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IDAPA 27
TITLE 01
CHAPTER 01

27.01.01. - RULES OF THE IDAHO STATE BOARD OF PHARMACY

Subchapter A -- Standard Provisions
(Rules 0 through 9 -- Standard Provisions)

000. LEGAL AUTHORITY.
This chapter is adopted under the legal authority of the Uniform Controlled Substances Act, Title 37, Chapter 27, Idaho Code; the Idaho Pharmacy Act, the Idaho Wholesale Drug Distribution Act, and the Idaho Legend Drug Donation Act, Title 54, Chapter 17, Idaho Code; and specifically pursuant to Sections 37-2702, 37-2715, 54-1717, 54-1753, 54-1755, and 54-1763, Idaho Code. (3-21-12)

001. TITLE AND SCOPE.

01. **Title**. The title of this chapter is "Rules of the Idaho State Board of Pharmacy," IDAPA 27, Title 01, Chapter 01. (3-21-12)

02. **Scope**. The scope of this chapter includes, but is not limited to, provision for, and clarification of, the Board's assigned responsibility to: (3-21-12)

a. Regulate and control the manufacture, distribution, and dispensing of controlled substances within or into the state, pursuant to the Uniform Controlled Substances Act, Section 37-2715, Idaho Code; (3-21-12)

b. Regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Section 54-1718, Idaho Code; and (3-21-12)

c. Carry out its duties in regard to drugs, devices and other materials used in the diagnosis, mitigation and treatment, or prevention of injury, illness, and disease, pursuant to Section 54-1719, Idaho Code, or in regard to professionals or other individuals licensed or registered by the Board or otherwise engaged in conduct subject to regulation under these Acts. (3-21-12)

002. WRITTEN INTERPRETATIONS.
Written interpretations, explanatory comments that accompanied a notice of proposed rulemaking, comments submitted in a rulemaking process, or written statements that the Board may have or prepare that pertain to the interpretation of the rules of this chapter may be obtained through submission of a public records request pursuant to Title 74, Chapter 1, Idaho Code. (3-21-12)

003. ADMINISTRATIVE PROCEEDINGS AND APPEALS.
Administrative proceedings and appeals are administered by the Board in accordance with the Idaho Rules of Administrative Procedure of the Attorney General, IDAPA 04.11.01, Subchapter B -- Contested Cases, Rules 100 through 800. (3-21-12)

01. **Place and Time for Filing**. Documents in rulemakings or contested cases must be filed with the executive director of the Board at the Board office between the hours of 8 a.m. and 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (3-21-12)

02. **Manner of Filing**. One (1) original of each document is sufficient for filing; however, the person or officer presiding over a particular rulemaking or contested case proceeding may require the filing of additional copies. A document may be filed with the Board by e-mail or fax if legible, complete, and received during the Board's office hours. The filing party is responsible for verifying with Board staff that an e-mail or fax was successfully and legibly received. (3-21-12)

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into these rules. (3-21-12)

005. BOARD OFFICE INFORMATION.

01. Street Address. The office is located at 1199 Shoreline Lane, Suite 303, Boise, Idaho. (3-21-12)

02. Mailing Address. The mailing address is P.O. Box 83720, Boise, Idaho 83720-0067. (3-21-12)

03. Telephone Number. The telephone number is (208) 334-2356. (3-21-12)

04. Fax Number. The fax number is (208) 334-3536. (3-21-12)

05. Electronic Address. The website address is http://bop.idaho.gov. (3-21-12)

06. Office Hours. The office hours are 8 a.m. to 5 p.m., Mountain Time, Monday through Friday, excluding state holidays. (3-21-12)

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 74, Chapiter, Idaho Code. (3-21-12)

007. OFFICIAL BOARD JOURNAL.
The official journal of the Board is the Idaho Board of Pharmacy Newsletter. A link to recent versions of the newsletter is posted on the Board's website and copies may be obtained from the Board office. Board licensees and registrants are presumed to have knowledge of the contents of the newsletter on the date of publication. The newsletter may be used in administrative hearings as proof of notification. (3-21-12)

008. MAINTENANCE, RETENTION, AND INSPECTION OF RECORDS.

01. Records Maintenance and Retention Requirement. Unless an alternative standard is stated for a specified record type, form, or format, records required to evidence compliance with statutes or rules enforced by the Board must be maintained as required and retained in a readily retrievable form and location for at least three (3) years. (3-21-12)

02. Records Subject to Board Inspection. Records created, maintained, or retained by Board licensees or registrants in compliance with statutes or rules enforced by the Board must be made available for inspection upon request by Board inspectors or authorized agents. It is unlawful to refuse to permit or to obstruct a Board inspection. (3-21-12)

009. POLICIES AND PROCEDURES.
Policies and procedures required by this chapter must be written and maintained onsite or immediately retrievable in electronic form, operationally implemented and enforced, and updated or revised as necessary to maintain compliance with these rules. (3-21-12)

010. DEFINITIONS AND ABBREVIATIONS (A -- I).

01. Accredited School or College of Pharmacy. A school or college that meets the minimum standards of the ACPE and appears on its list of accredited schools or colleges of pharmacy. (3-21-12)

02. ACPE. Accreditation Council for Pharmacy Education. (3-21-12)

03. Acute Care Hospital. A facility in which concentrated medical and nursing care is provided by, or under the supervision of, physicians on a twenty-four (24) hour basis to inpatients experiencing acute illnesses. (3-21-12)

04. ADS -- Automated Dispensing and Storage. A mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing, or distribution of drugs and that collects, controls, and maintains transaction information. (3-21-12)

05. Biological Product. A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), that is applicable to the prevention, treatment, or cure of a disease or condition of human beings and licensed under Section 351(k) of the Public Health Service Act, 42 U.S.C. Section 262(i). (4-11-15)

06. Biosimilar. A biological product highly similar to a specific reference biological product that is licensed by the FDA pursuant to 42 U.S.C. Section 262(k) and published in the Purple Book. (4-11-15)

07. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. (3-21-12)

08. Central Drug Outlet. A resident or nonresident pharmacy, drug outlet or business entity employing or contracting pharmacists to perform centralized pharmacy services. (7-1-13)

09. Central Pharmacist. A pharmacist performing centralized pharmacy services. (7-1-13)

10. Central Pharmacy. A pharmacy performing centralized pharmacy services. (7-1-13)

11. Centralized Pharmacy Services. The processing by a central drug outlet or central pharmacist of a request from another pharmacy to fill, refill, or dispense a prescription drug order, perform processing functions, or provide cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations. (7-1-13)

12. Change of Ownership. A change of majority ownership or controlling interest of a drug outlet licensed or registered by the Board. (3-21-12)

13. Charitable Clinic or Center -- Authorized Personnel. A person designated in writing and authorized by the qualifying charitable clinic or center's medical director or consultant pharmacist to perform specified duties within the charitable clinic or center under the supervision of a pharmacist, physician, dentist, optometrist, physician assistant, or an advanced practice professional nurse with prescriptive authority. (3-21-12)

14. Chart Order. A lawful drug order for a drug or device entered on the chart or a medical record of an inpatient or resident of an institutional facility. (3-21-12)

15. CME. Continuing medical education. (3-21-12)

16. COE -- Central Order Entry. A pharmacy that processes information related to the practice of pharmacy, engages solely in centralized prescription processing but from which drugs are not dispensed, is physically located outside the institutional pharmacy of a hospital, and is part of a hospital system. (3-21-12)

17. Collaborative Pharmacy Practice. A pharmacy practice whereby one (1) or more pharmacists jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and DTM services not otherwise permitted to be performed by a pharmacist under specified conditions or limitations. (3-21-12)

18. Collaborative Pharmacy Practice Agreement. A written agreement between one (1) or more pharmacists and one (1) or more prescribers that provides for collaborative pharmacy practice. (3-21-12)

19. Continuous Quality Improvement Program. A system of standards and procedures to identify and evaluate quality-related events and to constantly enhance the efficiency and effectiveness of the structures and processes of a pharmacy system. (3-21-12)

20. Correctional Facility. Any place used for the confinement of persons charged with or convicted of an offense or otherwise confined under a court order. (4-4-13)

21. CPE. Continuing pharmacy education. (3-21-12)

22. **DEA**. United States Drug Enforcement Administration. (3-21-12)

23. **Distributor**. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. (3-21-12)

24. **DME**. Durable medical equipment. (3-21-12)

25. **Drug Order**. A prescription drug order issued in the unique form and manner permitted for a patient or resident of an institutional facility or as permitted for other purposes by these rules. Unless specifically differentiated, rules applicable to a prescription drug order are also applicable to a drug order. (3-21-12)

26. **Drug Product Selection**. The act of selecting either a brand name drug product or its therapeutically equivalent generic. (3-21-12)

27. **Drug Product Substitution**. Dispensing a drug product other than prescribed. (4-4-13)

28. **DTM -- Drug Therapy Management**. Selecting, initiating, or modifying drug treatment pursuant to a collaborative practice agreement. (3-21-12)

29. **Emergency Drugs**. Drugs required to meet the immediate therapeutic needs of one (1) or more patients that are not available from any other authorized source in sufficient time to avoid risk of harm due to the delay that would result from obtaining the drugs from another source. (3-21-12)

30. **Executive Director**. The Idaho State Board of Pharmacy executive director created by Sections 54-1713 and 54-1714, Idaho Code. (3-21-12)

31. **FDA**. United States Food and Drug Administration. (3-21-12)

32. **Flavoring Agent**. An additive used in food or drugs when the additive is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect. (3-21-12)

33. **Floor Stock**. Drugs or devices not labeled for a specific patient that are maintained at a nursing station or other department of an institutional facility, excluding the pharmacy, for the purpose of administering to patients of the facility. (3-21-12)

34. **FPGEC**. Foreign Pharmacy Graduate Examination Committee. (4-4-13)

35. **Hazardous Drug**. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: (3-25-16)

a. Carcinogenicity; (3-25-16)

b. Teratogenicity or developmental toxicity; (3-25-16)

c. Reproductive toxicity in humans; (3-25-16)

d. Organ toxicity at low doses in humans or animals; (3-25-16)

e. Genotoxicity; or (3-25-16)

f. New drugs that mimic existing hazardous drugs in structure or toxicity. (3-25-16)

36. **HIPAA**. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). (3-21-12)

37. **Hospital System**. A hospital or hospitals and at least one (1) on-site institutional pharmacy under

common ownership. A hospital system may also include one (1) or more COE pharmacies under common ownership. (3-21-12)

38. **Idaho State Board of Pharmacy or Idaho Board of Pharmacy**. The terms Idaho State Board of Pharmacy, Idaho Board of Pharmacy, State Board of Pharmacy, and Board of Pharmacy are deemed synonymous and are used interchangeably to describe the entity created under the authority of Title 54, Chapter 17, Idaho Code. Unless specifically differentiated, "the Board" or "Board" also means the Idaho State Board of Pharmacy. (3-21-12)

39. **Individually Identifiable Health Information**. Information that is a subset of health information, including demographic information, collected from an individual and that: (3-21-12)

a. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (3-21-12)

b. Relates to the past, present, or future physical or mental health or condition of an individual; or the past, present, or future payment for the provision of health care to an individual that: (3-21-12)

i. Identifies the individual; or (3-21-12)

ii. With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (3-21-12)

40. **Institutional Pharmacy**. A pharmacy located in an institutional facility. (3-21-12)

41. **Interchangeable Biosimilar**. A licensed biosimilar product determined by the FDA to be therapeutically equivalent to the reference biological product and published in the Purple Book. (4-11-15)

011. DEFINITIONS AND ABBREVIATIONS (J -- R).

01. **LTCF -- Long-Term Care Facility**. An institutional facility that provides extended health care to resident patients. (3-21-12)

02. **Mail Service Pharmacy**. A nonresident pharmacy that ships, mails, or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law. (7-1-13)

03. **MPJE**. Multistate Pharmacy Jurisprudence Exam. (3-21-12)

04. **MTM -- Medication Therapy Management**. A distinct service or group of services that optimize therapeutic outcomes for individual patients. MTM services are independent of, but can occur in conjunction with, the provision or administration of a drug or a device and encompass a broad range of activities and responsibilities. The MTM service model in pharmacy practice includes the following five core elements: (3-21-12)

a. Medication therapy review; (3-21-12)

b. Personal medication record; (3-21-12)

c. Medication-related action plan; (3-21-12)

d. Intervention or referral, or both; (3-21-12)

e. Documentation and follow-up. (3-21-12)

05. **NABP**. National Association of Boards of Pharmacy. (3-21-12)

06. **NAPLEX**. North American Pharmacists Licensure Examination. (3-21-12)

07. **NDC**. National Drug Code. (3-21-12)

08. **Non-Institutional Pharmacy**. A pharmacy located in a drug outlet that is not an institutional facility. (3-21-12)

09. **Outsourcing Drug Outlet**. A drug outlet that is registered by the United States Food and Drug Administration pursuant to 21 U.S.C. Section 353b and either registered or endorsed by the Board. (4-6-15)

10. **Parenteral Admixture**. The preparation and labeling of sterile products intended for administration by injection. (3-21-12)

11. **Pharmaceutical Care Services**. A broad range of pharmacist-provided cognitive services, activities and responsibilities intended to optimize drug-related therapeutic outcomes for patients. Pharmaceutical care services may be performed independent of, or concurrently with, the dispensing or administration of a drug or device and encompasses services provided by way of DTM under a collaborative practice agreement, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and MTM. Except as permitted pursuant to a collaborative practice agreement, nothing in these rules allows a pharmacist, beyond what is statutorily allowed, to engage in the unlicensed practice of medicine or to diagnose, prescribe, or conduct physical examinations. Pharmaceutical care services are not limited to, but may include one (1) or more of the following, according to the individual needs of the patient: (4-4-13)

a. Performing or obtaining necessary assessments of the patient's health status, including the performance of health screening activities that may include, but are not limited to, obtaining finger-stick blood samples; (3-21-12)

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization plan; (3-21-12)

c. Monitoring and evaluating the patient's response to drug therapy, including safety and effectiveness; (3-21-12)

d. Performing a comprehensive drug review to identify, resolve, and prevent drug-related problems, including adverse drug events; (3-21-12)

e. Documenting the care delivered; (3-21-12)

f. Communicating essential information or referring the patient when necessary or appropriate; (3-21-12)

g. Providing counseling education, information, support services, and resources applicable to a drug, disease state, or a related condition or designed to enhance patient compliance with therapeutic regimens; (3-21-12)

h. Conducting a drug therapy review consultation with the patient or caregiver; (3-21-12)

i. Preparing or providing information as part of a personal health record; (3-21-12)

j. Identifying processes to improve continuity of care and patient outcomes; (3-21-12)

k. Providing consultative drug-related intervention and referral services; (3-21-12)

l. Coordinating and integrating pharmaceutical care services within the broader health care management services being provided to the patient; (3-25-16)

m. Ordering and interpreting laboratory tests; and (3-25-16)

n. Other services as allowed by law. (3-21-12)

12. **Pharmacist Extern**. A person enrolled in an accredited school or college of pharmacy who is

pursuing a professional degree in pharmacy. (4-4-13)

13. **Pharmacist Intern**. A person who has successfully completed a course of study at an accredited school or college of pharmacy, has received a professional degree in pharmacy, and is obtaining practical experience under the supervision of a pharmacist. (3-21-12)

14. **Pharmacy Operations**. Activities related to and including the preparation, compounding, distributing, or dispensing of drugs or devices from a pharmacy. (3-21-12)

15. **PHI -- Protected Health Information**. Individually identifiable health information that is: (3-21-12)

a. Transmitted by electronic media (as defined by the HIPAA Privacy Rule at 45 CFR 160.103); (3-21-12)

b. Maintained in electronic media; and (3-21-12)

c. Transmitted or maintained in any other form or medium. (3-21-12)

d. PHI excludes individually identifiable health information in: (3-21-12)

i. Education records covered by the Family Education Right and Privacy Act, as amended (20 U.S.C. Section 1232g); (3-21-12)

ii. Records described at 20 U.S.C. Section 1232g(a)(4)(B)(iv); and (3-21-12)

iii. Employment records held by a covered entity (as defined by the HIPAA Privacy Rule at 45 CFR 160.103) in its role as an employer. (3-21-12)

16. **PIC**. Pharmacist-in-charge. (3-21-12)

17. **PMP**. Prescription Monitoring Program. (3-21-12)

18. **Prepackaging**. The act of transferring a drug, manually or using an automated system, from a manufacturer's original container to another container prior to receiving a prescription drug order. (3-21-12)

19. **Prescriber**. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. (3-21-12)

20. **Prescriber Drug Outlet**. A drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples. (3-21-12)

21. **Purple Book**. The list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations published by the FDA under the Public Health Service Act. (4-11-15)

22. **Readily Retrievable**. Records are considered readily retrievable if they are able to be completely and legibly produced upon request within seventy-two (72) hours. (3-21-12)

23. **Reconstitution**. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. (3-25-16)

24. **Relative Contraindication**. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. (3-21-12)

25. **Remote Dispensing Site**. A licensed pharmacy staffed by one or more certified technicians at which telepharmacy services are provided through a supervising pharmacy. (3-21-12)

26. **Remote Office Location**. A secured area that is restricted to authorized personnel, adequately protects private health information, and shares a secure common electronic file or a private, encrypted connection with a pharmacy, from which a pharmacist who is contracted or employed by a central drug outlet performs centralized pharmacy services. (7-1-13)

27. **Retail Non-Pharmacy Drug Outlet**. A retail outlet that sells non-prescription drugs or devices that is not a pharmacy. (3-21-12)

28. **Retail Pharmacy**. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. (3-21-12)

29. **R.N**. Registered nurse. (3-21-12)

012. DEFINITIONS AND ABBREVIATIONS (S -- Z).

01. **Sample**. A unit of a drug that is not intended to be sold and is intended to promote the sale of the drug. (3-21-12)

02. **Secured Pharmacy**. The area of a drug outlet where prescription drugs are prepared, compounded, distributed, dispensed, or stored. (3-21-12)

03. **Skilled Nursing Facility**. An institutional facility or a distinct part of an institutional facility that is primarily engaged in providing daily skilled nursing care and related services. (3-21-12)

04. **Student Pharmacist**. A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. (3-21-12)

05. **Technician**. Unless specifically differentiated, a term inclusive of pharmacy technician, certified pharmacy technician, and technician-in-training to indicate an individual authorized by registration with the Board to perform routine pharmacy support services under the supervision of a pharmacist. (3-21-12)

06. **Telepharmacy**. The use of telecommunications and information technologies in the practice of pharmacy to provide pharmaceutical care services to patients at a distance. (3-21-12)

07. **Therapeutic Equivalent Drugs**. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) and animal drug products published in the FDA Approved Animal Drug Products (Green Book). (4-4-13)

08. **Unit Dose**. Drugs packaged in individual, sealed doses with tamper-evident packaging (for example, single unit-of-use, blister packaging, unused injectable vials, and ampules). (3-21-12)

09. **USP**. United States Pharmacopeia. (3-21-12)

10. **USP-NF**. United State Pharmacopeia-National Formulary. (3-21-12)

11. **USP 795**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 795. (3-25-16)

12. **USP 797**. The current edition of the United States Pharmacopeia-National Formulary, Chapter 797. (3-25-16)

13. **VAWD -- Verified Accredited Wholesale Distributor**. An accreditation program for wholesale distributors offered through NABP. (3-21-12)

14. **VDO -- Veterinary Drug Outlet**. A registered establishment that employs a qualified VDT to distribute prescription veterinary drugs pursuant to lawful orders of a veterinarian. (3-21-12)

15. VDT -- Veterinary Drug Technician. A non-pharmacist qualified by registration with the Board to distribute prescription veterinary drugs in a VDO. (3-21-12)

16. Veterinary Drug Order. A lawful order by a veterinarian issued pursuant to the establishment of a veterinarian-patient-client relationship as recognized by the American Veterinary Medical Association. (3-21-12)

17. VIS. Vaccine Information Statement. (3-21-12)

013. WAIVERS OR VARIANCES.

01. Criteria. The Board may grant or deny, in whole or in part, a waiver of, or variance from, specified Board rules based on consideration of the following: (3-21-12)

a. The application of a certain rule or rules is unreasonable and would impose an undue hardship or burden on the petitioner; (3-21-12)

b. The waiver or variance requested would not allow conduct specifically prohibited by, or otherwise contrary to, state or federal law; and (4-4-13)

c. The granting of the waiver or variance is consistent with the Board's mandate to promote, preserve, and protect public health, safety, and welfare. (4-4-13)

02. Content and Filing of a Waiver or Variance Petition. A petition for waiver or variance must be submitted in writing and must include at least the following: (3-21-12)

a. The name, address, and telephone number of the petitioner; (3-21-12)

b. A specific reference to the rule or rules from which a waiver or variance is requested; (3-21-12)

c. A statement detailing the waiver or variance requested, including the precise scope and duration; (3-21-12)

d. The name, address, and telephone number of any public agency or political subdivision that also regulates the activity in question or that might be affected by the granting of the waiver or variance; and (3-21-12)

e. The name, address, and telephone number of any known person who would be adversely affected by the granting of the waiver or variance. (3-21-12)

f. A description of how the waiver or variance, if granted, will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. (4-4-13)

03. Additional Information. Prior to granting or denying the waiver or variance, the executive director may request additional information from the petitioner and may require the petitioner to appear before the Board at an upcoming Board meeting. (3-21-12)

04. Granting or Denying the Petition for Waiver or Variance. The decision to grant or deny the petition for waiver or variance will be at the discretion of the Board or, pursuant to Board authorization, its executive director based upon consideration of relevant factors. (3-21-12)

05. Prohibited Requests. A waiver or variance request that is contrary to federal law or Idaho Code or that seeks to delay or cancel an administrative deadline will not be considered or granted by the Board. (3-21-12)

06. Conditions. Waivers or variances may be granted subject to binding conditions, limitations, or restrictions determined necessary to protect the public health, safety, and welfare. (3-21-12)

07. Time Period of Waiver or Variance. Waivers or variances may be granted on a permanent or temporary basis. Temporary waivers or variances have no automatic renewal, but may be renewed if the Board finds that sufficient grounds to allow the waiver or variance continue to exist. (3-21-12)

08. Cancellation or Modification of a Waiver or Variance. A waiver or variance granted by the Board may be cancelled or modified if the Board finds any of the following: (3-21-12)

a. The petitioner or other person who was the subject of the waiver or variance withheld or misrepresented material facts; (3-21-12)

b. The alternative means for ensuring adequate protection of public health, safety, or welfare are demonstrated to be insufficient after issuance of the waiver or variance; or (3-21-12)

c. The subject of the waiver or variance has failed to comply with the prescribed conditions, limitations, or restrictions of the waiver or variance. (3-21-12)

09. Violations. Violation of a condition, restriction, or limitation of a waiver or variance will be deemed a violation of the particular rule or rules for which the waiver or variance was granted. (3-21-12)

014. BOARD-RECOGNIZED EXAMINATIONS, CERTIFICATIONS, AND PROGRAMS.
A specific reference in these rules to a named examination or examining body, certification or certifying body, or other item or program indicates the Board's review and determination that the referenced item or entity meets the Board's objectives or desired criteria and has thus been granted Board recognition. Nevertheless, a specific reference in these rules is not intended to, and does not, indicate exclusivity, and alternative equivalents may also be accepted upon prior Board consideration and approval. (3-21-12)

015. BOARD INSPECTIONS AND INVESTIGATIONS.

01. Inspections. Prior to the commencement of business, if required, and thereafter at reasonable times, in a reasonable manner, to the extent authorized by law, and upon presentation of appropriate identification, registrants and licensees must permit the Board or its compliance officers to enter and inspect the premises and to audit the records of each drug outlet for compliance with laws enforced by or under the Board's jurisdiction. (3-21-12)

02. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. If required, one (1) follow-up inspection may be performed by the Board at no cost. Additional follow-up inspections will be at the expense of the drug outlet. Charges for additional inspections will be actual travel and personnel costs incurred in the inspection and must be paid within ninety (90) days of inspection. (3-21-12)

03. Inspection Reports. Inspection reports must be reviewed with the Board inspector and signed by an agent of the drug outlet upon completion of the exit interview. The licensee or registrant must retain a copy of the inspection report issued by the inspector or investigator in an immediately retrievable manner. (3-21-12)

04. Investigations. Licensees or registrants must also fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, to gather information pertinent to a complaint received by the Board, or to enforce disciplinary actions. (3-21-12)

05. Prosecution of Violations -- Reporting Discretion Reserved. The executive director will report violations of law to proper prosecuting authorities as required by law or otherwise ordered by the Board. These rules should not be construed as requiring the Board, through its executive director, to report violations for the initiation of formal proceedings when not required by law and if the Board believes, under the circumstances, that public interest will be adequately served through administrative disciplinary processes. (3-21-12)

016. BOARD OF PHARMACY LICENSURE AND REGISTRATION.
The Board is responsible for the control and regulation of the practice of pharmacy in or into the state of Idaho, which includes the licensure or registration of professional, supportive, and ancillary personnel who engage in or support the

practice. The Board is also responsible for the control, regulation, and registration of persons or drug outlets that manufacture, distribute, or dispense controlled substances within or into the state. Licenses or registrations required by state or federal law, or both, must be obtained prior to engaging in these practices or their supportive functions, except that the Board may suspend such requirements for the duration of a national, state or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, for individuals engaged in the scope of practice for which they are licensed in another state. (3-25-16)

01. Pharmacy Practice Act Licenses and Registrations. The Board will issue or renew a license or a certificate of registration upon application and determination that the applicant has satisfied the requirements of the Idaho Pharmacy Act and any additional criteria specified by these rules for the license or registration classification. Licenses and certificates of registration issued pursuant to Title 54, Chapter 17, Idaho Code, expire annually on June 30 unless an alternate expiration term or date is specifically stated in these rules. (3-21-12)

02. Idaho Controlled Substances Act Registrations. The Board will issue or renew controlled substance registrations upon application and determination that the applicant has satisfied the requirements of the Idaho Controlled Substances Act and any additional criteria specified by state or federal law applicable to applicants that manufacture, distribute, or dispense, or conduct research with, controlled substances. Registrations issued pursuant to Title 37, Chapter 27, Idaho Code, must be renewed annually by June 30 for pharmacists and by December 31 for all other registrants. (4-4-13)

a. Unless a wholesaler, an applicant for an Idaho controlled substance registration must hold a valid, unrestricted Idaho license to prescribe, dispense, or administer controlled substances and, unless a pharmacist or certified euthanasia technician, a valid federal DEA registration. If a required license or registration is cancelled or otherwise invalidated by the issuing agency, the Idaho controlled substance registration will be correspondingly cancelled. (3-21-12)

b. A registrant engaging in more than one (1) group of independent activities, as defined by federal law, must obtain a separate Idaho controlled substance registration for each group of activities if not exempted from separate DEA registration by federal law. (3-21-12)

017. LICENSURE AND REGISTRATION: APPLICATION AND RENEWAL.

01. Board Forms. Initial licensure and registration applications, annual renewal applications, and other forms used for licensure, registration, or other purposes must be in such form as designated by the Board. (3-21-12)

02. Incomplete Applications. Information requested on the application or other form must be provided and submitted to the Board office with the applicable fee or the submission will be considered incomplete and will not be processed. (3-21-12)

03. On-Time Annual Renewal Application. Licenses and registrations must be renewed annually to remain valid. Applications for renewal must be completed and submitted to the Board office prior to the license or registration expiration. Timely submission of the renewal application is the responsibility of each licensee or registrant. (3-21-12)

04. Late Application. Failure to submit a renewal application prior to the expiration date will cause the license or registration to lapse and will result in the assessment of a late fee and possible disciplinary action. A lapsed license or registration is invalid until renewal is approved by the Board and if not renewed within thirty (30) days after its expiration will require reinstatement. (3-21-12)

05. Exemption. New licenses and registrations issued ten (10) weeks or less prior to the renewal due date are exempt from the renewal requirements that year only. (3-21-12)

06. Reporting Information Changes. Changes to required information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change. (3-21-12)

018. LICENSE AND REGISTRATION: REINSTATEMENT.
The Board may, at its discretion, consider reinstatement of a license or registration upon receipt of a written petition and payment of the reinstatement and other fees due or delinquent at the time reinstatement is requested. (3-21-12)

01. Satisfactory Evidence. If applicable, reinstatement applicants must also provide satisfactory evidence of completion of continuing education requirements and compliance with any direct orders of the Board. (3-21-12)

02. Additional Requirements. A pharmacist reinstatement applicant must provide evidence of completion of a minimum of thirty (30) CPE hours within the twenty-four (24) months prior to reinstatement application and may be required to appear before the Board. The Board may also, at its discretion, impose additional requirements on a pharmacist reinstatement applicant who has not practiced as a pharmacist for the preceding twelve (12) months or longer that may include taking and passing an examination, completion of forty (40) intern hours for each year away from the practice of pharmacy, completion of additional CPE hours, or other requirements determined necessary to acquire or demonstrate professional competency. (4-4-13)

019. LICENSE AND REGISTRATION: INSPECTION.
Licenses and registrations issued under the Idaho Pharmacy and the Uniform Controlled Substances Acts must be immediately retrievable at the licensed or registered location or at the drug outlet where the licensee or registrant is employed. (4-4-13)

01. Application Pending. Pending receipt of the current registration or license from the Board, the confirmation of successful submission of an online application must be printed. (4-4-13)

02. Temporary Locations. A licensee or registrant engaged in professional practice at a temporary or alternate location or in training must be able to produce written proof of licensure or registration immediately upon request. (3-21-12)

020. BOARD FEES.

01. Fee Determination and Collection. Pursuant to the authority and limitations established by Sections 37-2715 and 54-1720(5)(a), Idaho Code, the Board has determined and will collect fees for the issuance, annual renewal, or required reinstatement of licenses and certificates of registration to persons and drug outlets engaged in acts or practices regulated by the Board. The Board may also charge reasonable fees for specified administrative services or publications. (3-21-12)

02. Time and Method of Payment. Fees are due and must be paid by cash, credit card, or by personal, certified, or cashier's check or money order payable to the "Idaho State Board of Pharmacy" at the time of application, submission, or request. Fees are nonrefundable and will not be prorated. (3-21-12)

03. Fee For Dishonored Payment. A reasonable administrative fee may be charged for a dishonored check or other form of payment. If a license or registration application has been approved or renewed by the Board and payment is subsequently dishonored, the approval or renewal is immediately cancelled on the basis of the submission of an incomplete application. The board may require subsequent payments to be made by cashier's check, money order, or other form of guaranteed funds. (3-21-12)

04. Overpayment of Fees. "Overpayment" refers to the payment of any fee in excess of the required amount. Refunds issued will be reduced by a reasonable processing fee. (3-21-12)

05. Fee Exemption for Controlled Substance Registrations. Persons or drug outlets exempt pursuant to federal law from fee requirements applicable to controlled substance registrations issued by the DEA are also exempt from fees applicable to controlled substance registrations issued by the Board. (3-21-12)

021. FEE SCHEDULE.

01. Licenses -- Professionals. (3-21-12)

a. Original pharmacist license: one hundred dollars ($100). (3-21-12)

b. Licensure by reciprocity: two hundred fifty dollars ($250). (3-21-12)

c. Pharmacist license annual renewal. (3-21-12)

i. Active: ninety dollars ($90). (3-21-12)

ii. Inactive: fifty dollars ($50). (3-21-12)

d. Late payment processing: fifty dollars ($50). (3-21-12)

e. License reinstatement fee: seventy-five dollars ($75). (3-21-12)

02. Certificates of Registration -- Professionals. (3-21-12)

a. Pharmacist registration or annual renewal: two hundred fifty dollars ($250). (7-1-13)

b. Pharmacist intern - registration or annual renewal: fifty dollars ($50). (3-21-12)

c. Pharmacist extern registration and annual renewal: fifty dollars ($50) due upon enrollment in an accredited school or college of pharmacy and renewed annually at no charge. (3-21-12)

d. Technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

e. Veterinary drug technician - registration or annual renewal: thirty-five dollars ($35). (3-21-12)

f. Registration reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

03. Certificates of Registration and Licensure - Facilities. (3-21-12)

a. Retail pharmacy - registration or annual renewal: one hundred dollars ($100). (3-21-12)

b. Institutional facility - registration or annual renewal. (3-21-12)

i. Hospital pharmacy: one hundred dollars ($100). (3-21-12)

ii. Nursing home: thirty-five dollars ($35). (3-21-12)

c. Manufacturer (including a repackager that is a manufacturer's authorized distributor of record) - registration or annual renewal: one hundred dollars ($100). (3-21-12)

d. Wholesaler. (3-21-12)

i. License or annual renewal: one hundred thirty dollars ($130); or (3-21-12)

ii. Registration or annual renewal: one hundred dollars ($100). (3-21-12)

e. Veterinary drug outlet - registration or annual renewal: one hundred dollars ($100). (3-21-12)

f. Nonresident central drug outlet. (7-1-13)

i. Initial license: five hundred dollars ($500). (7-1-13)

ii. License annual renewal: two hundred fifty dollars ($250). (7-1-13)

g. Mail service pharmacy. (3-21-12)

i. Initial license: five hundred dollars ($500). (3-21-12)

ii. License annual renewal: two hundred fifty dollars ($250). (3-21-12)

h. Limited service outlet - registration or annual renewal. (3-21-12)

i. Limited service outlet, if not listed: one hundred dollars ($100). (3-21-12)

ii. Sterile product pharmacy: one hundred dollars ($100). (4-4-13)

iii. Remote dispensing pharmacy: one hundred dollars ($100). (3-21-12)

iv. Facility operating a narcotic treatment program: one hundred dollars ($100). (3-21-12)

v. Durable medical equipment outlet: fifty dollars ($50). (3-21-12)

vi. Prescriber drug outlet: thirty five dollars ($35). (3-21-12)

vii. Outsourcing facilities: (4-6-15)

(1) Initial nonresident registration: five hundred dollars ($500). (4-6-15)

(2) Initial resident registration: two hundred fifty dollars ($250). (4-6-15)

(3) Registration annual renewal: two hundred fifty dollars ($250). (4-6-15)

i. Analytical or research lab -- registration or annual renewal: forty dollars ($40). (3-21-12)

j. Retail non-pharmacy outlets. (3-24-16)

i. Retail store registration or annual renewal: thirty-five dollars ($35). (3-24-16)

ii. "V" (Vending machines): ten dollars ($10) per machine. (3-21-12)

k. Supplemental facility registrations or annual renewals. (3-21-12)

i. Laminar flow or other hood, biological safety cabinet, or barrier isolator -- single registration required for one (1) or more hoods: no charge. (3-21-12)

ii. ADS system -- single registration required for one (1) or more systems: no charge. (3-21-12)

l. Reinstatement: one-half (1/2) the amount of the annual fee. (3-21-12)

04. Controlled Substance Registration. (3-21-12)

a. Controlled substance - registration or annual renewal: sixty dollars ($60). (3-21-12)

b. Wholesaler or distributor-controlled substance - registration or annual renewal: one hundred dollars ($100). (3-21-12)

c. Controlled substance registration reinstatement: seventy-five dollars ($75). (3-21-12)

05. Administrative Services and Publications. (3-21-12)

a. Experiential hours certification: twenty-five dollars ($25). (3-21-12)

b. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). (3-21-12)

c. Duplicate registration or license card: ten dollars ($10). (3-21-12)

d. Commercial lists. (3-21-12)

i. Except for Subparagraph 021.05.d.ii. below, any registrant or licensee lists: fifty dollars ($50). (3-24-16)

ii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). (3-21-12)

e. Official Idaho Register: fifteen dollars ($15). (3-21-12)

f. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). (3-21-12)

g. Hearing transcript: five dollars ($5) per page. (3-21-12)

022. -- 028. (RESERVED)

029. PHARMACIST LICENSE OR REGISTRATION.

01. Practice in Idaho. All pharmacists practicing pharmacy in the state of Idaho must be licensed according to the Board's laws. (7-1-13)

02. Practice Into Idaho. Unless statutorily exempted, all pharmacists practicing pharmacy into the state of Idaho must be licensed or registered as follows: (7-1-13)

a. The following pharmacists must be licensed to provide centralized pharmacy services into Idaho: (7-1-13)

i. Pharmacists engaged in the independent practice of pharmacy across state lines as defined by the Pharmacist Independent Practice Rule. (7-1-13)

ii. Pharmacists practicing from a central drug outlet that is not a pharmacy. (7-1-13)

iii. Pharmacists practicing from a remote office location. (3-20-14)

b. The following pharmacists not licensed in Idaho must be registered to practice pharmacy into Idaho. (7-1-13)

i. The PIC or director of a nonresident central drug outlet or mail service pharmacy. (7-1-13)

ii. Pharmacists practicing from a pharmacy or its COE. (7-1-13)

Subchapter B -- Professional and Drug Outlet Licensure and Registration Provisions
(Rules 30 Through 99 -- Professional And Drug Outlet Licensure and Registration Provisions)

030. PHARMACIST LICENSURE BY EXAMINATION: ACCREDITED SCHOOL OR COLLEGE OF PHARMACY GRADUATES.
To be considered for licensure, a graduate of an accredited school or college of pharmacy within the United States must satisfy the requirements of Section 54-1722(1)(a) through (e), Idaho Code, and submit to the Board an application for licensure by examination. (3-21-12)

031. PHARMACIST LICENSURE BY EXAMINATION: FOREIGN PHARMACY GRADUATES.

01. Licensure Submission Requirements. To be considered for licensure, a graduate of a school or college of pharmacy located outside of the United States must submit an application for licensure by examination, certification of completion of a minimum of seventeen hundred forty (1740) experiential hours, and; (3-24-16)

a. Certification by the FPGEC; or (4-11-15)

b. Certification of graduation from a doctorate of pharmacy program from an accredited school or college of pharmacy within the United States. (4-11-15)

02. Affidavit. An Idaho State Board of Pharmacy Employer's Affidavit certifying the experiential hours of a foreign pharmacy graduate must be signed by a pharmacist licensed and practicing in the United States and submitted to the Board. The Board may also request verifiable business records to document the hours. (3-21-12)

032. PHARMACIST LICENSURE EXAMINATIONS.
Qualified applicants may sit for and to obtain licensure must pass the NAPLEX and the MPJE in accordance with NABP standards. (3-21-12)

033. PHARMACIST LICENSURE BY RECIPROCITY.
An applicant for pharmacist licensure by reciprocity must satisfy the requirements of Section 54-1723, Idaho Code, and this rule to obtain an Idaho license. The Board will issue a reciprocal license only to a pharmacist licensed in good standing in another state at the time of application and issuance of the Idaho license. (3-21-12)

01. Transfer Application. The applicant must submit a preliminary application for licensure transfer through NABP. (3-21-12)

02. MPJE. The applicant must pass the Idaho-based MPJE. (3-21-12)

03. Intern Hours. An applicant not actively engaged in the practice of pharmacy during the year preceding the date of application may also be required to complete up to forty (40) intern hours for each year away from the practice of pharmacy. (3-21-12)

034. PHARMACIST INACTIVE STATUS LICENSE.

01. Required Criteria. Upon Board approval, an inactive status pharmacist license may be issued if an applicant: (3-21-12)

a. Is a pharmacist in the state of Idaho licensed in good standing; (3-21-12)

b. Is unable or unwilling to practice pharmacy due to physical limitations or changes in circumstance; and (3-21-12)

c. Has submitted the required application. (3-21-12)

02. Exemptions and Restrictions. Inactive status licensees are exempt from CPE requirements and are prohibited from engaging in the practice of pharmacy while on inactive status. (3-21-12)

03. Return to Active Status. If an inactive status licensee wishes to return to active status, the licensee must comply with the reinstatement requirements of these rules. (4-4-13)

035. PHARMACIST REGISTRATION TO PRACTICE PHARMACY INTO IDAHO.
To be registered to practice pharmacy into Idaho an applicant must submit an application in the manner and form prescribed by the Board including, but not limited to: (7-1-13)

01. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; (7-1-13)

02. Facility License Information. The license or registration number of the facility for which the

applicant will be practicing. (3-20-14)

036. STUDENT PHARMACIST REGISTRATION.

01. Registration Requirements. (4-4-13)

a. To be approved for and maintain registration as a pharmacist extern, the applicant must currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy. (4-4-13)

b. To be approved for and maintain registration as a pharmacist intern, the applicant must be: (4-4-13)

i. A graduate of an accredited school or college of pharmacy within the United States or; (4-4-13)

ii. A graduate of a school or college of pharmacy located outside the United States and obtain certification by the FPGEC. (4-4-13)

02. Renewal. (4-4-13)

a. A pharmacist extern registration must be renewed annually by July 15; however, the renewal fee will be waived for the duration of the student's enrollment in the school or college of pharmacy and until July 15 following graduation. (4-4-13)

b. A pharmacist intern registration must be renewed annually by June 30. (4-4-13)

03. Cancellation of Registration. Failure to maintain the requirements for student pharmacist registration will result in the cancellation of registration. (4-4-13)

037. -- 039. (RESERVED)

040. CERTIFIED PHARMACY TECHNICIAN REGISTRATION.
To be approved for registration as a certified pharmacy technician, a person must satisfy the following requirements: (3-21-12)

01. Age. Be at least eighteen (18) years of age unless a waiver is granted by the Board's executive director; (3-21-12)

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma unless a waiver is granted by the Board's executive director; (3-21-12)

03. Personal Characteristics. Be of good moral character and temperate habits; and (3-21-12)

04. Certification. Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the National Healthcare Association, or their successors unless qualified for a continuous employment exemption. (3-24-16)

05. Cancellation of Registration. Failure to maintain the certification requirements for certified pharmacy technician registration may result in cancellation of the registration. (3-24-16)

041. TECHNICIAN-IN-TRAINING REGISTRATION.
A person who has not obtained or maintained technician certification may apply for registration as a technician-in-training if the person satisfies all other requirements for registration as a technician and obtains and maintains employment as a technician-in-training. (4-4-13)

01. Duties. Upon registration, a technician-in-training may perform any of the duties allowed by statute or rule to be delegated to a registered technician under the supervision of a pharmacist. (3-21-12)

02. **Renewal**. The registration of a technician-in-training must be renewed by June 30 annually, however a technician-in-training may only renew a technician-in-training registration twice. (4-11-15)

03. **Registration Expiration**. Upon the final expiration of a technician-in-training registration, a person must satisfy the technician certification and registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (3-21-12)

04. **Cancellation of Registration**. Failure to maintain employment will result in the cancellation of the registration. (4-4-13)

042. PHARMACY TECHNICIAN CERTIFICATION: CONTINUOUS EMPLOYMENT EXEMPTION.
A technician registered with the Board and employed as a technician on June 30, 2009, is not required to obtain or maintain certification as a condition of registration renewal after June 30, 2009, as long as the registrant remains continuously employed as a technician by the same employer. If a registrant that qualifies for this exemption disrupts continuous employment as a technician with one employer, the technician registration will become invalid. The person must thereafter satisfy the certified pharmacy technician registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. (4-4-13)

043. -- 044. (RESERVED)

045. VETERINARY DRUG TECHNICIAN REGISTRATION.
A person must have a valid, active Board registration to be employed as, or perform the duties of, a VDT. To qualify for registration as a VDT, a person must: (3-21-12)

01. **Age**. Be at least eighteen (18) years of age; (3-21-12)

02. **Education**. Be a high school graduate or the recipient of a high school equivalency diploma; and (3-21-12)

03. **Examination**. Score at least seventy-five percent (75%) on a Board examination designed to measure knowledge of these rules. (3-21-12)

046. -- 049. (RESERVED)

050. CPE: PROGRAM CRITERIA.

01. **Board Approval of CPE Programs**. The Board recognizes CPE program accreditation by ACPE and CME. CPE programs not accredited by either ACPE or CME must be approved by the Board. A sponsoring organization, presenter or continuing education coordinator may apply to the Board for accreditation of a CPE program. An application must be submitted twenty-one (21) days in advance of the program and must include: (3-20-14)

a. The name of the sponsoring organization, if applicable; (3-20-14)

b. The title of the program offered; (3-20-14)

c. The learning objectives and a description of the subject matter; (3-20-14)

d. The method and materials for assessing the learning objectives; (3-20-14)

e. The method of evaluating satisfactory completion of the program; (3-20-14)

f. The dates, time schedule, number of clock hours and location of the program; and (3-20-14)

g. The names and curriculum vitae or resume of instructors or other persons responsible for the delivery and content of the program; and (3-20-14)

h. A copy of the materials to be offered to the participants and the program to be presented (electronic or hard copy), if applicable. (3-20-14)

02. Postgraduate Education. A CPE program must consist of postgraduate education in one or more of the following general areas: (3-21-12)

a. The socioeconomic and legal aspects of health care; (3-21-12)

b. The properties and actions of drugs and dosage forms; or (3-21-12)

c. The etiology, characteristics, and therapeutics of a disease state. (3-21-12)

03. Evidence of Satisfactory Completion. A CPE program must provide evidence of satisfactory completion by participants. (3-21-12)

04. Qualified Instruction. The program presenter must be qualified in the subject matter by education or experience. (3-21-12)

051. CPE: INSTRUCTION CREDITS.

01. Pharmacists. A 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 CPE or in-service programs will be granted CPE credit for time expended during actual presentation upon the provision of adequate documentation to the Board. (3-21-12)

02. Educators. A pharmacist whose primary responsibility is the education of health professionals will be granted CPE 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. (3-21-12)

052. CPE: REQUIREMENTS.
Each pharmacist applicant for license renewal must annually complete fifteen (15) CPE hours. (4-4-13)

01. ACPE or CME. At a minimum, twelve (12) of the CPE hours obtained must be all or a combination of ACPE or CME accredited programs. ACPE accredited activities must have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. (3-20-14)

02. Pharmacy Law. One (1) of the CPE hours obtained must address federal, state or local law effecting the practice of pharmacy. (3-20-14)

03. Board Approved. A maximum of three (3) of the CPE hours obtained may be Board-approved programs not accredited through ACPE or CME. (3-20-14)

04. Live Attendance. Three (3) of the CPE hours obtained must be by attendance at live or synchronous online CPE programs. (4-4-13)

05. Immunizer Qualification. To maintain qualification to administer immunizations, a minimum of one (1) of the ACPE-approved CPE hours must be related to vaccines, immunizations, or their administration. (4-4-13)

06. Sterile Compounding Requirement. To engage in the practice of sterile compounding a minimum of one (1) of the CPE hours must be ACPE accredited and related to the practice of sterile compounding. (3-20-14)

07. Carryover of Certain Unused Units. CPE hours accrued during June of a licensing period may be carried over into the next licensing period to the extent that a pharmacist's total CPE hours for the current licensing period exceed the total CPEs hours required by these rules. (4-4-13)

08. New Pharmacist Exemption. Recent pharmacist graduates applying for the first license renewal are not required to complete or certify the annual CPE requirements. (3-21-12)

09. Requirements for Dual Licenses. (3-20-14)

a. An Idaho-licensed pharmacist residing in another state must meet Idaho CPE requirements to be granted an Idaho license renewal. (3-20-14)

b. CPE programs attended by an Idaho-licensed pharmacist for purposes of satisfying licensing requirements of another state must be accredited by either ACPE or CME or must be approved by the Board to also be recognized for purposes of renewal of the pharmacist's Idaho license. (3-20-14)

053. -- 059. (RESERVED)

060. DRUG OUTLET LICENSURE AND REGISTRATION.
A license or a certificate of registration, as applicable, is required for drug outlets doing business in or into Idaho. A license or certificate of registration will be issued by the Board to drug outlets pursuant to, and in the general classifications defined by, Section 54-1729, Idaho Code. (3-21-12)

01. New Drug Outlet Inspections. Prior to approving the issuance of a new license or registration, each drug outlet may be inspected to confirm that the facility is appropriately equipped and has implemented proper procedures and minimum standards necessary for compliance with applicable law. Prescription drugs may not be delivered to a new drug outlet location and the drug outlet may not open for business prior to satisfactory completion of the opening inspection, if required. (3-21-12)

02. Licenses and Registrations Transferability. (3-25-16)

a. Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place, except in the event of a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. (3-25-16)

b. Temporary Pharmacy Facilities and Mobile Pharmacies. To provide pharmacy services during a national, state, or local emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, pharmacies may arrange to temporarily locate or relocate to a temporary pharmacy facility or mobile pharmacy if the temporary pharmacy facility or mobile pharmacy: (3-25-16)

i. Is under the control and management of the pharmacist-in-charge, director, or designated supervising pharmacist; (3-25-16)

ii. Is located within the declared disaster area or is intended for affected populations; (3-25-16)

iii. Notifies the Board of its proposed location; (3-25-16)

iv. Is properly secured to prevent theft and diversion of drugs; (3-25-16)

v. Maintains records in accordance with laws and rules of the state; and (3-25-16)

vi. Ceases the provision of services with the termination of the declared emergency, or as otherwise authorized by the Board. (3-25-16)

03. Nonresident Drug Outlet. The Board may license or register a drug outlet licensed or registered under the laws of another state if the other state's standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report. (7-1-13)

061. -- 069. (RESERVED)

070. LIMITED SERVICE OUTLET REGISTRATION.
Pursuant to Section 54-1729(3), certificates of registration may be limited, conditioned, or restricted based upon the outlet type and the specialized or limited products or services provided. Examples of limited service outlet registrations include, but are not limited to: sterile product, nuclear, remote dispensing, cognitive service, and COE pharmacies and DME outlets. (3-21-12)

01. Required Waivers. An applicant for a limited service outlet registration must submit a registration application and a request for waiver of applicable Board rules that are unfeasible or impractical for the specialized or limited products or services offered, if any. (3-21-12)

02. Compliance Standards. A limited service outlet registration will be subject to continuous compliance with any required policies and procedures, applicable law, any of these rules applicable to the practice setting unless specifically waived in writing by the Board, and any limitations, conditions, or restrictions established by the Board. (3-21-12)

03. Inspection and Review. If required, policies and procedures must be available for review and approval during the initial inspection and thereafter retained on the outlet premises. (3-21-12)

071. REMOTE DISPENSING SITE REGISTRATION.

01. Remote Dispensing Site Registration. A limited service outlet registration must be obtained by a remote dispensing site prior to participating in the practice of telepharmacy. (3-21-12)

02. Supplemental Registration Application Requirements. Prior to construction, an applicant for registration of a remote dispensing site must submit and obtain Board approval of a registration application. The application must include: (3-21-12)

a. An attached description of the telepharmacy communication, electronic recordkeeping, and ADS systems; (3-21-12)

b. The operating specifications; and (3-21-12)

c. An accurate scale drawing of the facility that illustrates: (3-21-12)

i. The layout and location of the systems; (3-21-12)

ii. The location of a patient counseling area; and (3-21-12)

iii. All access points to the electronic recordkeeping system and the ADS system. (3-21-12)

072. STERILE PRODUCT DRUG OUTLET REGISTRATION.
A separate registration that requires an onsite Board inspection must be obtained prior to engaging in sterile product preparation. (3-21-12)

01. Floor Plan Approval. Floor plans for construction of a new sterile product preparation area must be submitted along with the registration application and must be approved by the Board prior to commencement of construction. (3-21-12)

02. Hood or Aseptic Environment Control Device Registration. A drug outlet engaged in sterile product preparation must obtain a single registration for one or more hood or aseptic environmental control devices. (3-21-12)

073. NONRESIDENT CENTRAL DRUG OUTLET AND MAIL SERVICE PHARMACY REGISTRATION.

A nonresident central drug outlet or mail service pharmacy must be registered with the Board in order for its employee or contract pharmacist to practice pharmacy into Idaho. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: (7-1-13)

01. **Executive Summary**. An executive summary describing the centralized pharmacy services to be performed; (7-1-13)

02. **PIC or Director**. Identity of a pharmacist licensed to practice pharmacy in the state of domicile, who shall be the PIC or director of the nonresident central drug outlet or mail service pharmacy. (7-1-13)

074. OUTSOURCING FACILITY REGISTRATION.

An outsourcing facility must be registered with the Board in order to distribute compounded drug product for human use in or into Idaho. (4-6-15)

01. **Application**. An applicant must submit an application in the manner and form prescribed by the Board, including, but not limited to: (4-6-15)

a. A copy of a valid FDA registration as an outsourcing facility as required by 21 U.S.C. Section 353b; (4-6-15)

b. Identity of a pharmacist licensed or registered in Idaho who is designated the PIC of the outsourcing facility; and (4-6-15)

c. An inspection report indicating compliance with applicable state and federal law. (4-6-15)

02. **Coincidental Activity**. An outsourcing facility applicant currently registered by the Board as a pharmacy or mail service pharmacy will be considered for an outsourcing facility registration with a supplemental pharmacy or mail service pharmacy registration at no additional fee. Exemption from registration fees does not excuse compliance with all laws and rules pertaining to pharmacies and mail service pharmacies. (4-6-15)

075. -- 079. (RESERVED)

080. WHOLESALER LICENSURE AND REGISTRATION.

01. **Wholesaler Licensure**. In addition to the information required pursuant to Section 54-1753, Idaho Code, the following information must be provided under oath by each applicant for wholesaler licensure as part of the initial licensing procedure and for each renewal. (3-21-12)

a. The name of the owner and operator of the applicant, including: (3-21-12)

i. If a person, the name of the person; (3-21-12)

ii. If a partnership, the name of each partner, and the name of the partnership; (3-21-12)

iii. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any; or (3-21-12)

iv. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity. (3-21-12)

b. Any felony conviction or any conviction of the applicant relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-21-12)

c. Any discipline of the applicant by a regulatory agency in any state for violating any law relating to wholesale or retail prescription drug distribution or distribution of controlled substances. (3-21-12)

02. **Wholesaler Licensure -- Other Eligibility Factors**. The Board will consider at least the following

factors in determining the applicant's eligibility for licensure as a wholesaler: (3-21-12)

a. The qualifications of the wholesaler's designated representative; (3-21-12)

b. Any convictions of the applicant, including those relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances; (3-21-12)

c. The applicant's past experience in the manufacture or distribution of drugs, including controlled substances; (3-21-12)

d. The provision by the applicant of false or fraudulent material in an application made in connection with drug manufacturing or distribution; (3-21-12)

e. Suspension or revocation by a local, state, or federal government of a registration or license currently or previously held by the applicant for the manufacture or distribution of drugs, including controlled substances; (3-21-12)

f. Compliance with licensing requirements under previously granted licenses, if any; and (3-21-12)

g. Compliance with the requirements to maintain and make available to the state licensing authority or to local, state, or federal law enforcement officials those records required to be maintained by wholesale drug distributors. (3-21-12)

03. Controlled Substance Registration. All wholesalers distributing controlled substances must register with both the Board and the DEA. (3-21-12)

04. VAWD Accreditation. The Board will recognize a wholesaler's VAWD accreditation by NABP for purposes of reciprocity and satisfying the new drug outlet inspection requirements of these rules. (3-21-12)

05. Wholesaler Registration. Except when licensed pursuant to the Idaho Wholesale Drug Distribution Act and these rules, a wholesaler that engages in wholesale distribution of DME supplies, prescription medical devices, or non-prescription drugs in or into Idaho must be registered by the Board. (3-21-12)

081. -- 089. (RESERVED)

090. MANUFACTURER REGISTRATION.
A manufacturer located in Idaho must be inspected and registered by the Board prior to engaging in drug manufacturing. Non-resident manufacturers that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident must be registered by the Board as a mail service pharmacy. (7-1-13)

091. -- 099. (RESERVED)

Subchapter C -- General Practice Standards
(Rules 100 through 299 -- General Practice Standards)

100. ELECTRONIC RECORDKEEPING SYSTEM.
Unless specifically exempted by these rules, an electronic recordkeeping system must be used to establish and store patient medication records and prescription drug order, refill, and transfer information. (3-21-12)

01. Real-time Online Retrieval of Information. The electronic recordkeeping system must be capable of real-time, online retrieval of information stored therein for a minimum of fifteen (15) months from the date of entry. (3-21-12)

02. Immediately Retrievable Refill Data. The electronic recordkeeping system must have functionality that allows required refill data to be immediately retrievable and produced upon request; for example, a refill-by-refill audit trail for a specified strength and dosage form of a drug. (3-21-12)

03. Audit Trail Documentation. The electronic recordkeeping system must also have audit trail functionality that documents for each prescription drug order the identity of each individual involved at each step of its processing, filling, and dispensing or, alternatively, the identity of the pharmacist or pharmacists responsible for the accuracy of these processes. Systems that automatically generate user identification without requiring an entry by the responsible individual are prohibited. (3-21-12)

04. System Security. The electronic recordkeeping system must include security features to protect the confidentiality and integrity of patient records including: (3-21-12)

a. Safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription drug order information and patient medication records; and (3-21-12)

b. Functionality that documents any alteration of prescription drug order information after a prescription drug order is dispensed, including the identification of the individual responsible for the alteration. (3-21-12)

05. System Downtime. Pharmacies may use handwritten records or another auxiliary procedure for documentation of refills of prescription drug orders in the event the system becomes inoperative while the pharmacy is open that ensures: (3-21-12)

a. Refills are authorized by the original prescription drug order; (3-21-12)

b. If a controlled substance, the maximum number of refills is not exceeded; and (3-21-12)

c. The required data is retained for entry into the system within ninety-six (96) hours after the electronic recordkeeping system is restored. (3-21-12)

d. Nothing in Subsection 100.05 precludes a pharmacist from exercising professional judgment in the issuance of an emergency prescription refill, pursuant to these rules, for the benefit of a patient's health or safety. (3-21-12)

06. System Backup and Recovery. The drug outlet must implement routine system backup, maintenance, and recovery procedures to protect its data and provide reasonable continuity of service in the event of human error, power failure, system malfunction, accident, or catastrophe resulting in the loss, destruction, or corruption of data. (3-21-12)

07. Board Approval. The Board reserves the right to approve and revoke approval of the use of an electronic recordkeeping system. (3-21-12)

08. Exemption. Recordkeeping systems in use as of the effective date of this rule may continue to be used as long as the information required by these rules for an electronic recordkeeping system is collected and retained in an immediately retrievable manner for a minimum of fifteen (15) months. (3-21-12)

101. ELECTRONIC RECORDKEEPING SYSTEM: PATIENT MEDICATION RECORDS.
A patient medication record must be created and maintained for each patient who has a prescription drug order filled or refilled, and a reasonable effort must be made to obtain and record in it the following: (3-21-12)

01. Patient Personal Information. The patient's name, address, telephone number, date of birth (or age), and gender; (3-21-12)

02. Prospective Drug Review Information. Information relevant to a prospective drug review; (3-21-12)

03. Prescriber-Provided Information. Relevant information provided by the prescriber; and (3-21-12)

04. Other Information. Any other information that the pharmacist deems appropriate. (3-21-12)

102. ELECTRONIC RECORDKEEPING SYSTEM: PRESCRIPTION DRUG ORDER INFORMATION.

01. Original Prescription Drug Order Information. For each original prescription drug order, the information entered into the electronic recordkeeping system must include at least the following: (3-21-12)

a. The serial number, if any; (3-21-12)

b. The date of issuance; (3-21-12)

c. The date filled; (3-21-12)

d. The identity of each individual involved in or, alternatively, the pharmacist ultimately responsible for its processing, filling, or dispensing; (3-21-12)

e. The drug name, strength, dosage form, quantity prescribed (and quantity dispensed if different from the quantity prescribed); (3-21-12)

f. The directions for use; (3-21-12)

g. The total number of refills authorized by the prescriber, if applicable; (3-21-12)

h. The name of the prescriber; and (3-21-12)

i. For controlled substances, the prescriber's address and DEA registration number. (3-21-12)

02. Prescription Drug Order Refill Information. For each prescription drug order refill, at least the following information must be added to the original prescription drug order information in the electronic recordkeeping system: (3-21-12)

a. The date of dispensing of each refill; (3-21-12)

b. The quantity dispensed; (3-21-12)

c. Unless dispensed in a hospital, the identification of the dispensing pharmacist for each refill; and (3-21-12)

d. The total number of refills dispensed to date. (3-21-12)

03. Refill Verification of Controlled Substances. Written verification of the accuracy of the refill information entered into the electronic recordkeeping system for controlled substances must be provided by pharmacists utilizing the system. Verification must be documented in a bound log book or separate file in which each pharmacist involved in the dispensing of controlled substance refills signs a statement attesting to the fact that the refill information entered into the electronic recordkeeping system each day has been reviewed and is correct as shown. (3-21-12)

103. -- 104. (RESERVED)

105. PATIENT COUNSELING DOCUMENTATION.
Documentation must be created and retained sufficient to evidence compliance with the offer to counsel and counseling requirements of the Idaho Pharmacy Act. (3-21-12)

106. -- 109. (RESERVED)

110. PRESCRIPTION DRUG ORDER: VALIDITY.
Prior to filling or dispensing a prescription drug order, a pharmacist must verify its authenticity and validity.

(3-21-12)

01. **Invalid Prescription Drug Orders**. A prescription drug order is invalid if not issued: (3-21-12)

a. In good faith; (3-21-12)

b. For a legitimate medical purpose; (3-21-12)

c. By a licensed prescriber; (3-21-12)

d. Within the course and scope of the prescriber's professional practice and prescriptive authority; (3-21-12)

e. Pursuant to a valid prescriber-patient relationship, unless statutorily exempted; and (4-4-13)

f. In the form and including the elements required by law. (3-21-12)

02. **Antedating or Postdating**. A prescription drug order is invalid if antedated or postdated. (3-21-12)

03. **Tampering**. A prescription drug order is invalid if it shows evidence of alteration, erasure, or addition by any person other than the person who wrote it. (3-21-12)

04. **Prescriber Self-Use**. A prescription drug order written for a controlled substance is invalid if written for the prescriber's own use. (3-21-12)

05. **Family Members**. A prescription drug order written for a prescriber's family member is invalid if inconsistent with the scope of practice and prescriptive authority of the prescriber's profession. (3-21-12)

111. PRESCRIPTION DRUG ORDER: MINIMUM REQUIREMENTS.
A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for a drug order, must include at least the following: (3-21-12)

01. **Patient's Name**. The patient's name and: (3-21-12)

a. If for a controlled substance, the patient's full name and address; and (3-21-12)

b. If for an animal, the species. (3-21-12)

02. **Date**. The date issued. (3-21-12)

03. **Drug Information**. The drug name, strength, quantity, and if for a controlled substance, the dosage form. (3-21-12)

04. **Directions**. The directions for use. (3-21-12)

05. **Prescriber Information**. The name and, if for a controlled substance, the address and DEA registration number of the prescriber. (3-21-12)

06. **Signature**. If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, or if statutorily allowed, the prescriber's agent's signature, and if electronic, the prescriber's electronic signature. (3-20-14)

112. DRUG ORDER: MINIMUM REQUIREMENTS.
A drug order must comply with applicable requirements of federal law and must include at least the following: (3-21-12)

01. **Patient's Name**. The patient's name. (3-21-12)

02. **Date**. The date issued. (3-21-12)

03. **Drug Information**. The drug name, strength, and route of administration. (3-21-12)

04. **Directions**. The directions for use. (3-21-12)

05. **Prescriber Information**. The name of the prescriber. (3-21-12)

06. **Signature**. If written, the signature of the prescriber or if statutorily allowed, the prescriber's agent. (3-20-14)

113. PRESCRIPTION DRUG ORDER: CONTROLLED SUBSTANCES.

01. **Schedule II Faxed Prescription Drug Order Documentation**. A Schedule II prescription must not be dispensed pursuant to a faxed prescription drug order, with the faxed copy serving as the original, except as follows: (3-21-12)

a. To be compounded for direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion; (3-21-12)

b. For a resident of an LTCF; and (3-21-12)

c. For a patient enrolled in a hospice care program, if so indicated on the prescription drug order. (3-21-12)

02. **Schedule II Multiple Prescription Drug Orders**. A prescriber may issue and a pharmacy may fill multiple prescription drug orders, written on and dated with the same date, that allow the patient to receive up to a ninety-day supply of a Schedule II controlled substance if the prescriber provides written instructions on each prescription drug order indicating the earliest date on which a pharmacy may fill each prescription, except instructions may be omitted from the first prescription drug order if it is to be filled immediately. (3-21-12)

114. PRESCRIPTION DRUG ORDER: PARTIAL FILLING.

01. **Partial Filling of Schedule II Prescriptions**. A Schedule II controlled substance prescription drug order may be partially filled and dispensed if the pharmacist is unable to supply the full quantity ordered. (3-21-12)

a. The remaining portion of the prescription drug order may be filled if within seventy-two (72) hours of the first partial filling. If the remaining portion is not or cannot be filled within seventy-two (72) hours, the pharmacist must notify the prescriber. (3-21-12)

b. Additional quantities must not be dispensed beyond seventy-two (72) hours without a new prescription drug order. (3-21-12)

02. **Partial Filling of Schedule II Prescriptions for LTCF or Terminally Ill Patients**. A Schedule II controlled substance prescription drug order for a patient in an LTCF or for a patient with a documented terminal illness may be filled in partial quantities and individual dosage units. The pharmacist must record that the patient is either "terminally ill" or an "LTCF patient." (3-21-12)

03. **Schedule II Partial-Fill Documentation**. For each partially filled prescription drug order, the following information must be recorded: (3-21-12)

a. The date; (3-21-12)

b. The quantity dispensed; (3-21-12)

c. The remaining quantity authorized for dispensing; and (3-21-12)

d. The identification of the dispensing pharmacist. (3-21-12)

04. Partial Filling of Schedule III, IV, and V Prescriptions. The partial filling of a prescription drug order for a controlled substance listed in Schedules III, IV, or V is permissible if: (3-21-12)

a. Each partial fill is recorded in the same manner as a refill; (3-21-12)

b. The total quantity dispensed in partial fillings does not exceed the total quantity prescribed; and (3-21-12)

c. Dispensing does not occur after six (6) months from the date on which the prescription drug order was issued. (3-21-12)

115. PRESCRIPTION DRUG ORDER: TRANSFERS.

01. Communicating Prescription Drug Order Transfers. Except prescription drug orders for Schedule II controlled substances, a pharmacist may transfer prescription drug order information for the purpose of filling or refilling if the information is communicated from pharmacist to pharmacist verbally, electronically, or via fax. (3-21-12)

a. Prescription drug order information may also be communicated verbally by a student pharmacist, under the supervision of a pharmacist, to another pharmacist as long as one (1) of the parties involved in the communication is a pharmacist. (3-21-12)

b. If transferring by fax transmission, the transfer document used must be signed by the transferring pharmacist. (3-21-12)

02. Documentation Required of the Transferring Pharmacy. The pharmacist transferring prescription drug order information must void or otherwise indicate that the original prescription drug order has been transferred and record the following information: (3-21-12)

a. The name of the transferring pharmacist; (3-21-12)

b. The name of the receiving pharmacist; (3-21-12)

c. The name of the receiving pharmacy; (3-21-12)

d. The date of the transfer; (3-21-12)

e. The number of authorized refills available; and (3-21-12)

f. If written for a controlled substance, the address and DEA registration number of the receiving pharmacy. (3-21-12)

03. Documentation Required of the Receiving Pharmacy. The pharmacist receiving a transferred prescription drug order must document that the prescription drug order is a “transfer” and record the following information: (3-21-12)

a. The name of the receiving pharmacist; (3-21-12)

b. The name of the transferring pharmacist; (3-21-12)

c. The name of the transferring pharmacy; (3-21-12)

d. The date of issuance of the original prescription drug order; (3-21-12)

e. The number of refills authorized by the original prescription drug order; (3-21-12)

f. The number of authorized refills available; and (3-21-12)

g. If written for a controlled substance: (3-21-12)

i. The dates and locations of the original dispensing and previous refills; and (3-21-12)

ii. The name, address, DEA registration number, and the serial number assigned to the prescription by the transferring pharmacy and any additional pharmacy that filled the prescription, if applicable. (4-4-13)

04. Electronic Prescription Drug Order Transfers. For electronic prescription drug orders that are transferred electronically, the transferring pharmacist must provide all of the information required to be recorded by the receiving pharmacist in addition to the original electronic prescription data. The receiving pharmacist must create an electronic record for the prescription drug order that includes the receiving pharmacist's name and all of the information transferred with the prescription. (3-21-12)

05. Pharmacies Using Common Electronic Files. Pharmacies may establish and use a common electronic file to maintain required dispensing information. (3-21-12)

a. Pharmacies using a common electronic file are not required to transfer prescription drug order information for dispensing purposes between or among other pharmacies sharing the common electronic file. (3-21-12)

b. Common electronic files must contain complete and accurate records of each prescription and refill dispensed. (3-21-12)

06. Transferring Prescription Drug Orders for Controlled Substances. A prescription drug order for a controlled substance listed in Schedules III, IV, or V may be transferred only from the pharmacy where it was originally filled and never from the pharmacy that received the transfer, except that pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. (3-21-12)

07. Transferring Prescription Drug Order Refills. Prescription drug orders for non-controlled substances may be transferred more than one (1) time if there are refills remaining and other legal requirements are satisfied. (3-21-12)

116. PRESCRIPTION DRUG ORDER: REFILLS.

01. Refill Authorization. A prescription drug order may be refilled when permitted by state and federal laws and only as specifically authorized by the prescriber. (3-21-12)

a. A pharmacist, utilizing his best professional judgment, may dispense a prescription drug that is not a controlled substance up to the total amount authorized by the prescriber including refills. (3-21-12)

b. Refills exceeding those authorized by the prescriber on the original prescription drug order may only be authorized through issuance of a new and separate prescription drug order. (3-21-12)

02. Emergency Prescription Refills. A pharmacist may refill a prescription for a patient when: (3-25-16)

a. The prescriber is not available for authorization if, in the professional judgment of the pharmacist, a situation exists that threatens the health or safety of the patient should the prescription not be refilled. Only sufficient medication may be provided, consistent with the dosage instructions, to maintain the prescribed treatment until, at the earliest possible opportunity, the issuing or an alternative prescriber is contacted for further renewal instructions. (3-25-16)

b. Upon the declaration of a national, state, or local emergency by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, a pharmacist may dispense a refill of a prescription drug to an affected patient, not to exceed a thirty (30)-day supply if, in the pharmacist's professional judgment, the prescription drug is essential to the patient's health or continuation of therapy. (3-25-16)

117. PRESCRIPTION DRUG ORDER: EXPIRATION.
A prescription drug order expires no later than fifteen (15) months after its date of issue. (3-21-12)

01. Schedule II Prescription Drug Orders. A prescription drug order for a Schedule II controlled substance must not be filled or dispensed more than ninety (90) days after its date of issue. (3-21-12)

02. Schedule III, IV, and V Prescription Drug Orders. A prescription drug order for a controlled substance listed in Schedules III, IV, or V must not be filled or refilled more than six (6) months after its date of issue. (3-21-12)

118. PRESCRIPTION DRUG ORDER: PRESCRIBER CHANGE OF STATUS.

01. Change of Status. A prescription drug order is invalid after a period reasonably necessary to allow the patient to maintain continuity of care, which must not exceed ninety (90) days, from the date the pharmacist learns of a change of status that precludes a continued prescriber-patient relationship such as death, incapacity, suspension or revocation of the prescriber's license, or permanent relocation. (3-21-12)

02. Patient Notification. A pharmacist who becomes aware of a prescriber's change of status that precludes a continued patient-prescriber relationship must advise the patient of the resultant change to the status of the prescription drug order, advise the patient that a new prescriber will be required, and unless otherwise prohibited by law, provide a sufficient amount of prescribed drug to allow for continuity of care for a period that considers the healthcare needs of the patient but does not exceed ninety (90) days. (3-21-12)

119. PRESCRIPTION DRUG ORDER: RETENTION, INSPECTION, AND COPYING.

01. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner, in the paper or electronic form issued, and must be made available for inspection by the issuing prescriber upon request. (3-21-12)

02. Prescription Drug Order Copies. A copy of a prescription drug order may only be provided as allowed or required by law, and the copy must be marked across its face: "Copy for Information Only. Not to be Filled." (3-21-12)

120. VETERINARY DRUG ORDERS.

01. Veterinary Drug Order Forms. Veterinary drug orders for prescription drugs must be written or documented by a veterinarian licensed to practice veterinary medicine in this or any state sharing an Idaho border on an official, numbered, three (3) part drug order form available through the Idaho Department of Agriculture. For purposes of this rule, the top copy of the official order form is considered the original order, the middle copy (the first duplicate) is "copy one (1)" and the bottom copy (the second duplicate) is "copy two (2)." (3-21-12)

02. Veterinary Drug Order Handling. Copy two (2) of a veterinary drug order must be retained by the prescribing veterinarian. The original and copy one (1) of a veterinary drug order must be presented to a VDO for product preparation and for completion and handling by a VDT as follows: (3-21-12)

a. The VDT must complete the bottom portion of the veterinary drug order with the date filled, the serial number assigned, and the VDT's signature. The serial number must also appear on the copy one (1) that accompanies the order. (3-21-12)

b. Upon completion, the VDT must file the original and attach the copy one (1) to the prepared order. (3-21-12)

03. Veterinary Drug Order -- Required Information. A veterinary drug order must include at least the following information: (3-21-12)

a. The client's name and address; (3-21-12)

b. The animal species; (3-21-12)

c. The date issued; (3-21-12)

d. The name, strength, and quantity of product; (3-21-12)

e. The product instructions or directions for use and any applicable cautionary statements; and (3-21-12)

f. The name, license number, and signature of the prescribing veterinarian. (3-21-12)

04. Verbal Veterinary Drug Orders. Verbal veterinary drug orders must be issued directly by a prescribing veterinarian, received directly by a VDT, and are subject to the following additional requirements: (3-21-12)

a. The verbal order must be promptly reduced to writing on an official, unnumbered, three (3) part telephone drug order form available through the Idaho Department of Agriculture. (3-21-12)

b. If the issuing veterinarian is unknown by the VDT, the VDT must make a reasonable effort to determine the validity of the order. (3-21-12)

c. The verbal order must be otherwise handled and processed as required for written orders. (3-21-12)

d. Written confirmation of the verbal order must be documented on the original of an official, numbered order form, signed by the prescribing veterinarian, and provided to the VDO within seven (7) days. Upon receipt, the VDT must attach the original, verbal order to the original, official, numbered order. (3-21-12)

05. Veterinary Drug Order Processing. Veterinary drug orders must be processed exactly as written and never for more than the original quantity indicated by the prescribing veterinarian. (3-21-12)

a. Refilling or reprocessing of veterinary drug orders is prohibited. (3-21-12)

b. For a split shipment, the VDT must indicate on the back of the original order the date, quantity, and initials of the person supplying the partial order. The remaining quantity must be delivered within ninety (90) days. (3-21-12)

c. Substitution is prohibited. Supplying a different brand or product, including a generic, is prohibited. (3-21-12)

d. Only original manufacturers' containers bearing the entire label intact may be delivered (no partial containers). (3-21-12)

e. Compounding by a VDT is prohibited. (3-21-12)

121. -- 129. (RESERVED)

130. DRUG PRODUCT: SUBSTITUTION.
Drug product substitutions are allowed only as follows: (4-4-13)

01. Hospital. Pursuant to a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital; (4-4-13)

02. Skilled Nursing Facility. At the direction of the quality assessment and assurance committee of a skilled nursing facility consisting of the director of nursing services, a physician designated by the facility, a consultant pharmacist, and at least two (2) other members of the facility's staff; or (4-4-13)

03. Drug Shortage. Upon a drug shortage, a pharmacist, using his best professional judgment, without contacting the prescriber, may substitute an alternative dose of a prescribed drug, so long as the prescriber's directions are also modified, to equate to an equivalent amount of drug dispensed as is prescribed. (4-4-13)

04. Biosimilars. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: (4-11-15)

a. The biosimilar has been determined by the FDA to be interchangeable and published in the Purple Book; (4-11-15)

b. The prescriber does not indicate by any means that the prescribed biological product must be dispensed; and (4-11-15)

c. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. (4-11-15)

131. DRUG PRODUCT: SELECTION.
Drug product selection is allowed only between therapeutic equivalent drugs. (3-21-12)

01. Brand Name Drug Dispensing. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug selection is permitted. (4-4-13)

02. Documentation. If a generic is selected by a non-institutional pharmacy, the name of the drug and the manufacturer or the NDC number must be documented in the patient medication record. (4-4-13)

132. -- 134. (RESERVED)

135. DRUG PRODUCT: FLAVORING.
A flavoring agent may be added to a drug product at the discretion of a pharmacist or upon request by the prescriber, the patient, or the patient's agent. (3-21-12)

136. -- 139. (RESERVED)

140. STANDARD PRESCRIPTION DRUG LABELING.
Unless otherwise directed by these rules, a prescription drug must be dispensed in an appropriate container that bears the following information: (3-21-12)

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business). (3-21-12)

02. Serial Number. The serial number. (4-4-13)

03. Date. The date the prescription is filled. (3-21-12)

04. Prescriber. The name of the prescriber. (3-21-12)

05. Name. (4-11-15)

a. If a person, the name of the patient; (4-11-15)

b. If an animal, the name and species of the patient; or (4-11-15)

c. If a school for epinephrine auto-injectors pursuant to Section 33-520A, Idaho Code, the name of the school. (4-11-15)

06. Drug Name and Strength. Unless otherwise directed by the prescriber, the name and strength of the drug (the generic name and its manufacturer's name or the brand name). (3-21-12)

07. Quantity. The quantity of item dispensed. (3-21-12)

08. Directions. The directions for use. (3-21-12)

09. Cautionary Information. Cautionary information as required or deemed appropriate for proper use and patient safety. (3-21-12)

10. Expiration. An expiration date that is the lesser of: (3-21-12)

a. One (1) year from the date of dispensing; (3-21-12)

b. The manufacturer's original expiration date; (3-21-12)

c. The appropriate expiration date for a reconstituted suspension or beyond use date for a compounded product; or (3-21-12)

d. A shorter period if warranted. (3-21-12)

11. Refills. The number of refills remaining, if any, or the last date through which the prescription is refillable. (4-11-15)

12. Warning. The warning: "Caution: State or federal law, or both, prohibits the transfer of this drug to any person other than the patient for whom it was prescribed," except when dispensing to an animal, when a warning sufficient to convey "for veterinary use only" may be utilized. (4-11-15)

13. Identification. The initials or other unique identifier of the dispensing pharmacist or dispensing prescriber. (4-11-15)

141. INSTITUTIONAL FACILITY: DRUG LABELING.

01. Labeling for Patient Use While in the Facility. Except if dispensed in unit dose packaging, a drug dispensed for patient use while in a hospital must be dispensed in an appropriate container that bears at least the following information: (3-21-12)

a. The date filled; (3-21-12)

b. The name of the patient; (3-21-12)

c. The name and strength of the drug; (3-21-12)

d. The quantity of item dispensed; (3-21-12)

e. The directions for use, including the route of administration; (3-21-12)

f. Cautionary information as required or deemed appropriate for proper use and patient safety; (3-21-12)

g. The expiration or beyond use date, if appropriate; and (3-21-12)

h. The initials or other unique identifier of the dispensing pharmacist. (3-21-12)

02. Labeling for Patient Use Outside of the Facility. A drug dispensed for patient use outside of the facility must be labeled pursuant to the standard prescription drug labeling requirements. (3-21-12)

142. PARENTERAL ADMIXTURE LABELING.
If one or more drugs are added to a parenteral admixture the admixture's container must include a distinctive, supplementary label with at least the following information: (3-21-12)

01. Ingredient Information. The name, amount, strength, and if applicable, the concentration of the drug additive and the base solution or diluent; (3-21-12)

02. Date and Time. The date and time of the addition, or alternatively, the beyond use date and time; (3-21-12)

03. Identification. The initials or other unique identifier of the pharmacist or preparing prescriber responsible for its accuracy; (4-4-13)

04. Prescribed Administration Regimen. The rate or appropriate route of administration or both, as applicable; and (3-21-12)

05. Special Instructions. Any special handling, storage, or device-specific instructions. (3-21-12)

143. PREPACKAGED PRODUCT LABELING.
The containers of prepackaged drugs prepared for ADS systems or other authorized uses must include a label with at least the following information: (3-21-12)

01. Drug Name and Strength. The name and strength of the drug; (3-21-12)

02. Expiration Date. An expiration date that is the lesser of: (3-21-12)

a. The manufacturer's original expiration date; (3-21-12)

b. One (1) year from the date the drug is prepackaged; or (3-21-12)

c. A shorter period if warranted (A prepackaged drug returned unopened from an institutional facility and again prepackaged must be labeled with the expiration date used for the initial prepackaging.); (3-21-12)

03. Conditional Information. If not maintained in the records of the pharmacy, the manufacturer's name and lot number and the identity of the pharmacist responsible for the prepackaging. (3-21-12)

144. LABELING OF DISTRIBUTED COMPOUNDED DRUG PRODUCT.
Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription drug order, solely as permitted for outsourcing facilities and pharmacies herein, must be labeled with the following information: (4-11-15)

01. Drug Name. The name of each drug included. (4-11-15)

02. Strength or Concentration. The strength or concentration of each drug included. (4-11-15)

03. Base or Diluents. If a sterile compounded drug product, the name and concentration of the base or diluents. (4-11-15)

04. Administration. If applicable, the dosage form or route of administration. (4-11-15)

05. Quantity. The total quantity of the drug product. (4-11-15)

06. Date. The expiration or beyond use date. (4-11-15)

07. Compounder Identifier. The initials or unique identifier of the compounder responsible for the accuracy of the drug product. (4-11-15)

08. Resale. If: (4-11-15)

a. A pharmacy that is distributing, the statement: "not for further dispensing or distribution;" and (4-11-15)

b. An outsourcing facility, the statement: "not for resale." (4-11-15)

09. Instructions, Cautions, and Warnings. Handling, storage or drug specific instructions, cautionary information, and warnings as required or deemed appropriate for proper use and patient safety. (4-11-15)

145. PRESCRIPTION DRUG PACKAGING.
Prescription drugs must be dispensed in packaging materials that preserve the integrity, cleanliness, and potency of commercially available and compounded drug products. (3-21-12)

146. REPACKAGING.
A pharmacy may repackage a drug previously dispensed to a patient, pursuant to the patient or the patient's agent's request, if: (4-11-15)

01. Unit Dose. The drugs are repackaged into unit dose packaging. (4-11-15)

02. Pharmacist Verification. The repackaging pharmacist verifies: (4-11-15)

a. The identity of the previously dispensed drugs as matching the label on the container that the drugs were initially dispensed within; and (4-11-15)

b. The validity and accuracy of the original prescription drug order. (4-11-15)

03. Adulterated Drugs. In the repackaging pharmacist's best professional judgment, the drug has not been adulterated. (4-11-15)

04. Intermingled Drugs. The drugs are never intermingled with the repackaging pharmacy's regular stock. (4-11-15)

05. Time for Repackaging. The pharmacy repackages the entire amount that was delivered to it for repackaging no later than three (3) days after receipt. (4-11-15)

06. Date of Repackaging. The date of repackaging is less than one (1) year from the original date of dispensing and the original expiration date is also used on the repackaged drug's label. (4-11-15)

07. Labeling. The repackaging pharmacy affixes to the container of the repackaged drug a label that complies with the standard labeling rule and includes: (4-11-15)

a. The original dispensed prescription's serial number; (4-11-15)

b. The name, address, and phone number of the original dispensing pharmacy; and (4-11-15)

c. A statement that indicates that the drug has been repackaged, such as the words "repackaged by" followed by the name of the repackaging pharmacy. (4-11-15)

08. Record. The repackaging pharmacy makes a record of: (4-11-15)

a. All required components of the standard prescription drug labeling rule; (4-11-15)

b. The original dispensing pharmacy's name, address, and phone number; (4-11-15)

c. The original dispensed prescription's serial number; and (4-11-15)

d. The name of the pharmacist responsible for compliance with this rule. (4-11-15)

09. Policy and Procedures. The repackaging pharmacy develops policy and procedures to ensure compliance with this rule. (4-11-15)

147. -- 199. (RESERVED)

200. CONTROLLED SUBSTANCES: POSITIVE IDENTIFICATION REQUIRED.
A potential recipient of a controlled substance must first be positively identified or the controlled substance must not be dispensed. (3-21-12)

01. Positive Identification Presumed. Positive identification is presumed and presentation of identification is not required if dispensing directly to the patient and if: (3-21-12)

a. The controlled substance will be paid for, in whole or in part, by an insurer; or (3-21-12)

b. The patient is being treated at an institutional facility or is housed in a correctional facility.(4-4-13)

c. The filled prescription is delivered to the patient's residence either by mail, common carrier, or an employee of the pharmacy. (4-4-13)

02. Personal Identification. Presentation of identification is also not required if the individual receiving the controlled substance is personally and positively known by a pharmacy or prescriber drug outlet staff member who is present and identifies the individual and the personal identification is documented by recording: (3-21-12)

a. The recipient's name (if other than the patient); (3-21-12)

b. A notation indicating that the recipient was known to the staff member; and (3-21-12)

c. The identity of the staff member making the personal identification. (3-21-12)

03. Acceptable Identification. The identification presented must include an unaltered photograph and signature and acceptable forms include: (3-20-14)

a. A valid U.S. state or U.S. military driver's license or identification card; (3-20-14)

b. A Western Hemisphere Travel Initiative (WHTI) compliant document (i.e., Enhanced Driver's License (EDL) or Nexus Air Card); (3-20-14)

c. A valid passport; and (3-20-14)

d. A U.S. passport card (PASS Card). (3-20-14)

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed controlled substance and must include: (3-21-12)

a. A copy of the identification presented; or (3-21-12)

b. A record that includes: (3-21-12)

i. The recipient's name; (3-21-12)

ii. A notation of the type of identification presented; (3-21-12)

iii. The government entity that issued the identification; and (3-20-14)

iv. The unique identification number. (3-20-14)

201. CONTROLLED SUBSTANCES: SCHEDULE II EMERGENCY DISPENSING.
In an emergency situation, as defined, a pharmacist may dispense a Schedule II controlled substance in accordance with a verbal prescription drug order issued by a prescriber. (3-21-12)

01. Emergency Situation Defined. For purposes of this rule, an emergency situation is one in which the prescriber determines: (3-21-12)

a. That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user; (3-21-12)

b. That no appropriate alternative treatment is available, including administration of a drug that is not a Schedule II controlled substance; and (3-21-12)

c. That it is not reasonably possible for the prescriber to provide a written prescription drug order prior to the dispensing. (3-21-12)

02. Limited Quantity. The quantity prescribed and dispensed must be limited to the amount adequate to treat the patient during the emergency situation. (3-21-12)

03. Verbal Prescription Drug Order. The verbal prescription drug order must be immediately reduced to writing by the pharmacist and must include all required prescription drug order information except the signature of the prescriber. (3-21-12)

04. Paper Prescription Drug Order. Within seven (7) days after issuing an emergency verbal prescription drug order, the prescriber must provide a written prescription drug order for the emergency quantity prescribed. (3-21-12)

a. The prescription drug order must conform to the requirements for a written prescription drug order and also have written on its face "Authorization for Emergency Dispensing" and the date the verbal prescription drug order was issued. (3-21-12)

b. A paper prescription drug order may be delivered by mail if postmarked within the seven-day period. (3-21-12)

05. Verbal Order Attachment or Annotation. Either a paper prescription drug order must be attached to the documented emergency verbal prescription drug order or an electronic prescription drug order must be annotated by a pharmacist with the original authorization and date of the verbal order. (3-21-12)

06. Board Notification. The pharmacist must notify the Board if the prescriber fails to provide a written prescription drug order within the seven-day period. (3-21-12)

202. CONTROLLED SUBSTANCES: NON-PRESCRIPTION DISPENSING.
A Schedule V non-prescription controlled substance may be dispensed to a retail purchaser as permitted or restricted by these rules. (3-21-12)

01. Dispensing by a Technician Prohibited. Technicians are prohibited from dispensing a non-prescription controlled substance even if under the direct supervision of a pharmacist, but may transact the sale and deliver the product after the pharmacist has fulfilled his professional and legal responsibilities. (3-21-12)

02. Restricted Quantity. No more than four (4) ounces of liquid containing a maximum of two hundred (200) milligrams of codeine per one hundred (100) milliliters or per one hundred (100) grams may be distributed at retail to the same purchaser in any forty-eight (48) hour period. (3-20-14)

03. Purchaser's Age. A purchaser of a non-prescription controlled substance must be at least eighteen (18) years of age. (3-21-12)

04. Identification Required for Purchase. The pharmacist must obtain positive identification as required by these rules that, if appropriate, includes proof of age of the purchaser of a non-prescription Schedule V controlled substance. (3-21-12)

05. Bound Record Book and Patient Signature Required. A bound record book must be used to document sales of non-prescription Schedule V controlled substances and must record the following: (3-21-12)

a. The name and address of the purchaser; (3-21-12)

b. The name and quantity of the controlled substance purchased; (3-21-12)

c. The date of the purchase; (3-21-12)

d. The name or initials of the pharmacist who dispensed the substance to the purchaser; and (3-21-12)

e. The signature of the purchaser. (3-21-12)

203. CONTROLLED SUBSTANCES: PRESCRIBER RESTRICTIONS.
Prescribing, administering, dispensing, or delivering a controlled substance for oneself or, when contrary to the prescriber's scope of practice or prescriptive authority, to an immediate family member is prohibited. (3-21-12)

204. CONTROLLED SUBSTANCES: PMP.
Specified data on controlled substances must be reported weekly, or more often as required by the Board, by all pharmacies holding a DEA retail pharmacy registration that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. Data on controlled substance prescription drug samples does not need to be reported. (4-4-13)

01. Online Access to PMP. Online access to the Board's PMP is limited to licensed prescribers and pharmacists for treatment purposes. To obtain online access, a prescriber or pharmacist must: (3-21-12)

a. Complete and submit a registration application and a written agreement to adhere to the access restrictions and limitations established by law; (3-21-12)

b. Obtain Board approval for access; and (3-21-12)

c. Be issued a user account, login name, and password. (3-21-12)

02. Use Outside Scope of Practice Prohibited. Information obtained from the PMP must not be used for purposes outside the prescriber's or pharmacist's scope of professional practice. (3-21-12)

03. Profile Requests. Authorized persons without online access may obtain a profile by completing the required form and submitting it to the Board office with proof of identification and other credentials required to confirm the requestor's authorized status pursuant to Section 37-2726, Idaho Code. (3-21-12)

04. Suspension, Revocation, or Restriction of PMP Access. Violation of this rule provides grounds for suspension, revocation, or restriction of the prescriber's or pharmacist's authorization for online access to the PMP. (3-21-12)

205. CONTROLLED SUBSTANCES: CURRENT, COMPLETE, AND ACCURATE RECORDS.
Each controlled substance registrant must maintain a current, complete, and accurate record of each substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed, or otherwise disposed of by the registrant, except that a registrant is not required by this rule to maintain a perpetual inventory. (3-21-12)

206. CONTROLLED SUBSTANCES: INVENTORIES.

01. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand annually no later than seven (7) days after the date of the prior year's inventory in a form and manner that satisfies the inventory requirements of federal law. (4-11-15)

02. Separate Inventories for Each Location. A separate controlled substances inventory must be taken and retained at each registered location. (3-21-12)

03. Inventory on PIC or Director Change. A complete controlled substance inventory must be conducted in the event of a change of PIC or director on or by the first day of employment of the incoming PIC or director. (4-4-13)

04. Inventory After Discovery of Theft or Loss. A complete controlled substance inventory must be conducted within forty-eight (48) hours of the discovery of a theft or reportable loss of a controlled substance. (3-21-12)

05. Inventory on Addition to Schedule of Controlled Substances. On the effective date of an addition of a substance to a schedule of controlled substances, each registrant that possesses that substance must take an inventory of the substance on hand, and thereafter, include the substance in each inventory. (3-21-12)

06. Annual Inventory Compliance. Complete inventories otherwise conducted may also be considered in complying with the annual inventory requirement. (4-11-15)

207. CONTROLLED SUBSTANCES: INVENTORIES AND RECORDS MAINTENANCE.
Each controlled substance registrant must maintain inventories and records of controlled substances as follows: (3-21-12)

01. Inventories and Records for Schedules I and II. Inventories and records of controlled substances listed in Schedules I and II must be maintained separately from all other records of the registrant. (3-21-12)

02. Inventories and Records for Schedules III, IV, and V. Inventories and records of controlled substances listed in Schedules III, IV, and V must be maintained separately from all other records or in a manner that the information required is readily retrievable. (3-21-12)

03. Controlled Substance Prescription Drug Orders. Each registered pharmacy must maintain prescription drug orders for controlled substances listed in Schedules II through V as follows: (3-21-12)

a. Paper prescription drug orders for Schedule II controlled substances must be maintained at the registered location in a separate prescription file. (3-21-12)

b. Paper prescription drug orders for Schedules III, IV, and V controlled substances must be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in a readily retrievable manner from other prescription records as required by federal law. (3-21-12)

c. Electronic prescription drug orders for controlled substances must be maintained in a system that meets the requirements of federal law. The records may be maintained at another location if readily retrievable at the registered location. The electronic application must be capable of printing or otherwise converting the records into a readily understandable format at the registered location and must allow the records to be sortable by prescriber name, patient name, drug dispensed, and date filed. (3-21-12)

04. Central Records Storage. Financial and shipping records including invoices, but excluding controlled substance order forms and inventories, may be retained at a central location if the registrant has provided DEA notification of central recordkeeping as required by federal law. (3-21-12)

05. Rebuttal Presumption of Violation. Evidence of an amount of a controlled substance that differs

from the amount reflected on a record or inventory required by state or federal law creates a rebuttable presumption that the registrant has failed to keep records or maintain inventories in conformance with the recordkeeping and inventory requirements of state and federal law. (3-21-12)

208. CONTROLLED SUBSTANCES --THEFT OR LOSS REPORTING.
A registrant must report to the Board on the same day reported to the DEA a theft or loss of a controlled substance that includes the information required by federal law. (3-21-12)

209. CONTROLLED SUBSTANCES: PRESCRIBER DISCIPLINE.
A prescriber who issues a prescription drug order for a controlled substance that does not comply with the requirements of Section 37-2725, Idaho Code, is subject to discipline by the Board as follows: (3-21-12)

01. Discipline of First Offense. A letter with a copy of the prescription drug order or orders issued in noncompliance with the law will be sent to the prescriber at the registered address. The letter will describe the offense and the basis for required action. A copy of the letter and its attachments will be sent to the prescriber's licensing board. The prescriber will have thirty (30) days from the date postmarked on the letter to comply with the requirements of Section 37-2725, Idaho Code. If the prescriber fails to comply within thirty (30) days, the prescriber's licensing board will be notified of the failure to comply and requested to initiate corrective or disciplinary action within thirty (30) days and to immediately notify the Board if action is taken. If not so notified, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

02. Discipline of Second Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended for a period of one (1) week and an administrative fine assessed equal to the prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension proceedings will be mailed to the prescriber at the registered address. To avoid the suspension action, the prescriber may submit to the Board a written explanation and plan of correction, including details of how the prescriber will avoid future offenses, and payment of one hundred dollars ($100) within thirty (30) days of the date postmarked on the notice. If the prescriber fails to comply with the requirements of this rule and Section 37-2725, Idaho Code, within thirty (30) days, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

03. Discipline of Third Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended for a period of thirty (30) days and an administrative fine assessed equal to the prosecution and administrative costs of bringing the action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension proceedings will be mailed to the prescriber at the registered address. To avoid the suspension action, the prescriber may submit to the Board a written explanation and plan of correction, including details of how the prescriber will avoid future offenses, and a payment of five hundred dollars ($500) within thirty (30) days of the date postmarked on the notice. If the prescriber fails to comply with the requirements of this rule and Section 37-2725, Idaho Code, within thirty (30) days, the Board may initiate disciplinary action pursuant to Board rules. (3-21-12)

04. Discipline of Fourth Offense. Pursuant to Sections 37-2718 and 2719, Idaho Code, the prescriber's controlled substance registration will be suspended or revoked, as the Board may determine based on the circumstances, and an administrative fine assessed equal to the prosecution and administrative costs of bringing the suspension or revocation action including, but not limited to, attorney's fees and costs and costs of hearing transcripts. A notice of the offense and of the Board's intention to initiate registration suspension or revocation proceedings will be mailed to the prescriber at the registered address. (3-21-12)

05. Cumulative Discipline. Offenses subject to discipline under this rule will accumulate for each subsequent offense that occurs within six (6) months of the date the prescriber is sent notice of the prior offense. An offense occurring more than six (6) months after the date the prescriber receives notice of any immediately prior offense will be deemed a first offense. (3-21-12)

06. Separate Offense. Prescribing or dispensing controlled substances by a prescriber whose registration has been suspended or revoked pursuant to this rule will be deemed a separate offense. (3-21-12)

210. CONTROLLED SUBSTANCE STORAGE.
Controlled substances must be stored as follows: (3-24-16)

01. Schedule I. Controlled substances listed in Schedule I must be stored in a securely locked, substantially constructed cabinet. (3-24-16)

02. Schedules II, III, IV and, V. Controlled substances listed in Schedules II, III, IV, and V must be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances, in whole or in part, throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances. (3-24-16)

211. CONTROLLED SUBSTANCES: SCHEDULE I.
Unless specifically excepted or unless listed in another schedule, U-47700 (3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide), its derivatives, salts, isomers, and salts of isomers with similar chemical structure shall be listed in Schedule I, under Article II, Title 37, Chapter 27, Idaho Code. (8-3-16)T

212. -- 219. (RESERVED)

220. EPHEDRINE PRESCRIPTION DRUG PRODUCTS.

01. Designated Prescription Drugs. The Board includes preparations containing ephedrine or salts of ephedrine as designated prescription drugs. (3-21-12)

02. Qualified Product Exemption. A qualified product that meets the following criteria is exempt from designation as a prescription drug: (3-21-12)

a. A product containing a formula with a ratio of twelve and one-half (12.5) milligrams ephedrine to two hundred (200) milligrams guaifenesin or twenty-five (25) milligrams ephedrine to four hundred (400) milligrams guaifenesin, not exceeding a maximum of twenty-five (25) milligrams of ephedrine per tablet, capsule, or dose, and in addition to the formula, may include only inert or inactive ingredients or substance; and (3-21-12)

b. A hemorrhoidal ointment containing not more than two tenths percent (0.2%) ephedrine sulfate and suppositories not exceeding four (4) milligrams ephedrine sulfate per suppository. (3-21-12)

03. Disqualified Product Exemption. An ephedrine-containing product that is an immediate precursor to amphetamine or methamphetamine and considered a Schedule II controlled substance pursuant to Section 37-2707(g), Idaho Code, is disqualified from the prescription drug exemption provided by this rule even if otherwise qualified. (3-21-12)

221. -- 229. (RESERVED)

230. INVESTIGATIONAL DRUGS.
Investigational drugs must be properly labeled and administered only under the supervision of a principal physician-investigator or an authorized clinician. (3-21-12)

231. -- 238. (RESERVED)

239. COMPOUNDING DRUG PRODUCTS.
Any compounding that is not permitted herein is considered manufacturing. (4-11-15)

01. Application. This rule applies to any person, including any business entity, authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: (4-11-15)

a. Compound positron emission tomography drugs; (4-11-15)

b. Radiopharmaceutics; (4-11-15)

c. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; (3-25-16)

d. The addition of a flavoring agent to a drug product; and (3-25-16)

e. Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling. (3-25-16)

02. General Compounding Standards. (4-11-15)

a. Active Pharmaceutical Ingredients. All active pharmaceutical ingredients must be obtained from an FDA registered manufacturer. FDA registration as a foreign manufacturer satisfies this requirement. (4-11-15)

b. Certificate of Analysis. Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a CO must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is required on the COA: (4-11-15)

i. Product name; (4-11-15)

ii. Lot number; (4-11-15)

iii. Expiration date; and (4-11-15)

iv. Assay. (4-11-15)

c. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. (4-11-15)

d. Disposal of Compromised Drugs. When the correct identity, purity, strength, and sterility of ingredients and components cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampoules, punctured stoppers of vials and bags, and containers of ingredients with incomplete labeling) or when the ingredients and components do not possess the expected appearance, aroma, and texture, they must be removed from stock and isolated for return, reclamation, or destruction. (4-11-15)

03. Prohibited Compounding. Compounding any drug product for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market for safety or efficacy reasons is prohibited. (4-11-15)

04. Limited Compounding. (4-11-15)

a. Triad Relationship. A pharmacist may compound a drug product in the usual course of professional practice for an individual patient pursuant to an established prescriber/patient/pharmacist relationship and a valid prescription drug order. (4-11-15)

b. Commercially Available Products. A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts and if: (4-11-15)

i. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or (4-11-15)

ii. The commercial product is not reasonably available in the market in time to meet the patient's needs. (4-11-15)

c. Anticipatory Compounding. Limited quantities of a drug product may be compounded or sterile prepackaged prior to receiving a valid prescription drug order based on a history of receiving valid prescription drug orders for the compounded or sterile prepackaged drug product. (4-11-15)

05. Drug Compounding Controls. (4-11-15)

a. Policies and Procedures. In consideration of the applicable provisions of USP 795 concerning pharmacy compounding of non-sterile preparations, USP 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations, policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product, and must include any of the following that are applicable to the scope of compounding practice being performed: (4-11-15)

i. Appropriate packaging, handling, transport, and storage requirements; (4-11-15)

ii. Accuracy and precision of calculations, measurements, and weighing; (4-11-15)

iii. Determining ingredient identity, quality, and purity; (4-11-15)

iv. Labeling accuracy and completeness; (4-11-15)

v. Beyond use dating; (4-11-15)

vi. Auditing for deficiencies, including routine environmental sampling, quality and accuracy testing, and maintaining inspection and testing records; (4-11-15)

vii. Maintaining environmental quality control; and (4-11-15)

viii. Safe limits and ranges for strength of ingredients, pH, bacterial endotoxins, and particulate matter. (4-11-15)

b. Accuracy. Components including, but not limited to, bulk drug substances, used in the compounding or sterile prepackaging of drug products must be accurately weighed, measured, or subdivided, as appropriate. The amount of each active ingredient contained within a compounded drug product must not vary from the labeled potency by more than the drug product's acceptable potency range listed in the USP-NF monograph for that product. If USP-NF does not publish a range for a particular drug product, the active ingredients must not contain less than ninety percent (90%) and not more than one hundred ten percent (110%) of the potency stated on the label. (4-11-15)

c. Non-Patient Specific Records. Except for drug products that are being compounded or sterile prepackaged for direct administration, a production record of drug products compounded or sterile prepackaged in anticipation of receiving prescription drug orders or distributed in the absence of a patient specific prescription drug order ("office use") solely as permitted in these rules, must be prepared and kept for each drug product prepared, including: (4-11-15)

i. Production date; (4-11-15)

ii. Beyond use date; (4-11-15)

iii. List and quantity of each ingredient; (4-11-15)

iv. Internal control or serial number; and (4-11-15)

v. Initials or unique identifier of all persons involved in the process or the compounder responsible for the accuracy of these processes. (4-11-15)

240. STERILE PRODUCT PREPARATION.

01. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products, these rules apply to all persons, including any business entity, engaged in the practice

of sterile compounding and sterile prepackaging in or into Idaho. (4-11-15)

02. Dosage Forms Requiring Sterility. The sterility of compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug product must be sterilized when prepared in the following dosage forms: (4-11-15)

a. Aqueous bronchial and nasal inhalations, except sprays intended to treat bronchial mucosa only; (4-11-15)

b. Baths and soaks for live organs and tissues; (4-11-15)

c. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); (4-11-15)

c. Irrigations for wounds and body cavities; (4-11-15)

d. Ophthalmic drops and ointments; and (4-11-15)

e. Tissue implants. (4-11-15)

03. Compounder Responsibilities. Compounders and sterile prepackagers are responsible for ensuring that sterile products are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed, as well as prepared in a manner that maintains sterility and minimizes the introduction of particulate matter; (4-11-15)

a. Unless following manufacturer's guidelines or another reliable literature source, opened or partially used packages of ingredients for subsequent use must be properly stored as follows; (4-11-15)

i. Opened or entered (such as needle-punctured) single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile products shall be used within one (1) hour if opened in non-sterile conditions, and any remaining contents must be discarded; (4-11-15)

ii. Single-dose vials needle-punctured in a sterile environment may be used up to six (6) hours after initial needle puncture; (4-11-15)

iii. Opened single-dose ampules shall not be stored for any time period; and (4-11-15)

iv. Multiple-dose containers (for example, vials) that are formulated for removal of portions on multiple occasions because they contain antimicrobial preservatives, may be used for up to twenty-eight (28) days after initial opening or entering, unless otherwise specified by the manufacturer; (4-11-15)

b. Water-containing compounded sterile products that are non-sterile during any phase of the compounding procedure must be sterilized within six (6) hours after completing the preparation in order to minimize the generation of bacterial endotoxins; (4-11-15)

c. Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated areas where components and ingredients of sterile products are prepared. (4-11-15)

04. Environmental Controls. Except when prepared for immediate administration, the environment for the preparation of sterile products in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. (3-21-12)

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every six (6) months or if relocated. (4-11-15)

b. Filters must be inspected and replaced in accordance with the manufacturer's recommendations. (4-11-15)

05. Sterile Product Preparation Equipment. A drug outlet in which sterile products are prepared must be equipped with at least the following: (3-21-12)

a. Protective apparel including gowns, masks, and sterile (or the ability to sterilize) non-vinyl gloves, unless the PIC or director can provide aseptic isolator manufacturer's written documentation that any component of garbing is not required; (4-11-15)

b. A sink with hot and cold water in close proximity to the hood; (3-21-12)

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when necessary; and (4-11-15)

d. An appropriate laminar airflow hood or other aseptic environmental control device such as a laminar flow biological safety cabinet. (4-11-15)

06. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: (3-21-12)

a. Justification of beyond use dates assigned, pursuant to direct testing or extrapolation from reliable literature sources; (4-11-15)

b. Training records, evidencing that personnel are trained on a routine basis and are adequately skilled, educated, and instructed; (4-11-15)

c. Audits appropriate for the risk of contamination for the particular sterile product including: (4-11-15)

i. Visual inspection to ensure the absence of particulate matter in solutions, the absence of leakage from bags and vials, and the accuracy of labeling with each dispensing; (4-11-15)

ii. Periodic hand hygiene and garbing competency; (4-11-15)

iii. Media-fill test procedures (or equivalent), aseptic technique, and practice related competency evaluation at least annually by each compounder or sterile prepackager; (4-11-15)

iv. Environmental sampling testing at least upon registration of a new drug outlet, following the servicing or re-certification of facilities and equipment, or in response to identified problems with end products, staff techniques or patient-related infections, or every six (6) months, including: (4-11-15)

(1) Total particle counts; (4-11-15)

(2) Viable air sampling; (4-11-15)

(3) Gloved fingertip sampling; (4-11-15)

(4) Surface sampling; (4-11-15)

v. Sterility testing of high risk batches of more than twenty-five (25) identical packages (ampules, bags, vials, etc.) before dispensing or distributing; (4-11-15)

d. Temperature, logged daily; (4-11-15)

e. Beyond use date and accuracy testing, when appropriate; and (4-11-15)

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. (4-11-15)

07. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet preparing sterile pharmaceutical products and must include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, including: (4-11-15)

a. Antiseptic hand cleansing; (4-11-15)

b. Disinfection of non-sterile compounding surfaces; (4-11-15)

c. Selecting and appropriately donning protective garb; (4-11-15)

d. Maintaining or achieving sterility of sterile products while maintaining the labeled strength of active ingredients; (4-11-15)

e. Manipulating sterile products aseptically, including mixing, diluting, purifying, and sterilizing in the proper sequence; (4-11-15)

f. Choosing the sterilization method, pursuant to the risk of a contamination of particular compounded sterile product; and (4-11-15)

g. Inspecting for quality standards before dispensing or distributing. (4-11-15)

241. HAZARDOUS DRUGS PREPARATION.
In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Products and Sterile Product Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: (4-11-15)

01. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. (4-11-15)

02. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. (4-11-15)

a. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; (4-11-15)

b. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. (4-11-15)

c. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: (4-11-15)

i. The hazardous drugs in use will not volatilize while they are being handled; or (4-11-15)

ii. The PIC or Director can provide manufacturer written documentation attesting to the safety of such ventilation. (4-11-15)

03. Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs. (4-11-15)

04. Labeling. Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills. (4-11-15)

05. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. (4-11-15)

06. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs

separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit does or unit-of-use packaging. (4-11-15)

07. Compliance With Laws. Comply with applicable local, state, and federal laws including for the disposal of hazardous waste. (4-11-15)

08. Training. Ensure that personnel working with hazardous drugs are trained in: (4-11-15)

a. Hygiene; (4-11-15)

b. Garbing; (4-11-15)

c. Receipt; (4-11-15)

d. Storage; (4-11-15)

e. Handling; (4-11-15)

f. Transporting; (4-11-15)

g. Compounding; (4-11-15)

h. Spill control; (4-11-15)

i. Clean up; (4-11-15)

j. Disposal; (4-11-15)

k. Dispensing; (4-11-15)

l. Medical surveillance; and (4-11-15)

m. Environmental quality and control. (4-11-15)

09. Policy and Procedures Manual. Maintain a policy and procedures manual to ensure compliance with this rule. (4-11-15)

242. -- 259. (RESERVED)

260. DRUG PRODUCT STORAGE.
Drugs must be stored in accordance with USP-NF requirements in an area maintained and secured appropriately to safeguard product integrity and protect against product theft or diversion. (4-4-13)

261. EXPIRED, ADULTERATED, DAMAGED, OR CONTAMINATED DRUGS.

01. Removal and Isolation of Damaged Drugs Required. Expired, deteriorated, adulterated, damaged, or contaminated drugs must be removed from stock and isolated for return, reclamation, or destruction. (3-21-12)

02. Sale or Distribution of Damaged Drugs Prohibited. Dispensing, delivering, or placing in saleable stock damaged or contaminated drugs is prohibited without first obtaining written Board approval. (3-21-12)

03. Adulterated Drug Reporting Required. A licensee or registrant must report to the Board any adulteration of a prescription drug. (3-21-12)

262. RESTRICTED RETURN OF DRUGS OR DEVICES.
Once removed from the premises from which it was dispensed, a drug or prescription device must only be accepted

for return under the conditions permitted by this rule or pursuant to the Legend Drug Donation Act and rules. (3-21-12)

01. Qualifying Returns. Unless dispensed in any manner inconsistent with the prescriber's instructions and returned for quarantine for destruction purposes only, a drug or prescription device that has been received from or delivered to the patient or the patient's representative is ineligible for return. Drugs or devices that may qualify for return include: (3-21-12)

a. Those intended for inpatients of an institutional facility that have been maintained in the custody and control of the institutional facility or dispensing pharmacy; and (3-21-12)

b. That are liquid or in unit dose or unit-of-use packaging and, if a controlled substance, returned from a hospital daily delivery system; and (3-21-12)

c. Those for which the following conditions are satisfied: (3-21-12)

i. The drug was delivered by the dispensing pharmacy directly to the institutional facility or its authorized agent and subsequently stored in a suitable drug storage area that is inaccessible to patients; (3-21-12)

ii. The drug is returned in an unopened manufacturer-sealed container or with other tamper-evident packaging intact; (3-21-12)

iii. In the professional judgment of the pharmacist, the safety and efficacy of the drug has not been compromised; and (3-21-12)

iv. A system is in place to track the restocked drug for purposes of a recall. (3-21-12)

02. Marking Ineligible Returns. Drugs or devices otherwise eligible for return that are or will become ineligible for any reason must be clearly marked "Not Eligible for Return" prior to leaving the institutional facility or upon discovery and before storing in an area with other eligible returns. (3-21-12)

03. Consulting Pharmacy and PIC Responsibilities. The pharmacy and its PIC are responsible for: (4-4-13)

a. Consulting with an institutional facility from which returns will be accepted; (4-4-13)

b. Ensuring that the institutional facility has an employee trained and knowledgeable in the proper storage, use, and administration of drugs and devices; (4-4-13)

c. Reviewing, approving, and enforcing written protocols that will ensure compliance with the conditions necessary to allow returns; and (4-4-13)

d. Storing a copy of the protocols, as well as the written approval thereof, in an immediately retrievable fashion. (4-4-13)

263. CONTROLLED SUBSTANCE DISPOSAL.
A controlled substance registrant must dispose of expired, excess, or unwanted controlled substances through the services of a DEA-registered reverse distributor or by another method permitted by federal law. (3-21-12)

264. (RESERVED)

265. LEGEND DRUG DONATION -- STANDARDS AND PROCEDURES.

01. Drug Donation Criteria. A drug considered for donation to a qualifying charitable clinic or center must meet the following eligibility criteria or it must not be accepted for donation. (3-21-12)

a. The drug name, strength, lot number, and expiration date must appear on the package or label.

(3-21-12)

b. The drug must be FDA-approved and: (3-21-12)

i. Be in the original unit dose packaging; or (3-21-12)

ii. Be an oral or parenteral drug in a sealed, single dose container approved by the FDA; or (3-21-12)

iii. Be a topical or inhalant drug in a sealed, unit-of-use container approved by the FDA; or (3-21-12)

iv. Be a parenteral drug in a sealed, multiple dose container approved by the FDA from which no doses have been withdrawn. (3-21-12)

c. The drug must not be the subject of a mandatory recall by a state or federal agency or of a voluntary recall by a drug wholesaler or manufacturer. (3-21-12)

d. The drug must not require storage temperatures other than normal room temperature as specified by the manufacturer or the USP. (3-21-12)

e. The drug must not be subject to an FDA-restricted drug distribution program such as and including, but not limited to, thalidomide and lenalidomide. (3-21-12)

02. Donation Standards. (3-21-12)

a. A pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority at the qualifying charitable clinic or center must be designated as responsible for defining the drugs included in the qualifying charitable clinic or center's formulary. (3-21-12)

b. Donating nursing homes may only donate drugs that appear on the formulary. (3-21-12)

c. Prior to the delivery of donated drugs to the qualifying charitable clinic or center, a pharmacist, nurse, physician, or physician assistant from the donating nursing home must sign and date a manifest that: (3-21-12)

i. Attests that the donated drugs have been maintained in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and the USP standards; (3-21-12)

ii. Attests that the drugs have been continuously under the control of a healthcare professional and have never been in the custody of a patient or other individual; (3-21-12)

iii. Attests that the donated drugs are those qualified for donation by their inclusion in the qualifying charitable clinic or center's formulary; (3-21-12)

iv. Attests that the donation is fully compliant with these rules; (3-21-12)

v. Attests that all PHI has been removed or redacted from the package; (3-21-12)

vi. Lists the name of the donating nursing home and the name of the receiving qualifying charitable clinic or center; and (3-21-12)

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug donated. (3-21-12)

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. (3-21-12)

03. Receipt and Handling of Donated Drugs. Donated drugs may be received and handled at a qualifying charitable clinic or center by a pharmacist, physician, physician assistant, advanced practice professional

nurse with prescriptive authority, dentist, optometrist, or other authorized clinic or center personnel. (3-21-12)

04. Verification of Received Drugs. (3-21-12)

a. Each donated drug must be verified against the donation manifest by an individual authorized to receive the drugs. (3-21-12)

b. If all PHI has not been removed by the donating entity, the information must be removed or redacted prior to dispensing. (3-21-12)

c. Before donated drugs are placed with a qualifying charitable clinic or center's regular stock, a pharmacist, physician, physician assistant, or an advanced practice professional nurse with prescriptive authority must: (3-21-12)

i. Using a current drug identification book, a computer program, or an online service, verify that each donated drug unit meets the criteria specified by these rules; (3-21-12)

ii. Verify that the name and strength indicated on the label of each donated drug unit is correct; and (3-21-12)

iii. Determine for each donated drug that it is not adulterated or misbranded and is safe to dispense. (3-21-12)

d. Donated drugs that do not meet the criteria of these rules must be destroyed and documentation of the destruction retained. (3-21-12)

05. Storage of Donated Drugs. (3-21-12)

a. Donated drug storage must have proper environmental controls to ensure the integrity of the drug in accordance with the manufacturer's recommendations and USP standards. (3-21-12)

b. Donated drugs may be commingled with the qualifying charitable clinic or center's regular stock of drugs only if the packaging on the donated drug has been labeled to indicate that the drug was obtained from a nursing home and otherwise must be segregated. (3-21-12)

c. The drug storage area must be secured at all times and accessible only to persons authorized to handle donated drugs. (3-21-12)

06. Dispensing Donated Drugs. (3-21-12)

a. Donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not stored in appropriate conditions must not be re-dispensed, must be destroyed, and their destruction must be appropriately documented. (3-21-12)

b. A pharmacist, physician, physician assistant, dentist, optometrist, or an advanced practice professional nurse with prescriptive authority at a qualifying charitable clinic or center who re-dispenses donated drugs to a patient must: (3-21-12)

i. Use an appropriate container; (3-21-12)

ii. Label the container as required by these rules except that the expiration date must be the same as on the original container; and (3-21-12)

iii. Initial the prescription label. (3-21-12)

c. A qualifying charitable clinic or center must retain records for each donated drug dispensed. (3-21-12)

d. Pharmacists, physicians, physician assistants, dentists, optometrists, and advanced practice professional nurses with prescriptive authority dispensing donated drugs must perform prospective drug review and provide patient counseling. (3-21-12)

07. Miscellaneous. (3-21-12)

a. The qualifying charitable clinic or center must maintain a list of the names of authorized clinic or center personnel, their individual duties, and a summary of their qualifications. (3-21-12)

b. A qualifying charitable clinic or center that receives donated drugs must adopt policies and procedures requiring and with sufficient detail to ensure that authorized clinic or center personnel will comply with applicable local, state, and federal laws. (3-21-12)

c. Drugs donated pursuant to these rules must not be sold, resold, offered for sale, traded, or transferred to another qualifying charitable clinic or center. (3-21-12)

d. Nothing in these rules precludes a qualifying charitable clinic or center from charging a dispensing fee. (3-21-12)

266. -- 289. (RESERVED)

290. ADS SYSTEMS: MINIMUM STANDARDS.
This rule establishes the minimum standards for the use of an ADS system to dispense and store drugs and devices. (3-21-12)

01. System Registration and Approved Utilization Locations. One or more ADS systems may be utilized by the following drug outlets if registered as required by the Board: (3-21-12)

a. In a pharmacy, remote dispensing site, or other ambulatory healthcare setting where utilization of the ADS system is under the adequate personal or electronic supervision of a pharmacist, as defined by these rules; (3-21-12)

b. In a prescriber drug outlet; and (3-21-12)

c. In an institutional facility. (3-21-12)

02. Multiple System Documentation. At least the following documentation must be maintained for each ADS system by the supervising pharmacy or prescriber drug outlet utilizing multiple ADS systems: (3-21-12)

a. The manufacturer's name and model of the ADS system; (3-21-12)

b. The state and, if applicable, federal ADS system registrations; and (3-21-12)

c. The name, address, and specific location where the ADS system is operational. (3-21-12)

03. System Access, Monitoring, and Control. Access to the ADS system must be monitored and controlled as follows: (3-21-12)

a. Proper identification controls, including electronic passwords or other coded identification, must be utilized and access control must be limited and authorized by the prescriber, PIC, director or their authorized designee; (4-4-13)

b. The prescriber, PIC, or director must be able to stop or change access at any time; (3-21-12)

c. The prescriber, PIC, or director must maintain a current and immediately retrievable list of persons who have access and the limits of that access; (3-21-12)

d. Review of user access reports must be conducted periodically to ensure that access by persons no longer employed has been appropriately disabled; and (3-21-12)

e. Access for maintenance or repair must be pre-approved by the prescriber, PIC, or director and must be performed under the continuous supervision of a person with appropriate access authorization. (3-21-12)

04. System Security and Patient Confidentiality. The ADS system must have adequate system security and safeguards to prevent and detect unauthorized access or use, maintain the integrity of patient records and prescription drug orders, and protect patient privacy. (3-21-12)

05. System Filling, Stocking, Replenishing. The filling, stocking, or replenishing of drugs into the ADS system must be accomplished by a pharmacist, technician, prescriber, nurse or authorized prescriber drug outlet personnel. Timely pharmacist or prescriber verification of the accuracy of the filling, stocking, or replenishing of the ADS system must occur through a manual process, bar coding, or other electronic technology used for item identification. (4-4-13)

06. Stocked Drug Documentation. The ADS system must be able to generate a record on demand of drugs filled into the system that includes at least: (3-21-12)

a. The date; (3-21-12)

b. The drug name; (3-21-12)

c. The dosage form; (3-21-12)

d. The strength; (3-21-12)

e. The quantity; (3-21-12)

f. The drug expiration; (3-21-12)

g. The identity of the ADS system; and (3-21-12)

h. The name or initials of the authorized individual filling the ADS system and, if applicable, the verifying pharmacist or prescriber. (3-21-12)

07. System Access and Transaction Documentation. The ADS system must automatically document transactions and other events involving access to system contents that is immediately retrievable in written or electronic form and includes at least the following: (3-21-12)

a. The identity of the system and, if applicable, the component accessed; (3-21-12)

b. The name or other identification (e.g., electronic signature or unique identifier) of the person conducting the transaction; (3-21-12)

c. The type of transaction; (3-21-12)

d. The date and time of transaction; (3-21-12)

e. The name, strength, dosage form, and quantity of the drug or description of the medical device accessed; and (3-21-12)

f. If applicable, the name of the patient for whom the drug was ordered. (3-21-12)

08. ADS System Used for Tablets or Capsules. The lot number of each drug contained in an ADS system used to store in bulk and to count tablets or capsules for dispensing must be retained in an immediately

retrievable manner or posted on the device. (3-21-12)

09. Prepackaged Bulk Drug Cartridges or Containers. If the ADS system uses removable cartridges or containers to hold bulk drugs, the prepackaging of the cartridges or containers must occur at the pharmacy where the original inventory is maintained unless provided by an FDA-approved repackager that is licensed as a wholesaler. The prepackaged cartridges or containers may be sent to a remote dispensing site to be loaded into the ADS system by a pharmacist or a technician if: (3-21-12)

a. A pharmacist has verified the proper filling and labeling of the cartridge or container; (3-21-12)

b. The individual cartridges or containers are transported to the ADS system in a secure, tamper-evident container; and (3-21-12)

c. The ADS system utilizes technologies to ensure that the cartridges or containers are accurately loaded. (3-21-12)

10. Temperature Sensitive Drugs. Products that are temperature sensitive must not be provided unless the system is able to maintain required storage conditions. (4-4-13)

291. ADS SYSTEMS: SELF-SERVICE SYSTEMS.
The use of self-service ADS systems must comply with the ADS system minimum standards and the requirements of this rule. (4-4-13)

01. System Requirements. (4-4-13)

a. The system must only be operational: (4-4-13)

i. During the operating hours of the pharmacy, or prescriber drug outlet respectively; or (4-4-13)

ii. In a hospital's emergency room if no pharmacist is on duty in the community. (4-4-13)

b. The system must be substantially constructed, utilize adequate security, and be: (4-4-13)

i. Physically attached or immediately adjacent to the interior of the pharmacy in a manner that access to areas used to stock the device are only accessible through the pharmacy; or (4-4-13)

ii. Located within the hospital's emergency room or prescriber drug outlet. (4-4-13)

02. Dispensing Restrictions. (4-4-13)

a. Products requiring additional preparation for patient use must be dispensed by the system directly to a prescriber or registered nurse for subsequent preparation and not dispensed directly to the patient. (4-4-13)

b. A pharmacy system may only dispense drugs or devices that have been previously dispensed to the patient. (4-4-13)

c. Controlled substances are prohibited in a pharmacy or prescriber drug outlet system. (4-4-13)

d. Drugs must be prepackaged for use in hospital emergency room systems and no more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (4-4-13)

e. Hospital emergency room systems must only dispense to hospital emergency room patients. (4-4-13)

f. Hospital emergency room systems vouchers or their equivalent must expire within twenty-four (24)

hours. (4-4-13)

03. Counseling. (4-4-13)

a. When dispensed via a system in a prescriber drug outlet or a hospital's emergency room, a patient must receive counseling prior to receiving drugs or devices that have not been previously dispensed to the patient. (4-4-13)

b. Refilled or renewed drugs dispensed via a system must include written notification of how counseling may be obtained. (4-4-13)

04. Packaging and Labeling. Drugs dispensed via a system must be compliant with the standard prescription drug labeling rule, the prescription drug packaging rule, and other pertinent rules. (4-4-13)

292. ADS SYSTEMS: INSTITUTIONAL FACILITIES.
Institutional facilities utilizing one or more ADS systems must ensure compliance with the ADS system minimum standards and the requirements of this rule. (4-4-13)

01. Product Packaging and Labeling. Except as provided herein, drugs stored in the ADS system must be contained in the manufacturers' sealed, original packages or in prepackaged unit-of-use containers (e.g., unit dose tablet/capsule, tube of ointment, inhaler, etc.) and must be labeled as required by these rules. Exceptions to these packaging requirements include: (3-21-12)

a. Injectable drugs stored in a multi-dose vial (e.g., heparin) from which the drug may be withdrawn into a syringe or other delivery device for single patient use; or (3-21-12)

b. OTC products stored in a manufacturers' sealed, multi-dose container (e.g., antacids, analgesics) from which the drug may be withdrawn and placed into an appropriate container for single patient use. (3-21-12)

02. Pharmacist Review. A pharmacist must review the drug order prior to any removal from the system of a drug intended for immediate patient administration except if: (3-21-12)

a. The system is being used as an after-hours cabinet for drug dispensing in the absence of a pharmacist; (3-21-12)

b. The system is being used in place of an emergency kit; (3-21-12)

c. The system is being used to provide access to emergency drugs and only a quantity sufficient is removed to meet the immediate need of the patient; (3-21-12)

d. The drug is a subsequent dose from a previously reviewed drug order; or (4-4-13)

e. The prescriber controls the drug administration process in procedural areas. (4-4-13)

03. Drug Returns. The ADS system, except a self-service system used in a hospital's emergency room, must provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system. A drug removed from a system but not administered to a patient may be returned as follows if unopened, sealed, intact and stored in compliance with the drug product storage rule to: (4-4-13)

a. The pharmacy, immediately; (4-4-13)

b. The ADS system for immediate reuse by authorized personnel in hospitals utilizing bar code scanning technology at the bedside or the ADS system; (4-4-13)

c. The ADS return bin, until: (4-4-13)

i. Returned to the pharmacy; or (4-4-13)

ii. Returned to the ADS system; or (4-4-13)

d. An alternative, secure storage area until return to the pharmacy or the ADS is feasible only if the drug: (4-4-13)

i. Is too large or bulky to be inserted into the system's return bin; (4-4-13)

ii. Requires refrigeration; or (4-4-13)

iii. Requires immediate accessibility for limited critical patient care. (4-4-13)

04. Wasted Controlled Substances. If wasted before completing the transaction, the system must provide a mechanism for accounting for wasted controlled substances. Waste documentation must include at least the following: (4-4-13)

a. Date and time of transaction; (3-21-12)

b. Patient name and location; (3-21-12)

c. Drug and dose; (3-21-12)

d. Wasted amount; (3-21-12)

e. Authorized user identification; and (4-4-13)

f. Witness identification. (4-4-13)

05. Supervising Pharmacy Identification. If used in a nursing home, the ADS system must be clearly marked with the name, address, and phone number of the supervising pharmacy and pharmacist-in-charge. (3-21-12)

293. VENDING MACHINES.
Only non-prescription medical supplies and drugs that are unrestricted for over-the-counter sale may be stored and sold in vending machines which are subject to inspection by the Board upon reasonable notice. (4-4-13)

294. -- 299. (RESERVED)

Subchapter D -- Professional Practice Standards
(Rules 300 through 599 -- Professional Practice Standards)

300. PIC: QUALIFICATIONS.
A pharmacist may neither be designated nor function as the PIC of a pharmacy unless the designee spends a substantial part of the designee's working time each month at the pharmacy in which designated as the PIC. (3-21-12)

301. PIC: RESPONSIBILITIES.
The PIC is responsible for the management, and must maintain full and complete control, of every part of the pharmacy and its regulated operations. (3-21-12)

302. PIC: REPORTING REQUIREMENTS.

01. PIC Change. Both an outgoing and incoming PIC must report to the Board a change in a PIC designation within ten (10) days of the change. (3-21-12)

02. Annual Personnel Report. Coinciding with the annual renewal of the drug outlet registration, the PIC must annually report on the renewal application the names of the designated PIC, each employee pharmacist and technician, and each student pharmacist currently training in the pharmacy. (3-21-12)

03. Employment Changes. Changes in employment of pharmacists, technicians, or student pharmacists must be reported to the Board by the PIC within ten (10) days of the change. (3-21-12)

303. PHARMACIST: ASSIGNMENT OF FUNCTIONS.

01. Assignment to Licensed or Registered Persons Only. A pharmacist must neither delegate to, nor permit performance by, a person other than a pharmacist, student pharmacist, or technician any function related to pharmacy operations. (3-21-12)

02. Assignment of Functions to a Technician. A pharmacist may assign to and allow performance by a technician only those functions performed in pharmacy operations that meet the following criteria: (3-21-12)

a. The function is routine; (3-21-12)

b. The function is one for which the technician is adequately trained; (3-21-12)

c. The function is performed under a pharmacist's supervision; and (3-21-12)

d. The function does not require the use of a pharmacist's professional judgment. (3-21-12)

03. Pharmacist Supervision. If a student pharmacist or a technician performs one (1) or more functions in connection with pharmacy operations, the student pharmacist or technician must be under the supervision of a pharmacist who, in addition to the pharmacy and the PIC, is responsible for every element of the filled prescription. (3-21-12)

304. -- 309. (RESERVED)

310. COLLABORATIVE PHARMACY PRACTICE AND STATEWIDE PROTOCOL AGREEMENTS.

01. Collaborative Agreement. Pharmacists or pharmacies and prescribers may enter into collaborative pharmacy practice through a written collaborative pharmacy practice agreement that defines the nature and scope of authorized DTM or other patient care services to be provided by a pharmacist. (3-25-16)

a. Agreement Elements. The collaborative pharmacy practice agreement must include: (3-21-12)

i. Identification of the parties to the agreement; (3-21-12)

ii. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; (3-21-12)

iii. The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; (3-21-12)

iv. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; (3-21-12)

v. A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; (3-21-12)

vi. A provision allowing any party to cancel the agreement by written notification; (3-21-12)

vii. An effective date; and (3-21-12)

viii. Signatures of the parties to the agreement and dates of signing. (3-21-12)

ix. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and

dated. (3-21-12)

b. Board Review. The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. (3-21-12)

c. Agreement Review. The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. (3-21-12)

d. Documentation of Pharmacist Activities. The patient care provided pursuant to the agreement must be documented in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. (3-25-16)

02. Statewide Protocol Agreement. A pharmacist may perform DTM or other patient care services according to a statewide protocol agreement issued by the director of the Idaho Department of Health and Welfare, in conjunction with the Board, for the purpose of improving public health. The protocol agreement must include: (3-25-16)

a. An effective date range; (3-25-16)

b. The geographical portion of the state where the protocol agreement is to be effective; and(3-25-16)

c. The drug name, class, or category and protocol, formulary or clinical guidelines that describe or limit a pharmacist's authority to perform DTM or other patient care services. (3-25-16)

311. -- 319. (RESERVED)

320. PHARMACIST: INDEPENDENT PRACTICE.
An Idaho-licensed pharmacist may provide pharmaceutical care services and MTM outside of a drug outlet or institutional facility, including into Idaho, if the following conditions are met, however nothing herein shall be construed to excuse compliance with the rules governing centralized pharmacy services when applicable: (7-1-13)

01. Access to Relevant Information. The pharmacist has access to prescription drug order records, patient profiles, or other relevant medical information and appropriately reviews the information; (3-21-12)

02. Information Protected from Unauthorized Use. Access to the information required by these rules is protected from unauthorized access and use; and (3-21-12)

03. Records Maintained in Electronic Recordkeeping System. The pharmacist maintains the records or other patient-specific information created, collected, or used in an electronic recordkeeping system that complies with the requirements of these rules. (3-21-12)

321. -- 329. (RESERVED)

330. PHARMACIST: ADMINISTERED IMMUNIZATIONS.

01. Patient Eligibility. A pharmacist may administer an immunization to a healthy patient without immunization contraindications pursuant to the latest recommendations by the CDC or other qualified government authority or to any patient pursuant to a prescription drug order issued by another prescriber. (3-21-12)

02. Pharmacist Qualifications. To qualify to administer immunizations, a pharmacist must first: (3-21-12)

a. Successfully complete an ACPE-accredited or comparable course that meets the standards for pediatric, adolescent, and adult immunization practices recommended and approved by the CDC's Advisory Committee on Immunization Practices and includes at least the following: (3-21-12)

i. Basic immunology, vaccine, and immunization protection; (3-21-12)

ii. Diseases that may be prevented by vaccination or immunization; (3-21-12)

iii. Current recommended immunization schedules; (3-21-12)

iv. Vaccine and immunization storage and management; (3-21-12)

v. Informed consent; (3-21-12)

vi. Physiology and techniques for administration of immunizations; (3-21-12)

vii. Pre-immunization and post-immunization assessment and counseling; (3-21-12)

viii. Immunization reporting and records management; and (3-21-12)

ix. Identification response, documentation, and reporting of adverse events. (3-21-12)

b. Hold a current certification in basic life support for healthcare providers offered by the American Heart Association or a comparable Board-recognized certification program that includes cardiopulmonary resuscitation (CPR) and automated electronic defibrillator (AED) training and requires a hands-on skills assessment by an authorized instructor. (3-21-12)

03. Maintaining Qualification. To maintain qualification to administer immunizations, a pharmacist must annually complete a minimum of one (1) CPE hour of ACPE-approved CPE related to vaccines, immunizations, or their administration, which may also be applied to the general CPE requirements of these rules. (4-4-13)

04. Student Pharmacist Administration. A pharmacist may not delegate authority to administer immunizations; however, a student pharmacist who has satisfied the qualifications may administer immunizations under the direct supervision of a qualified immunizing pharmacist. (3-21-12)

05. Waste Disposal. An immunizing pharmacist must properly dispose of used or contaminated supplies. (3-21-12)

06. Required Reports. An immunizing pharmacist must report: (3-21-12)

a. Adverse events to the healthcare provider identified by the patient, if any, and to the Vaccine Adverse Event Reporting System (VAERS); and (3-21-12)

b. Administration of immunizations to the Idaho Immunization Reminder Information System (IRIS), as required. (3-21-12)

07. Required Resources. A pharmacist must have a current copy of, or on-site access to, the CDC's Epidemiology and Prevention of Vaccine-Preventable Diseases. (3-21-12)

08. Vaccine Information Statements. A corresponding, current CDC-issued VIS must be provided to the patient or the patient's representative for each administered immunization. (3-21-12)

09. Recordkeeping. For each administered immunization, the following information must be collected and maintained in the patient profile: (3-21-12)

a. The patient's name, address, date of birth, and known allergies; (3-21-12)

b. The date of administration; (3-21-12)

c. The product name, manufacturer, dose, lot number, and expiration date of the vaccine; (3-21-12)

d. Documentation identifying the VIS provided; (3-21-12)

e. The site and route of administration and, if applicable, the dose in a series (e.g. one (1) of three (3)); (3-21-12)

f. The name of the patient's healthcare provider, if any; (3-21-12)

g. The name of the immunizing pharmacist and of the student pharmacist, if any; (3-21-12)

h. Adverse events observed or reported, if any, and documentation including at least the dates of any subsequent required reporting; and (3-21-12)

i. Completed informed consent forms. (3-21-12)

10. Emergencies. (3-21-12)

a. An immunizing pharmacist must maintain an immediately retrievable emergency kit sufficiently stocked to manage an acute allergic reaction to an immunization. At a minimum, the kit must include: (4-11-15)

i. Intramuscular diphenhydramine; (4-11-15)

ii. Oral diphenhydramine; (4-11-15)

iii. Appropriate needles and syringes for injection; (4-11-15)

iv. Alcohol; and (4-11-15)

v. At least one (1) of the following: (4-11-15)

(1) Auto-inject epinephrine; (4-11-15)

(2) A vial of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14); or (4-11-15)

(3) An ampule of epinephrine with a dosing chart based on average body mass by age for patients under the age of fourteen (14) and filter needles. (4-11-15)

b. An immunizing pharmacist may initiate and administer epinephrine, intramuscular diphenhydramine, or oral diphenhydramine to treat an acute allergic reaction to an immunization pursuant to guidelines issued by the American Pharmacy Association. (4-11-15)

331. -- 339. (RESERVED)

340. NONRESIDENT PHARMACIST PRACTICE STANDARDS.
An Idaho licensed or registered nonresident pharmacist practicing pharmacy into Idaho must comply with the Board's rules and laws of this state unless compliance would violate the laws or rules in the state in which the registrant is located, except as follows: (4-11-15)

01. Pharmacy Technician. A pharmacist must not allow a technician to exceed the practice limitations for a technician in Idaho. (4-11-15)

02. Drug Product Substitution. A pharmacist must only substitute drug products in accordance with Idaho law. (4-11-15)

03. Drug Product Selection. A pharmacist must only select drug products in accordance with Idaho law. (4-11-15)

04. Staffing Ratio. A pharmacist must not exceed the pharmacy staffing ratio, as defined in rule.

(4-11-15)

341. -- 359. (RESERVED)

360. STUDENT PHARMACIST: UTILIZATION AND PRACTICE LIMITATIONS.

01. Activities. A student pharmacist may engage in the practice activities of a pharmacist if: (3-21-12)

a. The activity is not specifically required to be performed only by a pharmacist; (3-21-12)

b. The activity is commensurate with the education and skill of the student pharmacist and performed under the supervision of a pharmacist; (3-21-12)

c. Any activity of a compounding, dispensing, or interpretive nature is checked by a pharmacist; and (3-21-12)

d. Any recording activity that requires the initial or signature of a pharmacist is countersigned by a pharmacist. (3-21-12)

02. Unlawful Acceptance of Assignment. A student pharmacist must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the student pharmacist is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

03. Identification of Student Pharmacists. (3-21-12)

a. Each student pharmacist must be identified by a clearly visible name badge designating the individual as a student pharmacist. The name badge must contain the individual's printed first name and the title of student pharmacist, pharmacist intern, pharmacist extern, or another title that conveys the same meaning. (3-21-12)

b. Student pharmacists must identify themselves as a student pharmacist, pharmacist intern, or pharmacist extern on any phone calls initiated or received while on duty. (3-21-12)

361. -- 399. (RESERVED)

400. TECHNICIAN -- UTILIZATION AND PRACTICE LIMITATIONS.

01. Unlawful Acceptance of Assignment. A technician must not accept assignment of, or perform, any task or function connected with pharmacy operations unless the technician is authorized by the assigning pharmacist and the task or function meets the criteria set forth in this rule. (3-21-12)

02. Unlawful Performance. A technician must not perform tasks or functions connected with pharmacy operations that: (3-21-12)

a. Are not routine; (3-21-12)

b. The technician is not adequately trained to perform; (3-21-12)

c. The technician has inadequate pharmacist supervision to perform; or (3-21-12)

d. Requires the use of a pharmacist's professional judgment. (3-21-12)

03. Prohibited Tasks or Functions by a Technician. A technician must not do any of the following which, without limiting the scope of the term "professional judgment," is a non-exclusive list of actions requiring a pharmacist's professional judgment: (3-21-12)

a. Receive a new verbal prescription drug order from a prescriber or other person authorized by law and, either manually or electronically, reduce the order to writing; (3-21-12)

b. Consult with the prescriber prior to filling if clarification of information is needed regarding a patient or the prescription drug order; (3-21-12)

c. Perform prospective drug review or interpret clinical data in a patient's medication record (e.g., contraindications, drug interactions, etc.); (3-21-12)

d. Perform professional consultation with a prescriber, nurse, or other healthcare professional; (3-21-12)

e. Supervise the packaging of drugs and check the completed procedure and product, unless checked in compliance with the verification technician procedures allowed in institutional facilities; (3-21-12)

f. Provide patient consultation on a new or refilled prescription or on over-the-counter drugs or supplements; and (3-21-12)

g. Supervise the pharmacy operations activities of student pharmacists and technicians. (3-21-12)

04. Technician Identification. (3-21-12)

a. Each technician must be identified by a clearly visible name badge designating the individual as a technician. The name badge must contain the individual's printed first name and the title of technician. (3-21-12)

b. Technicians must identify themselves as a technician on any phone calls initiated or received while on duty. (3-21-12)

401. -- 409. (RESERVED)

410. VERIFICATION TECHNICIAN PROGRAM.
Only **i**nstitutional pharmacies located within acute care hospitals may utilize a verification technician program. A verification technician program allows qualified technicians to verify the work of other technicians in the filling of floor and ward stock and unit dose distribution systems for patients whose orders have previously been reviewed and approved by a pharmacist. (3-21-12)

01. Written Program Filing. Prior to initiating a verification technician program, an institutional pharmacy must prepare a written program description that includes at least the following: (3-21-12)

a. The name of the pharmacist assigned as the coordinator of the verification technician program; (3-21-12)

b. A description of the duties of the coordinator sufficient to ensure and demonstrate compliance by the institutional pharmacy with these verification technician program rules; (3-21-12)

c. A description of the duties of technicians designated to perform the functions of verifying the work of other technicians; (3-21-12)

d. Identification of the types of drugs verification technicians are authorized to verify; (3-21-12)

e. A description of the specialized and advanced training that must be provided to each verification technician; and (3-21-12)

f. A description of the monitoring and evaluation processes used by the institutional pharmacy to ensure the ongoing competency of each verification technician. (3-21-12)

02. Program Requirements. Each institutional pharmacy utilizing a verification technician program must comply with the following requirements: (3-21-12)

a. A technician must neither be designated to perform, nor may the technician perform, verification functions without competently completing the required training. (3-21-12)

b. A verification technician may verify only manufacturer prepared or robotically prepared unit dose drugs identified in the written program description for floor or ward stock or unit dose distribution systems of pharmacist reviewed and approved drug orders for hospital patients. If either the alteration of a unit dose or the combination of unit doses is required, a pharmacist must verify the resulting unit dose alteration or combination of unit doses. (3-21-12)

c. The institutional pharmacy must conduct ongoing monitoring and evaluation of each verification technician to ensure the ongoing competency of the technician. (3-21-12)

d. For each verification technician, an institutional pharmacy utilizing a verification technician program must maintain records containing: (3-21-12)

i. The date the technician was designated; (3-21-12)

ii. The date the technician completed the required training; (3-21-12)

iii. The dates and results of each competency evaluation; and (3-21-12)

iv. The dates of, and reasons for, any suspension or revocation of the technician's designation or other disciplinary action against the verification technician connected with the performance of the technician's duties in the verification technician program. (3-21-12)

e. While on duty, each verification technician must wear identification that includes the title, "Verification Technician." (3-21-12)

f. The duties of the verification technician program coordinator must include the supervision of verification technicians to ensure their duties are performed competently in a manner that protects patient safety. (3-21-12)

411. -- 499. (RESERVED)

500. UNPROFESSIONAL CONDUCT.
The following acts or practices by a pharmacist, student pharmacist, or technician are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. (3-21-12)

01. Unethical Conduct. Conduct in the practice of pharmacy or in the operation of a pharmacy that may reduce the public confidence in the ability and integrity of the profession of pharmacy or endangers the public health, safety, and welfare. A violation of this section includes committing fraud, misrepresentation, negligence, concealment, or being involved in dishonest dealings, price fixing, or breaching the public trust with respect to the practice of pharmacy. (3-21-12)

02. Lack of Fitness. A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, physical or mental illness, or for any other cause that endangers public health, safety, or welfare. (3-21-12)

03. On-Duty Intoxication or Impairment. Intoxication, impairment, or consumption of alcohol or drugs while on duty, including break periods after which the individual is expected to return to work, or prior to reporting to work. (3-21-12)

04. Diversion of Drug Products and Devices. Supplying or diverting drugs, biologicals, and other medicines, substances, or devices legally sold in pharmacies that allows the circumvention of laws pertaining to the legal sale of these articles. (3-21-12)

05. Unlawful Possession or Use of Drugs. Possessing or using a controlled substance without a lawful

prescription drug order. A failed drug test creates a rebuttable presumption of a violation of this rule. (3-21-12)

06. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. (4-4-13)

07. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate or filling a prescription if necessary components of the prescription drug order are missing or questionable. (3-21-12)

08. Excessive Provision of Controlled Substances. Providing a clearly excessive amount of controlled substances. Evidentiary factors of a clearly excessive amount include, but are not limited to, the amount of controlled substances furnished and previous ordering patterns (including size and frequency of orders). (3-21-12)

09. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. The failure to retain appropriate documentation evidencing compliance with patient counseling requirements creates a rebuttable presumption of a violation of this rule. (3-21-12)

10. Substandard, Misbranded, or Adulterated Products. Manufacturing, compounding, delivering, dispensing, or permitting to be manufactured, compounded, delivered, or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. (3-21-12)

11. Prescriber Incentives. Allowing a commission or rebate to be paid, or personally paying a commission or rebate, to a person writing, making, or otherwise ordering a prescription. (3-21-12)

12. Exclusive Arrangements. Participation in a plan or agreement that compromises the quality or extent of professional services or limits access to provider facilities at the expense of public health or welfare. (3-21-12)

13. Failure to Report. Failing to report to the Board any violation of statutes or rules pertaining to the practice of pharmacy or any act that endangers the health, safety, or welfare of patients or the public. (3-21-12)

14. Failure to Follow Board Order. Failure to follow an order of the Board. (3-21-12)

501. GROUNDS FOR DISCIPLINE.
The Board may refuse to issue or renew or may suspend, revoke, or restrict the registration of an individual on one (1) or more of the grounds provided in section 54-1726, Idaho Code. (3-21-12)

502. USE OF FALSE INFORMATION PROHIBITED.
Use of false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product is prohibited. (3-21-12)

503. PRESCRIPTION DELIVERY RESTRICTIONS.
A pharmacist must not participate in any arrangement or agreement whereby filled prescriptions may be left at, picked up from, accepted by, or delivered to any place of business not registered as a pharmacy except that a pharmacist or a pharmacy, by means of its agent, may deliver filled prescriptions to the patient, the patient's residence, the hospital or other institutional facility in which the patient is convalescing, the correctional facility in which a patient is housed, or if a non-controlled substance, to the patient's licensed or registered healthcare provider. (4-4-13)

504. UNLAWFUL ADVERTISING.

01. Unlawful Advertising or Inducements. A licensee or registrant may not promote or induce, directly or indirectly, the provision of professional services or products through the dissemination of a public communication that contains a false, misleading, or deceptive statement or claim. (3-21-12)

02. Advertising Controlled Substances Prohibited. A person must not advertise to the public controlled substances, Schedules I through V, in any manner, and a pharmacy must not display these products to their

patrons or members of the public. (3-21-12)

505. -- 599. (RESERVED)

Subchapter E -- Drug Outlet Practice Standards
(Rules 600 through 699 -- Drug Outlet Practice Standards)

600. PIC OR DIRECTOR.

01. Designated PIC or Director Required. A new pharmacy, outsourcing facility or central drug outlet must have a designated PIC or director by the date of opening and must not thereafter allow a vacancy or lapse in appointment of a designated PIC or director to continue for more than thirty (30) sequential days. (4-6-15)

02. Corresponding and Individual Responsibility. The pharmacy, outsourcing facility or central drug outlet and the PIC or director each have corresponding and individual responsibility for compliance with the law and these rules in all aspects of the sale and the dispensing of drugs, devices, and other materials at the drug outlet, including the safe, accurate, secure, and confidential handling and storage and the preparation, compounding, distributing, or dispensing of drugs and PHI. (4-6-15)

601. PHARMACY SPACE AND FIXTURES.

01. Preparation Area Standards. A pharmacy must be well-lit, ventilated, temperature controlled, and have sufficient floor and counter space to avoid overcrowding and to allow the pharmacy to be maintained in a clean and sanitary condition appropriate for the safe preparation and compounding of prescriptions. (3-21-12)

02. Equipment and Fixture Standards. A pharmacy must be equipped with a sink with hot and cold water, appropriate fixtures for waste disposal, and refrigerated storage equipment of reasonable capacity. (3-21-12)

03. Additional Retail Pharmacy Requirements. A retail pharmacy that is new or remodeled after the effective date of this rule must: (3-21-12)

a. Provide and maintain a patient consultation area that affords the patient auditory and visual privacy, is accessible through an entrance and exit that does not require the patient to enter or traverse any part of the secured area of the pharmacy, and is compliant with the Americans with Disabilities Act; and (4-4-13)

b. Include a lavatory facility in the pharmacy restricted to pharmacy staff. (3-21-12)

602. PHARMACY TECHNICAL EQUIPMENT.

01. Technical Equipment. A pharmacy must have appropriate technical equipment to maintain the electronic recordkeeping requirements of these rules and any additional equipment and supplies required by its scope of practice to ensure public safety. (3-21-12)

02. PHI Transmission Equipment Location. A non-institutional pharmacy that uses a fax machine or other equipment to electronically send or receive PHI must locate and maintain the equipment within the secured pharmacy. (3-21-12)

03. Separate Telephone. Pharmacies remodeled or constructed after the effective date of this rule must have a separate and distinct telephone line from that of the business that must not be answerable by non-pharmacy personnel. If a pharmacy uses an automatic answering system, messages must not be retrieved or pharmacy services performed by non-pharmacy personnel. (4-4-13)

603. PHARMACY REFERENCES.
Required pharmacy references include the latest hard copy or electronic editions and supplements of the following: (3-21-12)

01. Pharmacy Laws and Rules. Idaho Pharmacy Laws and Rules. (3-21-12)

02. **Current Pharmacy Reference**. One (1) of the following current pharmacy references: (3-21-12)

a. Facts and Comparisons; (3-21-12)

b. Clinical Pharmacology; (3-21-12)

c. Micromedex; or (3-21-12)

d. Lexicomp. (3-21-12)

03. **Additional Current Pharmacy Reference**. One (1) additional current pharmacy reference relevant to the practice setting. (3-21-12)

604. PHARMACY PRODUCT STORAGE AND REMOVAL.
Prescription drugs, devices, and other products restricted to sale or dispensing by, or under the supervision of, a pharmacist must be stored in the pharmacy and must not be sold, delivered, or otherwise removed from a pharmacy unless a pharmacist is present, except: (3-20-14)

01. **Emergency Drug Access and Pharmacist Absence**. As allowed by these rules for emergency access to an institutional pharmacy; (3-20-14)

02. **Institutional Facility Alternative Storage**. In an institutional facility these restricted products may also be stored in an alternative designated area that is appropriately equipped to ensure compliance with drug product storage requirements, to provide adequate security and protection from diversion, and that otherwise complies with applicable requirements of these rules; (3-20-14)

03. **Storage for Delivery**. Filled prescriptions may be picked up for delivery from a pharmacy when the pharmacy is closed for business if: (3-20-14)

a. The prescriptions are placed in a secured delivery area equipped with adequate security, including an alarm or comparable monitoring system, to prevent unauthorized entry, theft and diversion; (3-20-14)

b. The secured delivery area has walls that extend to the roof and solid core or metal doors, and all doors and other access points must be equipped with locking devices and be constructed in a manner so that the hinge hardware is tamper-proof when closed; (4-11-15)

c. The secured delivery area appropriately safeguards product integrity in accordance with USP-NF requirements; (3-20-14)

d. The secured delivery area is attached or located adjacent to the pharmacy that filled the prescriptions; (3-20-14)

e. The PIC, or a pharmacist designated by the PIC, and the approved transport agent solely have access to the secure delivery area. Two (2) factor credentialing is required for entry, which must include two (2) of the following: (3-20-14)

i. Something known (a knowledge factor); (4-11-15)

ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)

iii. Something biometric (fingerprint, retinal scan, etc.); (4-11-15)

f. The pharmacy has a means of recording the time of entry and the identity of all persons who access the secured delivery area; (3-20-14)

g. The pharmacy maintains immediately retrievable records of all persons who have accessed the secured delivery area and each prescription stored and removed for delivery; (3-20-14)

h. The pharmacy maintains written policies and procedures for secured delivery area storage and removal of prescriptions; and (3-20-14)

i. The PIC of a pharmacy that ships drugs by common carrier must require the common carrier to conduct criminal background checks on its employees who have access to the secured delivery area. (3-20-14)

04. Qualified Returns to the Secured Delivery Area. A pharmacist or a pharmacy, by means of its agent, may accept the return of the following drugs or devices to the secured delivery area: (3-20-14)

a. Emergency kits; (3-20-14)

b. Prescriptions that were unsuccessfully delivered by the pharmacy, a pharmacist, or its agent; and (3-20-14)

c. Those deemed qualified for return pursuant to the Restricted Return of Drugs or Devices rule. (3-20-14)

605. PHARMACY SECURITY.
A pharmacy must be constructed and equipped with adequate security to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. New construction or a remodeled pharmacy must meet the following minimum security requirements: (4-11-15)

01. Alarm. At least while closed an alarm or other comparable monitoring system is required. (4-11-15)

02. Walls. Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

03. Doors. Solid core or metal doors are required. (4-11-15)

04. Hinges and Locks. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

05. Differential Hours. When closed for business, a pharmacy must be: (4-11-15)

a. Completely enclosed in a manner sufficient to provide adequate security; or (4-11-15)

b. Located within a larger business establishment that is also closed. In such cases, the establishment must meet these minimum security requirements, and no person is allowed entry to the establishment unless a pharmacist is present. (4-11-15)

06. Drop Box. If used, a "drop box" or "mail slot" allowing delivery of prescription drug orders to the pharmacy during hours closed must be appropriately secured against theft, and the pharmacy hours must be prominently visible to the person depositing the prescription drug order. Prescriptions must not be accepted for delivery to the pharmacy or for depositing in the drop box by non-pharmacy employees of a retail establishment. (4-11-15)

606. PHARMACY NOTIFICATION AND ADVERTISING OF HOURS OPEN FOR BUSINESS.

01. Notification of Business Hours. A pharmacy must notify the Board and prominently display the hours open to the public for business, if applicable, on or adjacent to its entrance and the entrance of the business establishment in which it is located if the open hours are different. (3-21-12)

02. Notification of Change of Business Hours. The Board and the public must be notified of changes

to the hours that a pharmacy is open to the public for business, including changes resulting in differential hours, at least seven (7) days prior to the change except changes of hours in recognition of state holidays set forth in Section 73-108, Idaho Code. A change of hours for a holiday must be prominently posted for public notice at least seven (7) days in advance. (4-4-13)

607. PHARMACY STAFFING AND RATIO.

01. Staffing. A pharmacy must be staffed sufficiently to allow for appropriate supervision, to otherwise operate in compliance with the law, and if applicable, to remain open during the hours posted as open to the public for business. (3-21-12)

02. Ratio. The ratio of pharmacists to student pharmacists and technicians may not exceed one (1) pharmacist for every six (6) student pharmacists and technicians in total in any practice setting. A pharmacist must not operate a pharmacy, allow the operation of a pharmacy, or be required to operate a pharmacy with a ratio that results in, or would reasonably be expected to result in, an unreasonable risk of harm to public health, safety, or welfare. (3-21-12)

608. PHARMACY STRUCTURAL REMODEL APPROVAL.
Prior to the commencement of structural remodeling that impacts the periphery or security of an existing pharmacy, a floor plan must be submitted to, and approved by, the Board. The prescription preparation area (including the patient consultation, merchandising, and waiting areas, if applicable), storeroom, restroom, partitions (including, but not limited to, walls, doors, and windows), trade fixtures, and appropriate elevations must be indicated on the submitted floor plan. (3-21-12)

609. PHARMACY CHANGE OF OWNERSHIP OR PERMANENT CLOSING.

01. Board Notification. The registrant must notify the Board of a pharmacy's change of ownership or permanent closure at least ten (10) days prior to the event. The notice must include: (3-21-12)

a. The name and address of the pharmacy to be sold or closed; (3-21-12)

b. The date of sale or closure; (3-21-12)

c. The name and address of the business acquiring the prescription inventory; and (3-21-12)

d. The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. (3-21-12)

02. Public Notice. A registrant must notify the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the date of closure and the new location of the prescription files. Notice must be provided by prominent posting in a public area of the pharmacy. (3-21-12)

03. Pharmacy Signs. Unless sold and transferred to another pharmacy operator, a registrant must remove or completely cover each sign and other exterior indication that the premises was a pharmacy within thirty (30) days after the date a pharmacy permanently ceases operations. (3-21-12)

04. Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must: (4-4-13)

a. Adequately secure and protect the prescription files from unlawful use or disclosure; (4-4-13)

b. Secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition; and (4-4-13)

c. Retain a closing inventory of controlled substances. (4-4-13)

05. Pharmacy Change of Ownership. A change of ownership of a currently registered pharmacy will

require the submission and approval of a new pharmacy registration application but will not require an onsite inspection prior to issuance of a pharmacy registration unless structural remodeling occurs. (3-21-12)

610. CENTRALIZED PHARMACY SERVICES.
A pharmacy may centralize pharmacy services if: (7-1-13)

01. Written Contract. The originating pharmacy has a written contract with the central drug outlet or central pharmacist outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or the two (2) are jointly owned; (7-1-13)

02. Training. The central drug outlet or central pharmacist provides a training and orientation program that ensures the pharmacists who are providing centralized pharmacy services are competent to perform such services; (7-1-13)

03. Communication. Appropriate communications exist to allow the central drug outlet or central pharmacist to readily communicate with prescribers, the institutional facility, or the originating pharmacy; (7-1-13)

04. Secure Common Electronic File. The parties share a secure common electronic file or utilize other secure technology, including a private, encrypted connection, that allows access by the central drug outlet or central pharmacist to information required to perform centralized pharmacy services; (7-1-13)

05. Continuous Quality Improvement Program. The parties implement and maintain a quality improvement program designated to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems; (7-1-13)

06. Audit Trail Documentation. The central drug outlet or central pharmacist maintains an electronic recordkeeping system that must have audit trail functionality that documents for each prescription drug order the identity and location of each individual involved in each step of the centralized pharmacy services; (7-1-13)

07. Privacy. The parties demonstrate adequate security to protect the privacy of PHI and the centralized pharmacy services are performed from a secure area that is restricted to authorized personnel; (7-1-13)

08. Policies and Procedures. The parties adopt policies and procedures that are sufficiently detailed to ensure compliance with pertinent federal and Idaho law and protect public health, safety and welfare. (7-1-13)

09. Location. Centralized pharmacy services must be performed from a pharmacy, central drug outlet, or remote office location. (7-1-13)

10. Exemption. A single prescription drug order may be shared by an originating pharmacy and a central drug outlet or central pharmacist. The filling, processing and delivery of a prescription drug order by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription or as a wholesale distribution. (7-1-13)

611. PHARMACY AUTHORIZED ENTRY.

01. Open Pharmacy. A person other than a pharmacist, student pharmacist, or technician must not enter or work in the secured pharmacy, except that a pharmacist may authorize other persons to be present temporarily in the pharmacy for legitimate business purposes if under the direct supervision of a pharmacist at all times. (4-11-15)

02. Closed Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist. (4-11-15)

03. Non-Institutional Temporary Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except: (4-11-15)

a. If a technician or student pharmacist is on duty to allow brief pharmacist absences within the business establishment; or (4-11-15)

b. When a pharmacist performs professional services in the peripheral areas immediately outside of the pharmacy. (4-11-15)

04. Institutional Pharmacy Temporary Pharmacist Absence. To accommodate periods of temporary absence of a pharmacist from the institutional pharmacy, pharmacy students and technicians may remain within the pharmacy under the following conditions: (4-11-15)

a. No other person may be allowed access or entrance to the pharmacy; (4-11-15)

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and (4-11-15)

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. (4-11-15)

612. -- 614. (RESERVED)

615. DRUG DISTRIBUTION.

01. Authorized Distributors. The following drug outlets may distribute legend drugs in or into Idaho, in compliance with these rules, pursuant to the following restrictions: (4-11-15)

a. A licensed or registered wholesale distributor and a registered manufacturer in compliance with the Idaho Wholesale Distribution Act and the Idaho Pharmacy Act; (4-11-15)

b. An FDA and Idaho registered outsourcing facility in compliance with 21 U.S.C. Section 353b of the Food, Drug and Cosmetic Act; (4-11-15)

c. A dispenser without being licensed or registered as a wholesale distributor according to the following restrictions: (4-11-15)

i. A dispenser may distribute to authorized recipients for an emergency medical purpose in which an alternative source for a drug is not reasonably available in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining a drug. The amount of the drug distributed in an emergency must not reasonably exceed the amount required for immediate use; (4-11-15)

ii. A dispenser may distribute intracompany to any division, subsidiary, parent, affiliated or related company under common ownership and control of a corporate entity; (4-11-15)

iii. A pharmacy may distribute to another pharmacy pursuant to a sale, transfer, merger or consolidation of all or a part of a pharmacy, whether accomplished as a sale of stock or business assets; (4-11-15)

iv. A pharmacy may distribute compound positron emission tomography drugs or radiopharmaceutics, if in compliance with applicable federal law; and (4-11-15)

v. A pharmacy may distribute minimal quantities of prescription drugs to a prescriber for in-office administration, including the distribution of compounded drug product in the absence of a patient specific prescription drug order if: (4-11-15)

(1) The compounded drug product is not sterile and not intended to be sterile; (4-11-15)

(2) The compounded drug product is not further dispensed or distributed by the practitioner; and (4-11-15)

(3) The quantity of compounded drug product distributed is limited to five percent (5%) of the total number of compounded drug products dispensed and distributed on an annual basis by the pharmacy, which may include a drug compounded for the purpose of, or incident to, research, teaching or chemical analysis. (4-11-15)

02. Distribution. An authorized distributor must furnish: (4-11-15)

a. Drug product only to a person licensed by the appropriate state licensing agency to dispense, conduct research with or independently administer such drugs; (4-11-15)

b. Scheduled controlled substances only to a person who has been issued a valid controlled substance registration by the DEA and the Board, unless exempt by state or federal law; (4-11-15)

c. Federally required transaction documentation, including transaction information, transaction history, and transaction statements with each distribution; and (4-11-15)

d. Drug product only to the premises listed on the authorized receiving person's license or registration. Delivery to a hospital pharmacy receiving area satisfies this requirement, provided that authorized receiving personnel sign for receipt at the time of delivery. (4-11-15)

03. Controlled Substance Distribution Invoice. Distributions must be pursuant to an invoice and not a prescription drug order. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: (4-11-15)

a. The date of the transaction; (4-11-15)

b. The name, address, and DEA registration number of the distributing dispenser; (4-11-15)

c. The name, address, and DEA registration number or the receiving dispenser; (4-11-15)

d. The drug name, strength, and quantity for each product distributed; and (4-11-15)

e. The signature of the person receiving the drugs. (4-11-15)

04. Monitoring Purchase Activity. An authorized distributor must have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that identify potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, and orders of unusual frequency. (4-11-15)

05. Reporting. An authorized distributor must report specified data on controlled substances distributed at least monthly to the Board in a form and manner prescribed by the Board, except when distributing intracompany. (4-11-15)

06. Prohibited Acts. The following acts are prohibited: (4-11-15)

a. Distribution of any drug product that is adulterated, misbranded, counterfeit, expired, damaged, recalled, stolen, or obtained by fraud or deceit; and (4-11-15)

b. Failing to obtain a license or registration when one is required to distribute in or into Idaho. (4-11-15)

616. – 619. (RESERVED)

620. INSTITUTIONAL FACILITY: PRACTICE OF PHARMACY AND ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
These institutional facility rules are applicable to the practice of pharmacy and the administration and control of drugs and devices by institutional facilities or by persons employed by them. (3-25-16)

621. INSTITUTIONAL FACILITY: WITH ONSITE PHARMACY -- MINIMUM RESPONSIBILITIES.

01. Institutional Pharmacy Staffing. The director must be assisted by a sufficient number of additional pharmacists, student pharmacists, and technicians as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients of the facility. (3-21-12)

02. Inventory Management. The professional staff of the institutional facility must cooperate with the director to manage the responsibilities of ordering, administering, and accounting for drugs, devices, and other pharmaceutical materials. (3-21-12)

03. Prescribers Authorized by Institutional Facility. The institutional facility must designate and notify the pharmacy of the prescribers authorized to issue drug orders for facility patients. (3-21-12)

04. Approved Use of Abbreviations and Chemical Symbols. A listing of acceptable, or alternatively unacceptable, abbreviations and chemical symbols used by prescribers on drug orders must be developed and distributed by the appropriate committee of the institutional facility. (3-21-12)

05. Director Participation in Patient Care Evaluation Program. The director must participate in the aspects of the institutional facility's patient care evaluation program that relate to pharmaceutical utilization and effectiveness. (3-21-12)

622. INSTITUTIONAL PHARMACY: DIRECTOR: MINIMUM RESPONSIBILITIES.
Each institutional pharmacy must be supervised and directed by an Idaho-licensed pharmacist (referred to herein as "the director") who is knowledgeable in, and thoroughly familiar with, the specialized functions of institutional pharmacies. The director is responsible for ensuring compliance with applicable law and for each activity of the institutional pharmacy, including at least the following: (3-21-12)

01. Policies and Procedures. In coordination with the appropriate institutional facility personnel, the adoption of policies and procedures with sufficient specificity regarding the handling, storage, and dispensing of drugs within the institution to protect public health and safety and ensure compliance with these rules and other applicable law. (3-21-12)

02. Formulary or Drug List Development. The participation in any development of a formulary or drug list for the facility. (3-21-12)

03. Product Procurement. The procurement of drugs, chemicals, biologicals, devices, or other products used by the institutional facility for patient pharmaceutical care services or for which a drug order is required. (3-21-12)

04. Drug Use, Storage, and Accountability. The safe and efficient dispensing, distribution, control, and secured storage of, and accountability for, drugs within the facility, including at least the following: (3-21-12)

a. Ensuring that drugs stored within the institutional pharmacy or in alternative secured storage areas have proper sanitation, temperature, light, ventilation, moisture control, segregation and security; (3-21-12)

b. Ensuring that outdated or other unusable drugs are identified and stored in a manner that prevents their distribution or administration prior to disposition; (3-21-12)

c. Ensuring that emergency drugs are in adequate and proper supply at designated locations; (3-21-12)

d. Ensuring that requirements applicable to the purchasing, storing, distribution, dispensing, recordkeeping, and disposal of controlled substances are met throughout the institution, including but not limited to, ensuring that controlled substances stored in surgery or emergency departments, nursing stations, ambulatory clinics, diagnostic laboratories or other locations outside of the pharmacy are inaccessible to unauthorized personnel; (3-21-12)

e. Ensuring accurate filling and labeling of containers from which drugs are to be administered or dispensed; (3-21-12)

f. Ensuring appropriate admixture of parenteral products, including serving in an advisory capacity for nursing personnel concerning incompatibility and the provision of proper incompatibility information; and (3-21-12)

g. Ensuring appropriate provision and maintenance, in both the pharmacy and patient care areas, of a sufficient inventory of antidotes and other emergency drugs, current antidote information, telephone numbers of regional poison control centers and other emergency assistance organizations, and other materials and information determined necessary by the appropriate institutional facility personnel. (3-21-12)

05. Emergency Drug Access Protocol. In coordination with the appropriate institutional facility personnel, the development of an emergency drug access protocol and related training of R.N.s to ensure appropriate knowledge of the proper methods of access, removal of drugs, documentation, and other required procedures prior to the R.N.'s designation for access to emergency drug supplies. (3-21-12)

06. Suspected Adverse Drug Reaction Reporting. The reporting in a timely manner of a suspected adverse drug reaction to the ordering physician and to the appropriate institutional facility personnel. The director may use discretion and, if deemed necessary or advisable for public health or safety, report a suspected reaction to others such as MedWatch, the manufacturer, and the USP. (3-21-12)

07. Records Maintenance. The maintenance of records of institutional pharmacy transactions required by law. (3-21-12)

08. Teaching, Research, and Patient Care Evaluation Programs. The cooperation with any teaching and research programs and the participation in any patient care evaluation programs relating to pharmaceutical utilization and effectiveness within the institutional facility. (3-21-12)

09. Continuous Quality Improvement Program. The development and implementation of a continuous quality improvement program to review and evaluate pharmaceutical services and recommend improvements. (3-21-12)

10. Director Change. Both an outgoing and incoming director must report to the Board a change in the institutional pharmacy director within ten (10) days of the change. (4-4-13)

623. -- 629. (RESERVED)

630. INSTITUTIONAL FACILITY: GENERAL STANDARDS FOR ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.
Within an institutional facility, drugs and devices may be dispensed for administration to, or for self-administration or use by, a patient only as permitted by applicable law and these rules consistent with usual and customary standards of good medical practice: (3-25-16)

01, Drugs and Devices Dispensed for Administration Within an Institutional Facility. Drugs and devices must only be dispensed to inpatients of an institutional facility: (3-25-16)

a. Upon the drug orders of licensed facility prescribers; (3-21-12)

b. Pursuant to an emergency protocol for the administration of drugs without an order in life or death situations; or (3-25-16)

c. For self-administration or use if specifically authorized by the treating or ordering prescriber, the patient has been appropriately educated and trained to perform self-administration, and there is no risk of harm. (3-25-16)

02. Drugs and Devices Dispensed for Administration or Use Outside an Institutional Facility. A drug or device prepared for self-administration or use by a patient while outside the confines of the institutional facility must comply with the standard prescription drug labeling requirements, subject to the following: (3-25-16)

a. Permissible dispensing; (3-25-16)

i. In limited quantities and reasonable time duration as a continuation of or supplemental to treatment that was administered at the hospital to the following: (3-25-16)

(1) To emergency room patients pursuant to these rules; and (3-25-16)

(2) To other outpatients who receive treatment or consultation on the premises; (3-25-16)

ii. To hospital employees, medical staff, and students at the hospital and their dependents, for their own personal use only and not for resale. (3-25-16)

b. Impermissible dispensing; (3-25-16)

i. To former patients, employees, medical staff, students, and their dependents; and (3-25-16)

ii. To walk up customers who have no connection to the hospital. (3-25-16)

03. Controlled Substances Reporting and Documentation. Distribution, dispensing, delivery, or administration of controlled substances within an institutional facility or by facility personnel must be properly and adequately documented and reported in the time and manner required by the appropriate committee of the institutional facility and the director. (3-21-12)

04. Patient's Personal Drug Supplies. If an admitted patient brings a drug into the institutional facility, the drug must not be administered or used except pursuant to a drug order and only if it can be precisely identified and the quantity and quality of the drug visually evaluated by a pharmacist. (3-21-12)

a. If a patient's drug will not be administered or used, the pharmacy must package, seal, and return the drug to an adult member of the patient's immediate family or store and return it to the patient upon discharge. (3-21-12)

b. Drugs not returned to the patient or the patient's family may be disposed of after a reasonable number of days following discharge or death. (3-21-12)

05. Suspected Adverse Drug Reaction Reporting. Suspected adverse drug reactions must be communicated in a timely manner to the pharmacy. (3-21-12)

06. Required Pharmacy Returns. Discontinued, expired, and damaged drugs and containers with worn, illegible, or missing labels must be returned to the pharmacy for proper handling. (3-21-12)

631. INSTITUTIONAL FACILITY: EMERGENCY DRUG ACCESS.
The director must make advance arrangements necessary to facilitate continuity of patient care and for the provision of drugs to the medical staff and other authorized personnel of the institutional facility in emergencies and during the absences of a pharmacist in compliance with this rule. (4-11-15)

01. Emergency Pharmacy Access. If a drug is unavailable from any other authorized emergency source in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug and in the absence of a pharmacist from the premises of the institutional facility, it may be retrieved from an institutional pharmacy by an R.N. as follows: (3-21-12)

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; (3-21-12)

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate

means to prevent unauthorized access; and (3-21-12)

c. Only a non-controlled substance may be removed and only in an amount necessary to treat a patient's immediate need until the pharmacy is again attended by a pharmacist. (3-21-12)

02. Emergency Cabinets. A cabinet or similar enclosure located outside an institutional pharmacy may be used for emergency access of drugs by an R.N. as follows: (3-21-12)

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; and (3-21-12)

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. (3-21-12)

03. Emergency Drug Access. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows: (4-11-15)

a. Removal of a drug must be pursuant to a valid drug order; (3-21-12)

b. Removal of a drug must be documented in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The initials or other unique identifier of the designated nurse. (4-4-13)

c. The removal record and a copy of the drug order must be left conspicuously in the pharmacy, emergency cabinet, or alternative location to facilitate prompt accuracy verification and initialing by a pharmacist. (3-21-12)

632. INSTITUTIONAL FACILITY: EMERGENCY DRUG SUPPLY PREPARATION AND MONITORING.

The director or PIC and the appropriate institutional facility personnel must jointly approve and develop a listing of drugs, by identity and quantity, for inclusion in an emergency cabinet, emergency kit, crash cart, or other similar resource that is specifically approved for use by that type of institutional facility and for delivery to patients receiving emergency treatment. In addition to other applicable provisions of these rules, approved drugs are subject to the following limitations, restrictions, and requirements: (3-21-12)

01. Prepackaged Amounts. The drugs must be prepackaged in amounts sufficient to satisfy immediate therapeutic requirements only, except when delivered in a hospital emergency room consistent with these rules; (4-4-13)

02. Content Labeling. The drugs must be labeled as required by these rules for prepackaged products and with any additional information as may be required to prevent misunderstanding or risk of harm to patients; (3-21-12)

03. Access Documentation. Access to the emergency drugs must be documented by drug orders and, if applicable, proofs of use; (3-21-12)

04. Drug Expiration Monitoring. Drug expiration dates must be monitored and the drugs replaced as needed to ensure the emergency drug supply contains no outdated products; and (3-21-12)

05. Regular Inventory and Inspection. Emergency drug supplies must be regularly inventoried and inspected to ensure that they are properly stored and secured against pilferage or tampering. (3-21-12)

633. INSTITUTIONAL FACILITY: EMERGENCY KITS AND CRASH CARTS -- GENERAL RULES.
Emergency drugs prepared and packaged as required by these rules may be approved for inclusion in emergency kits or crash carts for use by personnel with authority granted by state or federal law to administer prescription drugs. (3-21-12)

01. Storage and Security. Emergency kits or crash carts must be sealed in a tamper-evident manner and stored in limited access areas to prevent unauthorized access and to ensure a proper environment for preservation of the drugs within them. (3-21-12)

02. Exterior Kit Labeling. The exterior of emergency kits must be clearly labeled as an emergency drug kit to be used only in emergencies. Additionally, an immediately retrievable list of the drugs contained therein must include: (3-21-12)

a. The name, strength, and quantity of each drug; (3-21-12)

b. The expiration date of the first expiring drug; and (3-21-12)

c. The name, address, and telephone number of the supplying pharmacist, if applicable. (3-21-12)

03. Drug Removal. Drugs must only be removed from emergency kits or crash carts by persons with authority granted by state or federal law to administer prescription drugs, pursuant to a valid drug order, or by a pharmacist. (3-21-12)

04. Notification of Authorized Use. Whenever an emergency kit or crash cart is opened, the pharmacy must be notified and the kit or cart must restocked and resealed within a reasonable time. (3-21-12)

05. Notification of Unauthorized Use. If an emergency kit or crash cart is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the institutional facility must be promptly notified. (3-21-12)

634. INSTITUTIONAL FACILITY: NURSING HOME EMERGENCY KITS.
In nursing homes without an institutional pharmacy, drugs may be provided by a licensed pharmacy, retained by the facility, in emergency kits located at the facility**.** (3-21-12)

01. Provider Pharmacy Documentation. The nursing home must document the pharmacy retained in writing. (3-21-12)

02. Provider Pharmacy Ownership of Prescription Drug. Prescription drugs included in a nursing home emergency kit must remain the property of, and under the responsibility of, the supplying pharmacy. (3-21-12)

635. HOME HEALTH OR HOSPICE EMERGENCY KITS.
A pharmacy may supply emergency kits for state licensed or Medicare certified home health or hospice agencies, or both, as follows: (3-21-12)

01. Storage and Security. Emergency kits used by home health or hospice agencies must be stored in locked areas suitable for preventing unauthorized access and for ensuring a proper environment for the preservation of the drugs, except that nurses licensed by the Idaho Board of Nursing and employed by state-licensed or Medicare-certified home health or hospice agencies may carry emergency kits on their person while on duty and in the course and scope of their employment for the agency. While not on duty or working within the course and scope of their employment, the nurses must return the emergency kits to a locked storage area. (3-21-12)

02. Prescription Drugs. Prescription drugs included in a home health or hospice agency emergency kit must remain the property of, and under the responsibility of, the Idaho-registered supplying pharmacy. (3-21-12)

03. Controlled Substances. Emergency kits supplied to home health or hospice agencies must not include controlled substances. (3-21-12)

636. INSTITUTIONAL FACILITY: HOSPITAL FLOOR STOCK.
Hospitals may use floor stock drugs if limited to a formulary of drugs and routinely used items developed and approved by the director in coordination with the appropriate institutional facility personnel. (3-21-12)

01. Pharmacist Routine Monitoring. Floor stock drugs must be routinely monitored by a pharmacist to ensure appropriate use and storage. (3-21-12)

02. Prescription Drugs. Prescription drugs included in floor stock must be in unit dose or unit-of-use packaging. (3-21-12)

03. Controlled Substances. For controlled substances included in the floor stock formulary, the director must ensure that: (3-21-12)

a. The floor stock contains appropriate controlled substances that are prepackaged in amounts sufficient for only immediate therapeutic requirements; (3-21-12)

b. Controlled substances maintained as floor stock are accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; (3-21-12)

c. Controlled substances removed from floor stock are documented by appropriate written drug orders and proofs of use, if applicable, and in a record that includes at least: (3-21-12)

i. The patient's name and location; (3-21-12)

ii. The name and strength of the drug; (3-21-12)

iii. The amount; (3-21-12)

iv. The date and time; and (3-21-12)

v. The signature or electronic personal verification of the person delivering the drug; and (3-21-12)

d. Controlled substances are inventoried at least weekly. (3-21-12)

637. INSTITUTIONAL FACILITY: EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.
Drugs may be delivered by an RN to outpatients being treated in a hospital emergency room as follows: (4-4-13)

01. Prerequisites: (4-4-13)

a. In the presence of a prescriber, acting as an agent of that prescriber, or outside the presence of a prescriber, when there is no prescriber present in the hospital in accordance with applicable state and federal law; (4-4-13)

b. Pursuant to a valid drug order issued by a prescriber; (4-4-13)

c. When no pharmacist is on duty in the community; and (4-4-13)

d. When drugs are stored and accessed in accordance with applicable laws and rules. (4-4-13)

02. Limitations. No more than one (1) prepackaged container of the same drug may be delivered unless more than one (1) package is required to sustain the patient until the first available pharmacist is on duty in the community except that the full course of therapy for anti-infective medications may be provided. (3-21-12)

03. Documentation. Delivery must be documented as required by these rules for institutional facility emergency drug access. (4-4-13)

04. Labeling. The institutional pharmacy must prepackage and affix a label to the container with the information required by the standard prescription drug labeling rules, except that blank spaces may be left for the names of the patient and prescriber and directions for use. (4-4-13)

638. -- 639. (RESERVED)

640. INSTITUTIONAL FACILITY: OFFSITE PHARMACY PRACTICE STANDARDS.

01. Offsite Pharmacy Services. If an institutional facility without an institutional pharmacy obtains drugs, devices, or other pharmacy services from outside the institutional facility, arrangements must be made to ensure that the offsite pharmacy provides services with sufficient professionalism, quality, and availability to adequately protect the safety of the patients and properly serve the needs of the facility. (3-21-12)

02. Written Agreement. The arrangements must be made in writing and must, at a minimum, specify that: (3-21-12)

a. An offsite pharmacist will act in the capacity of a part-time director; (3-21-12)

b. For nursing homes, on-call services by a pharmacist will be available at all times; (3-21-12)

c. The pharmacy will provide adequate storage facilities for drugs; and (3-21-12)

d. Drugs housed in an LTCF must be labeled as required by the standard prescription drug labeling rule and, unless maintained in an electronic record, must include a lot number for administration of recalls. (4-4-13)

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY.
A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13)

01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13)

02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13)

03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13)

04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. (7-1-13)

642. -- 649. (RESERVED)

650. INSTITUTIONAL FACILITY: CENTRALIZED PHARMACY SERVICES.
In addition to the rules for centralized pharmacy services, an institutional facility that centralizes pharmacy services must be in compliance with the following rules: (7-1-13)

01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents of the institutional facility or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13)

02. Policies and Procedures. An institutional pharmacy and its contracted central drug outlet or central pharmacist that provides centralized pharmacy services must adopt policies and procedures and retain documentation that evidences at least the following: (7-1-13)

a. A copy of the contract if required by these rules; (7-1-13)

b. Identification of the directors or PICs; (7-1-13)

c. The protocol for ensuring that the central drug outlet maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; (7-1-13)

d. The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central drug outlet or central pharmacist and for maintaining the security of the drugs; (7-1-13)

e. Essential information utilized by the institutional facility, such as its formulary, standard drip concentrations, standard medication administration times, standardized or protocol orders, pharmacokinetic dosing policies, and renal dosing policies, as well as protocols for ensuring timely and complete communication of changes to the information; and (7-1-13)

f. The protocol for the central drug outlet or central pharmacist to perform a review of the patient's profile, including but not limited to performing a prospective drug review. (7-1-13)

651. -- 669. (RESERVED)

670. VDO: OWNER AND MANAGER RESPONSIBILITIES.
Owners and managers of VDOs each have corresponding and individual responsibility for unauthorized drug distribution from, or other unlawful conduct in, the registered outlet and must have sufficient understanding of the regulated activities to detect improper conduct. (3-21-12)

671. VDO: POLICIES AND PROCEDURES.
Owners or managers must adopt policies and procedures for the handling of veterinary drug orders, managing product inventory, and other topics as needed to ensure compliance with applicable law and Board rules. (3-21-12)

672. VDO: REQUIRED REFERENCES.
The current Board rules applicable to the practice setting must also be made readily available to VDTs and other employees of the VDO for reference purposes. (3-21-12)

673. VDO: STAFFING.

01. Sufficient Staffing. VDOs must employ sufficient VDTs to ensure that one (1) VDT is on duty at all times the establishment is open to the public for business. (3-21-12)

02. Notification of Personnel Changes. Notification of VDT personnel changes must be provided to the Board within ten (10) days of the change and must include the names and addresses of both the resigning and the newly hired VDTs. (3-21-12)

674. VDO: DRUG PRODUCT INVENTORY AND MANAGEMENT.

01. Authorized Prescription Drugs. VDOs are authorized to stock, and VDTs are authorized to prepare and deliver, prescription veterinary drugs except the following: (3-21-12)

a. Controlled substances listed in Schedules I through V of either the state or federal Controlled Substances Acts; (3-21-12)

b. Euthanasia drugs or products; (3-21-12)

c. Tranquilizer drugs or products; (3-21-12)

d. Curare, succinylcholine, or other neuromuscular paralyzing drugs; and (3-21-12)

e. General anesthesia drugs or products. (3-21-12)

02. Prescription Drug Storage and Security. Prescription drugs must be separated from other drugs and stored in an area equipped with adequate security to prevent diversion, and only VDTs and authorized government inspectors or agents may have access to prescription drug areas. (3-21-12)

03. Returned Prescription Drugs. Prescription drugs returned to a VDO from a client must be treated as damaged or outdated drugs. Returned drugs may not be returned to stock or dispensed, distributed, or resold. (3-21-12)

04. Product Maintenance. The complete product inventory must be reviewed on at least a semi-annual basis to identify and remove from stock outdated, deteriorated, or damaged products for proper reclamation, destruction, or return. (3-21-12)

675. -- 699. (RESERVED)

Subchapter F -- Limited Service Outlet Practice Standards
(Rules 700 through 799 -- Limited Service Outlet Practice Standards)

700. LIMITED SERVICE PHARMACY.
A limited service outlet with a pharmacy must adopt policies and procedures that are sufficiently detailed to ensure the protection of public health, safety, and welfare and that include at least the following: (3-21-12)

01. Description of Services. A description of the type and method of specialized services to be provided; (3-21-12)

02. Times of Operation. The days and hours of operation; (3-21-12)

03. Drug Information. The types and schedules of drugs to be stored, distributed, or dispensed; and (3-21-12)

04. Equipment and Supplies. The equipment and supplies to be used. (3-21-12)

701. -- 709. (RESERVED)

710. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES.
Pharmacies and pharmacists commencing retail telepharmacy operations with a remote dispensing site after August 23, 2011, must comply with the following requirements: (3-21-12)

01. Telepharmacy Practice Sites and Settings. Prior to engaging in the practice of telepharmacy with a remote dispensing site, the supervising pharmacy must demonstrate that there is limited access to pharmacy services in the community in which the remote site is located. (3-21-12)

a. Information justifying the need for the remote dispensing site must be submitted with the initial registration application. (3-21-12)

b. The Board will consider the availability of pharmacists in the community, the population of the community to be served by the remote dispensing site, and the need for the service. (3-21-12)

c. The remote dispensing site must be located in a medical care facility operating in areas otherwise unable to obtain pharmaceutical care services on a timely basis. (3-21-12)

d. The Board will not approve a remote dispensing site if a retail pharmacy that dispenses

prescriptions to outpatients is located within the same community as the proposed remote dispensing site. (3-21-12)

02. Independent Entity Contract. Unless jointly owned, a supervising pharmacy and a remote dispensing site must enter into a written contract that outlines the services to be provided and the responsibilities and accountability of each party in fulfilling the terms of the contract. (3-21-12)

a. A copy of the contract must be submitted to the Board with the initial registration application and at any time there is a substantial change in a contract term. (3-21-12)

b. The contract must be retained by the supervising pharmacy. (3-21-12)

03. PIC Responsibility. Unless an alternative PIC from the supervising pharmacy is specifically designated in writing, the PIC of the supervising pharmacy is also considered the responsible PIC for the remote dispensing site. (3-21-12)

04. Remote Dispensing Site Limitations. The Board may limit the number of remote dispensing sites under the supervision and management of a single pharmacy. (3-21-12)

05. Technician Staffing. Unless staffed by a pharmacist, a remote dispensing site must be staffed by at least one (1) certified technician with at least two thousand (2,000) hours pharmacy technician experience in Idaho and under the supervision of a pharmacist at the supervising pharmacy at all times that the remote site is open. Supervision does not require the pharmacist to be physically present at the remote dispensing site, but the pharmacist must supervise telepharmacy operations electronically from the supervising pharmacy. (3-24-16)

06. Common Electronic Recordkeeping System. The remote dispensing site and the supervising pharmacy must utilize a common electronic recordkeeping system that must be capable of the following: (3-21-12)

a. Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site; and (3-21-12)

b. Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed from the supervising pharmacy. (3-21-12)

07. Records Maintenance. Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, federal law. (3-21-12)

08. Video and Audio Communication Systems. A supervising pharmacy of an ADS system used in a remote dispensing site must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site personnel and consumers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or delivery of drugs. The remote dispensing site must retain a recording of such video and audio surveillance for a minimum of ninety (90) days. (4-11-15)

a. Adequate supervision by the pharmacist in this setting is maintaining constant visual supervision and auditory communication with the site and full supervisory control of the automated system that must not be delegated to another person or entity. (3-21-12)

b. Video monitors used for the proper identification and communication with persons receiving prescription drugs must be a minimum of twelve inches (12") wide and provided at both the pharmacy and the remote location for direct visual contact between the pharmacist and the patient or the patient's agent. (3-21-12)

c. Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the remote dispensing site must be, or remain, closed if any component of the communication system is malfunctioning until system corrections or repairs are completed. (3-21-12)

09. Access and Operating Limitations. Unless a pharmacist is present, a remote dispensing site must

not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system must allow for tracking of entries into the remote dispensing site, and the PIC must periodically review the record of entries. (3-21-12)

10. Delivery and Storage of Drugs. If controlled substances are maintained or dispensed from the remote dispensing site, transfers of controlled substances from the supervising pharmacy to the remote dispensing site must comply with applicable state and federal requirements. (3-21-12)

a. Drugs must only be delivered to the remote dispensing site in a sealed container with a list identifying the drugs, drug strength, and quantities included in the container. Drugs must not be delivered to the remote dispensing site unless a technician or pharmacist is present to accept delivery and verify that the drugs sent were actually received. The technician or pharmacist who receives and checks the order must verify receipt by signing and dating the list of drugs delivered. (3-21-12)

b. If performed by a technician, a pharmacist at the supervising pharmacy must ensure, through use of the electronic audio and video communications systems or bar code technology, that a technician has accurately and correctly restocked drugs into the ADS system or cabinet. (3-21-12)

c. Drugs at the remote dispensing site must be stored in a manner to protect their identity, safety, security, and integrity and comply with the drug product storage requirements of these rules. (3-21-12)

d. Drugs, including previously filled prescriptions, not contained within an ADS system must be stored in a locked cabinet within a secured area of a remote dispensing site and access must be limited to pharmacists from the supervising pharmacy and the technicians authorized in writing by the PIC. (3-21-12)

11. Wasting or Discarding of Drugs Prohibited. Wasting or discarding of drugs resulting from the use of an ADS system in a remote dispensing site is prohibited. (3-21-12)

12. Returns Prohibited. The technician at a remote dispensing site must not accept drugs returned by a patient or patient's agent. (3-21-12)

13. Security. A remote dispensing site must be equipped with adequate security. (4-11-15)

a. At least while closed, a remote dispensing site must utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use. The site must have a means of recording the time of entry and the identity of all persons who access the site, which must be retained for ninety (90) days. Two (2) factoring credentialing is required for entry, which must include two (2) of the following: (4-11-15)

i. Something known (a knowledge factor); (4-11-15)

ii. Something possessed (a hard token stored separately from the computer being accessed); and (4-11-15)

iii. Something biometric (finger print, retinal scan, etc.); (4-11-15)

b. A remote dispensing site must be totally enclosed in a manner sufficient to provide adequate security for the pharmacy, as required by this rule and approved by the Board. All remote dispensing sites must meet the following security requirements: (4-11-15)

i. Walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. (4-11-15)

ii. Solid core or metal doors are required. (4-11-15)

iii. Doors and other access points must be constructed in a manner that the hinge hardware is tamper-proof when closed. (4-11-15)

c. Access to the area of the remote dispensing site where prescription drugs are prepared, distributed, dispensed or stored must be limited to technicians and pharmacists. Any other persons requiring access to the remote dispensing site for legitimate business reasons may only be present in the secured area with the permission and under the supervision of a pharmacist, which may be satisfied via audio/video communication. (4-11-15)

d. A remote dispensing site must be closed for business and secured during all times a pharmacist or technician is not present. (4-11-15)

14. Patient Counseling. A remote dispensing site must include an appropriate area for patient counseling. (3-21-12)

a. The area must be readily accessible to patients and must be designed to maintain the confidentiality and privacy of a patient's conversation with the pharmacist. (3-21-12)

b. Unless onsite, a pharmacist must use the video and audio communication system to counsel each patient or the patient's caregiver on new medications. (3-21-12)

15. Remote Dispensing Site Sign. A remote dispensing site must display a sign, easily visible to the public, that informs patients that: (3-21-12)

a. The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy; (3-21-12)

b. Identifies the city or township where the supervising pharmacy is located; and (3-21-12)

c. Informs patients that a pharmacist is required to speak with the patient using audio and video communication systems each time a new medication is delivered or if counseling is accepted at a remote dispensing site. (3-21-12)

16. Pharmacist Inspection of Remote Dispensing Site. A pharmacist must complete and document a monthly in-person inspection of a remote dispensing site and inspection reports must be retained. (3-21-12)

17. Continuous Quality Improvement Program. The PIC of the remote dispensing site must develop and implement a continuous quality improvement program. (4-11-15)

711. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: PRESCRIPTION DRUG ORDERS.

Prescription drug orders dispensed from a remote dispensing site must be previously filled by the supervising pharmacy or, unless a pharmacist is present, must only be filled on the premises of a remote dispensing site through the use of an ADS system and as follows: (3-21-12)

01. Pharmacist Verification of New Prescription Drug Order Information. If a technician at the remote dispensing site enters original or new prescription drug order information into the automated pharmacy system, the pharmacist at the supervising pharmacy must, prior to approving, verify the information entered against a faxed, electronic, or video image of the original prescription. (3-21-12)

a. The technician may transmit the prescription drug order to the pharmacist by scanning it into the electronic recordkeeping system if the means of scanning, transmitting, or storing the image does not obscure the prescription information or render the prescription information illegible. (3-21-12)

b. Alternatively, the technician may make the original prescription available to the pharmacist by placing the prescription in an appropriate position to facilitate viewing of the original prescription via video communication systems between the remote dispensing site and the supervising pharmacy. Using the video communication, the pharmacist must verify the accuracy of the drug dispensed and must check the prescription label for accuracy. (3-21-12)

c. Except when prohibited by law for controlled substances, the technician may also transmit the prescription drug order to the supervising pharmacist by fax. (3-21-12)

d. A technician at a remote dispensing site must not receive oral prescription drug orders from a prescriber or a prescriber's agent. Oral prescription drug orders must be communicated directly to a pharmacist. (3-21-12)

02. Pharmacist and Technician Identification. The initials or other unique identifiers of the pharmacist and technician involved in the dispensing must appear in the prescription record. (3-21-12)

03. Pharmacist Verification of Drug Product and Label. A pharmacist must compare, via video communication, the drug stock, the drug dispensed, and the label including the beyond use date. (3-21-12)

04. Electronic Verification System. The remote dispensing site must use an electronic verification system that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. The technician must electronically verify each prescription prepared for dispensing. (3-21-12)

712. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES: POLICIES AND PROCEDURES.
A supervising pharmacy commencing telepharmacy operations with a remote dispensing site must adopt policies and procedures that address each of the following areas prior to engaging in the practice of telepharmacy. (3-21-12)

01. Minimum Standards. The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality, including at least: (3-21-12)

a. Identification of personnel authorized to have access to drug storage and dispensing areas at the remote dispensing site and to receive drugs delivered to the remote dispensing site; (3-21-12)

b. Procedures for the procurement of drugs and devices to the remote site and into any ADS systems used; and (3-21-12)

c. The criteria for monthly in-person pharmacist inspections of the remote dispensing site and appropriate documentation. (3-21-12)

02. Training Standards. The adoption of standards and training required for remote dispensing site technicians and pharmacists to ensure the competence and ability of each person that operates the ADS system, electronic recordkeeping, and communication systems and a requirement for retention of training documentation. (3-21-12)

03. Written Recovery Plan. A written plan for recovery from an event that interrupts or prevents pharmacist supervision of, or otherwise compromises, the dispensing of drugs from the remote dispensing site that includes at least the following: (3-21-12)

a. Procedures for response while the communication or electronic recordkeeping systems are experiencing downtime or for an ADS system malfunction; and (3-21-12)

b. Procedures for the maintenance and testing of the written plan for recovery. (3-21-12)

713. -- 729. (RESERVED)

730. OUT-OF-STATE MAIL SERVICE PHARMACY.
An out-of-state mail service pharmacy, during its regular hours of operation, but no less than forty (40) hours in six (6) days per week, provide a toll-free telephone service to facilitate communication between Idaho patients and a pharmacist with access to the patient records. This toll-free number must be disclosed on the prescription label for drugs dispensed to Idaho patients. (4-4-13)

731. -- 739. (RESERVED)

740. OUTSOURCING FACILITY.

01. Federal Act Compliance. An outsourcing facility must ensure compliance with 21 U.S.C. Section 353b of the Federal Food, Drug and Cosmetic Act. (4-6-15)

02. Adverse Event Reports. Outsourcing facilities must submit a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with the content and format requirement established in Section 310.305 of Title 21 of the Code of Federal Regulations to the Board. (4-6-15)

03. Policies and Procedures. An outsourcing facility must adopt policies and procedures for maintaining records pertaining to compounding, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (4-6-15)

741. -- 749. (RESERVED)

750. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: (3-21-12)

a. Operational procedures for the appropriate provision and delivery of equipment; (3-21-12)

b. Operational procedures for maintenance and repair of equipment; and (3-21-12)

c. Recordkeeping requirements for documenting the acquisition and provision of products. (3-21-12)

02. Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: (4-4-13)

a. Pure oxygen for human application; (3-21-12)

b. Nitrous oxide; (3-21-12)

c. Sterile sodium chloride; and (3-21-12)

d. Sterile water for injection. (3-21-12)

03. Prescriber's Order Required. Prescription drugs and devices may only be sold or delivered by a DME outlet upon the lawful order of a prescriber. DME outlets may hold drugs that are not prescription drugs for sale. (3-21-12)

751. -- 799. (RESERVED)

Subchapter G -- Wholesaler and Manufacturer Practice Standards
(Rules 800 through 999 -- Wholesaler and Manufacturer Practice Standards)

800. WHOLESALER: STANDARDS.
These wholesaler rules establish the minimum standards for the storage and handling of drugs by wholesalers and their officers, designated representative, agents, and employees and for the establishment and maintenance of records required for persons engaged in wholesale drug distribution. (3-21-12)

801. WHOLESALER: FACILITY REQUIREMENTS.
Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must: (3-21-12)

01. Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations; (3-21-12)

02. Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; (3-21-12)

03. Quarantine Area Required. Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened; (3-21-12)

04. Maintenance Requirements. Be maintained in a clean and orderly condition; and (3-21-12)

05. Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind. (3-21-12)

802. WHOLESALER: FACILITY SECURITY.
Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: (3-21-12)

01. Access from Outside. Access from outside the premises must be kept to a minimum and well controlled; (3-21-12)

02. Perimeter Lighting. The outside perimeter of the premises must be well lighted; (3-21-12)

03. Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel; (3-21-12)

04. Alarm Systems. Facilities must be equipped with an alarm systems to detect entry after hours; and (3-21-12)

05. Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering. (3-21-12)

803. WHOLESALER: DRUG STORAGE REQUIREMENTS.
Drugs must be stored at temperatures and under conditions required by the labeling of the drugs, if any, or by current requirements of the USP-NF, to preserve product identity, strength, quality, and purity. Temperature and humidity recording equipment, devices, or logs must document proper storage of drugs. (3-21-12)

804. WHOLESALER DRUG SHIPMENT INSPECTION REQUIREMENTS.

01. Examination on Receipt. Each shipping container must be visually examined on receipt for identity and to avoid acceptance of drugs that are contaminated or otherwise unfit for distribution. (3-21-12)

02. Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents. (3-21-12)

805. WHOLESALER: QUARANTINE.
Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be physically separated from other drugs in a designated quarantine area until destroyed or returned to the original manufacturer or third party returns processor. (3-21-12)

01. Container Adulteration. Used drugs and those whose immediate or sealed outer or sealed secondary containers have been opened are adulterated and must be quarantined. (3-21-12)

02. Other Conditions Requiring Quarantine. Drugs must be quarantined under any condition that causes doubt as to a drug's safety, identity, strength, quality, or purity unless under examination, testing, or other investigation the drug is proven to meet required standards. (3-21-12)

806. WHOLESALER: RECORDKEEPING REQUIREMENTS.

Wholesalers and other entities engaged in wholesale drug distribution must establish and maintain inventories and records of transactions pertaining to the receipt and distribution or other disposition of drugs. (3-21-12)

01. Record Contents. The records must include at least: (3-21-12)

a. 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; (3-21-12)

b. The identity and quantity of the drugs received and distributed or disposed of; and (3-21-12)

c. The dates of receipt and distribution or other disposition of the drugs. (3-21-12)

02. Records Maintenance. Records may be maintained in an immediately retrievable manner at the inspection site or in a readily retrievable manner at a central location. (3-21-12)

807. WHOLESALER: PERSONNEL.

01. Responsible Person Designees. A wholesaler must establish and maintain a list of officers, directors, managers, a designated representative, and other persons responsible for wholesale drug distribution, storage, and handling and must include a description of each individual's duties and a summary of their qualifications. (3-21-12)

02. Adequate Personnel. A wholesaler must employ personnel in sufficient numbers and with adequate education, training, and experience to safely and lawfully engage in wholesale drug distribution activities. (3-21-12)

03. Designated Representative Continuing Education. A wholesaler's designated representative must complete training and continuing education on state and federal laws pertaining to wholesale distribution of prescription drugs provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance. (3-21-12)

808. WHOLESALER: POLICIES AND PROCEDURES.
Wholesalers must adopt policies and procedures for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting errors and inaccuracies in inventories, and as necessary to ensure compliance with the following: (3-21-12)

01. Distribution of Oldest Approved Stock First. The oldest approved stock of a drug product must be distributed first except if extraordinary circumstances require a temporary deviation. (3-21-12)

02. Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: (3-21-12)

a. A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; (3-21-12)

b. A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or (3-21-12)

c. An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design. (3-21-12)

03. Crisis Preparation. **W**holesalers must prepare for, protect against, and competently handle a crisis affecting the security or operation of a facility, including a fire, flood, or other natural disaster, a strike, or other situations of local, state, or national emergency. (3-21-12)

809. -- 849. (RESERVED)

850. DRUG MANUFACTURER OR WHOLESALER TRANSACTION RESTRICTION.

A manufacturer or wholesaler may furnish non-prescription drugs only to a person or drug outlet licensed or registered by the Board. Before furnishing non-prescription drugs to a person or drug outlet, the manufacturer or wholesaler must affirmatively verify that the recipient is legally authorized to receive the non-prescription drugs. (3-21-12)

851. -- 899. (RESERVED)

900. DRUG MANUFACTURERS.
These rules are applicable to drug manufacturers located within the state of Idaho. Non-resident manufacturers engaged in wholesale drug distribution in or into Idaho must comply with the Idaho Wholesale Drug Distribution Act and rules, as applicable. (3-21-12)

901. DRUG MANUFACTURER: STANDARDS.
A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements. (3-21-12)

902. DRUG MANUFACTURER: RECORDS.
A manufacturer must adopt policies and procedures for maintaining records pertaining to production, process control, labeling, packaging, quality control, distribution, complaints, and any information required by state or federal law. (3-21-12)

903. -- 999. (RESERVED)

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