the quantitative composition for one of the following drugs or which is the same except that it contains a lesser quantity of controlled substances, and which may be lawfully sold over-the-counter without a prescription, are exempt from the record-keeping requirements of Section 37-2720, Idaho Code. (7-1-93)

01. Exempt Trade Names. The following trade names are exempt from record keeping requirements: Bronkaid, Bronkotabs, Primatene. (8-4-94)

02. Exemptions. Drugs in unit dosage form, and any other drug of the quantitative composition which is the same except that it contains a lesser quantity of controlled substances, and which are restricted by law to dispensing on prescription, that are exempt from the requirements of Section 511(d)(1) of the Federal act, are also exempt from the record keeping requirements of Section 37-2720, Idaho Code. (7-1-93)

495. CONTROLLED SUBSTANCE DISPOSAL.
Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Executive Secretary of the Idaho State Board of Pharmacy for assistance 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 which he desires to dispose of, on IBP Form 15 in quadruplicate and submit three copies to the Idaho State Board of Pharmacy. (7-1-93)

02. Non-Registrant Request. If the person is not a registrant, he shall submit to the Secretary of the Board a letter stating the name and address of the person, the name and quantity of each controlled substance to be disposed of, how the applicant obtained the substance if known, and 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 Secretary shall authorize and instruct the applicant to dispose of the controlled substance in one of the following manners. (7-1-93)

a. By transfer to person registered under the act and authorized to possess the substance. (7-1-93)

b. By delivery to an agent of the Board of Pharmacy at the office of the Board. (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 Secretary 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 INVENTORY.
Each registered pharmacy shall maintain the inventories and records of controlled substances as follows: (7-1-93)

01. Inventories and Records for Schedule I and II. Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; (7-1-93)

02. Inventories and Records for Schedules III, IV, and V. Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy and prescriptions for such substances shall be maintained either in a separate prescription file for controlled substances listed in Schedules III, IV, and V only or in such form that they are readily retrievable from the other prescription records of the pharmacy. (7-1-93)

03. Readily Retrievable. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one (1) inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for non-controlled substances, provided that for pharmacies employing an electronic record-keeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy prescription with a red "C" is waived. (7-1-99)

04. Annual Inventory of Stocks of Controlled Substances. Each registered pharmacy shall annually, on the same date each year, take an inventory of all stocks of controlled substances on hand, following the general requirements for inventories. (7-1-93)

a. The annual inventory as required in Section 496 shall be a written record resulting from a physical (or actual) count of stock on hand or in the control of the pharmacist in charge of a particular pharmacy. (7-1-93)

b. Automated data processing equipment may be used to provide lists of items (products) and to record receipts and issues of various items but not to produce the annual inventory. (7-1-93)

c. The record of inventory shall be kept in the inventory book provided by the Board or in another bound book (not loose leaf) suitable to meet the needs of inventory reports. (7-1-93)

d. Upon completion, the inventory will be dated as of the day taken, indicating whether it was taken at the opening or closing of business and signed by the party that took the inventory. (7-1-93)

05. Separate Inventories for Each Location. A separate inventory shall be made by a registrant for each registered location, such inventory for a registered location shall be kept at the registered location. (7-1-93)

06. Time When Inventory Can Be Taken. The registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date indicating on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken. (7-1-93)

07. Inventory Must Be In Written Form. An inventory must be maintained in a written, typewritten or printed form, if taken by use of an oral recording device it must be promptly transcribed. (7-1-93)

08. Maintaining Written Inventory. Such inventory must be maintained on the premises for a minimum of three (3) years. (7-1-93)

09. Additions to Schedules of Controlled Substances. On the effective date of a rule adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand and thereafter such substance shall be included in each inventory made by the registrant pursuant to Subsection 496.04. (7-1-93)

10. Maintaining Current List of Each Substance. Each registered pharmacy shall maintain on a current basis a complete list of each substance manufactured, received, ordered, sold, delivered, or otherwise disposed of by him; order forms and other pertinent records in such a manner as to be readily retrievable. (7-1-93)

497. -- 999. (RESERVED).

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