Dear Senators LODGE, Broadsword, Bock, and
Representatives MCGEACHIN, Bilbao, Rusche:

The Legislative Services Office, Research and Legislation, has received the enclosed rules of the Board of Pharmacy:

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal) (Docket No. 27-0101-1101);

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Rewrite - Fee Rule) (Docket No. 27-0101-1102).

Pursuant to Section 67-454, Idaho Code, a meeting on the enclosed rules may be called by the cochairmen or by two (2) or more members of the subcommittee giving oral or written notice to Research and Legislation no later than fourteen (14) days after receipt of the rules analysis from Legislative Services. The final date to call a meeting on the enclosed rules is no later than 10/26/2011. If a meeting is called, the subcommittee must hold the meeting within forty-two (42) days of receipt of the rules analysis from Legislative Services. The final date to hold a meeting on the enclosed rules is 11/25/2011.

The germane joint subcommittee may request a statement of economic impact with respect to a proposed rule by notifying Research and Legislation. There is no time limit on requesting this statement, and it may be requested whether or not a meeting on the proposed rule is called or after a meeting has been held.

To notify Research and Legislation, call 334-4845, or send a written request to the address or FAX number indicated on the memorandum enclosed.

Legislative Services Office
Idaho State Legislature

Serving Idaho's Citizen Legislature

Jeff Youtz
Director

MEMORANDUM

TO: Rules Review Subcommittee of the Senate Health & Welfare Committee and the House Health & Welfare Committee

FROM: Legislative Research Analyst - Ryan Bush

DATE: October 6, 2011

SUBJECT: Pharmacy, Board of

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal) (Docket No. 27-0101-1101)

IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Rewrite - Fee Rule) (Docket No. 27-0101-1102)

(1) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal) (Docket No. 27-0101-1101)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Chapter Repeal). The Board states that it is necessary to repeal its existing rules to provide Board licensees and registrants, subject to regulation under the Idaho Pharmacy Act, the Uniform Controlled Substances Act, the Out-of-State Mail Service Pharmacy Act, and the Wholesale Drug Distribution Act, an updated and more comprehensive set of rules governing the practice of pharmacy in Idaho. This proposed action repeals the chapter in its entirety.

The Board states that negotiated rulemaking was conducted. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the May 4, 2011, Vol. 11-5, page 74; June 1, 2011, Vol. 11-6, page 38; and August 3, 2011, Vol. 11-8, page 225, Idaho Administrative Bulletins. A public hearing concerning this rulemaking is scheduled on Wednesday, October 26, 2011, at 1:00 p.m. MST, at the Hilton Garden Inn - Les Bois Room, 7699 West Spectrum St., Boise, ID.

The proposed rule appears to be within the authority granted to the Board in Section 54-1717, Idaho Code.

(2) 27.01.01 - Rules of the Idaho State Board of Pharmacy (Rewrite - Fee Rule) (Docket No. 27-0101-1102)

The Idaho State Board of Pharmacy submits notice of proposed rulemaking at IDAPA 27.01.01 - Rules of the Idaho State Board of Pharmacy (Rewrite - Fee Rule). The Board states that it is necessary to promulgate new and reorganized rules to provide Board licensees and registrants, subject to regulation under the Idaho Pharmacy Act, the Uniform Controlled Substances Act, the Out-of-State Mail Service Pharmacy Act, and the Wholesale Drug Distribution Act, an updated and more comprehensive set of rules governing the practice of pharmacy in Idaho. The proposed rewrite reorganizes several of the Board's rules; expands several areas of

existing rule, including unprofessional conduct, limited service pharmacy and institutional pharmacy practice standards; and clarifies or slightly changes some existing rules, including rules on registration and licensure. Many rule sections have been reduced, including pharmacy minimum standards, home health care nursing and pharmacy advertising. Some rules that overlap with Idaho Code or federal law have been eliminated.

The Board states that negotiated rulemaking was conducted. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the May 4, 2011, Vol. 11-5, page 74; June 1, 2011, Vol. 11-6, page 38; and August 3, 2011, Vol. 11-8, page 225, Idaho Administrative Bulletins. A public hearing concerning this rulemaking is scheduled on Wednesday, October 26, 2011, at 1:00 p.m. MST, at the Hilton Garden Inn - Les Bois Room, 7699 West Spectrum St., Boise, ID. The Board states that increases or changes to fees will not affect the general fund as it is a self-governing agency, funded mainly by license and registration fees, with no general fund appropriation.

The proposed rule appears to be within the authority granted to the Board in Section 54-1717, Idaho Code. We note that the Board did not list its statutory authority to collect fees in the Notice of Rulemaking. The Board does have such authority to collect fees as codified in Section 54-1720, Idaho Code.

cc: Pharmacy, Board of
Mark Johnston, R.Ph.

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1101 (CHAPTER REPEAL)

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be held as follows:

Wednesday, October 26th, at 1:00 p.m. MST

Hilton Garden Inn - Les Bois Room
7699 West Spectrum Street, Boise, ID

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

It is necessary to repeal the Board's existing rules and to promulgate new and reorganized rules to provide Board licensees and registrants, subject to regulation under the Idaho Pharmacy Act and the Uniform Controlled Substances Act, the Out-of-State Mail Service Pharmacy Act, and the Wholesale Drug Distribution Act, an updated and more comprehensive set of rules governing the practice of pharmacy in Idaho. This action repeals this chapter in its entirely. The rewritten rule is being published in the Bulletin immediately following this notice under Docket No. 27-0101-1102.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased: None.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking: N/A

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the May 4, 2011, Vol. 11-5, page 74; June 1, 2011, Vol. 11-6, page 38; and August 3, 2011, Vol. 11-8, page 225, Idaho Administrative Bulletins.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed repeal of this rule, contact Mark Johnston, R.Ph., Executive Director, (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 26, 2011.

DATED this 31st day of August, 2011.

Mark Johnston, R.Ph., Executive Director
Idaho State Board of Pharmacy
P. O. Box 83720
Boise, ID 83720-0067
3380 Americana Terrace, Ste. 320
Phone: (208) 334-2356 - Fax: (208)334-3536

IDAPA 27.01.01 IS BEING REPEALED IN ITS ENTIRETY

IDAPA 27 - BOARD OF PHARMACY

27.01.01 - RULES OF THE IDAHO STATE BOARD OF PHARMACY

DOCKET NO. 27-0101-1102 (REWRITE - FEE RULE)

NOTICE OF RULEMAKING - PROPOSED RULE

AUTHORITY: In compliance with Section 67-5221(1), Idaho Code, notice is hereby given that this agency has initiated proposed rulemaking procedures. The action is authorized pursuant to Section 54-1717, Idaho Code.

PUBLIC HEARING SCHEDULE: Public hearing(s) concerning this rulemaking will be held as follows:

Wednesday, October 26th, 2011
at 1:00 p.m. MST

Hilton Garden Inn - Les Bois Room
7699 West Spectrum Street, Boise, ID

The hearing site(s) will be accessible to persons with disabilities. Requests for accommodation must be made not later than five (5) days prior to the hearing, to the agency address below.

DESCRIPTIVE SUMMARY: The following is a nontechnical explanation of the substance and purpose of the proposed rulemaking:

It is necessary to repeal the Board's existing rules and to promulgate new and reorganized rules to provide Board licensees and registrants, subject to regulation under the Idaho Pharmacy Act and the Uniform Controlled Substances Act, the Out-of-State Mail Service Pharmacy Act, and the Wholesale Drug Distribution Act, an updated and more comprehensive set of rules governing the practice of pharmacy in Idaho. The proposed re-write reorganizes the Board's rules, provides a more comprehensive list of definitions and fee schedules, and provides new rules affecting the practice of pharmacy and controlled substance registrants not previously addressed, including the provisions of a waiver or variance to rule, mandated electronic record keeping systems, automated dispensing and storage systems, sterile product preparation, pharmacy closing procedures, and drug manufacturer rules. Several areas of existing rule have been expanded, such as limited service pharmacy, remote dispensing site registration, unprofessional conduct, student pharmacist practice standards, and institutional pharmacy practice standards. Other existing rules have been clarified or slightly changed, including parental admixture pharmacy, registration and licensure, records retention, labeling, technicians, controlled substance inventory, pharmacy security, durable medical equipment outlets, and veterinary drug orders. Many sections have been reduced, including therapeutic equivalents, pharmacy minimum standards, space and fixtures, home health care nursing, and pharmacy advertising. Some rules have been eliminated, including many overlapping rules with Idaho Code or federal law, student pharmacist experience hours, preceptor site registration, poison control, and many paper reports.

FEE SUMMARY: The following is a specific description of the fee or charge imposed or increased:

The proposed rules contain small changes to fees collected by the Board, including "a reasonable administrative fee may be charged for a dishonored check or other form of payment;" "refunds issued will be reduced by a reasonable processing fee;" "duplicate certificates of registration: ten dollars ($10)," which matches the existing duplicate pharmacist certificate of licensure; and "prescriber drug outlet: thirty-five dollars ($35)," which replaces "clinic: thirty-five dollars ($35)," thus this category is expanded somewhat, pursuant to 2011 changes to Idaho Code. 2011 changes to Section 54-1705(9), Idaho Code, allow the registration of a drug outlet that dispenses or distributes drugs. These proposed rules clarify that a prescriber drug outlet that only distributes, need not register, however one that dispenses does. Previously, just clinics were subject to registration in statute and imposed a thirty-five dollar ($35) registration fee in rule. These proposed rules maintain the thirty-five dollar ($35) fee, while expanding the number of outlets that may be registered.

FISCAL IMPACT: The following is a specific description, if applicable, of any negative fiscal impact on the state general fund greater than ten thousand dollars ($10,000) during the fiscal year resulting from this rulemaking:

The Board of Pharmacy is a self-governing agency, funded mainly by license and registration fees, that utilizes

no general fund appropriation. Increases or changes to fees will therefore not affect the general fund.

NEGOTIATED RULEMAKING: Pursuant to Section 67-5220(1), Idaho Code, negotiated rulemaking was conducted. The Notices of Intent to Promulgate Rules - Negotiated Rulemaking were published in the May 4, 2011, Vol. 11-5, page 74; June 1, 2011, Vol. 11-6, page 38; and August 3, 2011, Vol. 11-8, page 225, Idaho Administrative Bulletins.

INCORPORATION BY REFERENCE: Pursuant to Section 67-5229(2)(a), Idaho Code, the following is a brief synopsis of why the materials cited are being incorporated by reference into this rule: N/A

ASSISTANCE ON TECHNICAL QUESTIONS, SUBMISSION OF WRITTEN COMMENTS: For assistance on technical questions concerning the proposed rule, contact Mark Johnston, R.Ph., Executive Director. (208) 334-2356.

Anyone may submit written comments regarding this proposed rulemaking. All written comments must be directed to the undersigned and must be delivered on or before October 26, 2011.

DATED this 31st day of August, 2011.

Mark Johnston, R.Ph., Executive Director
Idaho State Board of Pharmacy
3380 Americana Terrace, Ste. 320
P. O. Box 83720
Boise, ID 83720-0067
Phone: (208) 334-2356
Fax: (208)334-3536

THE FOLLOWING IS THE PROPOSED TEXT FOR DOCKET NO. 27-0101-1102

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. ( )

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. ( )

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

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; ( )

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

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. ( )

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 Idaho Code 3-337, *et seq*. ( )

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. ( )

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. ( )

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. ( )

004. INCORPORATION BY REFERENCE.
No documents have been incorporated by reference into this rule. ( )

005. BOARD OFFICE INFORMATION.

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

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

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

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

05. Electronic Address. The website address is http://bop.accessidaho.org. ( )

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

006. PUBLIC RECORDS ACT COMPLIANCE.
Board of Pharmacy records and filings are subject to compliance with the Idaho Public Records Act, Title 9,

Chapter 3, Idaho Code. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

02. ACPE. Accreditation Council for Pharmacy Education. ( )

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. ( )

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. ( )

05. CDC. United States Department of Health and Human Services, Centers for Disease Control and Prevention. ( )

06. Central Pharmacy. A pharmacy within the state or a registered telepharmacy across state lines with which centralized pharmacy services have been contracted. ( )

07. Centralized Pharmacy Services. The processing by a pharmacy of a request from another pharmacy to fill, refill, or dispense a prescription drug order or to perform processing functions such as prospective drug review. ( )

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

09. 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. ( )

10. **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. ( )

11. **CME**. Continuing medical education. ( )

12. **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. ( )

13. **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. ( )

14. **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. ( )

15. **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. ( )

16. **CPE**. Continuing pharmacy education. ( )

17. **CPEU**. Continuing pharmacy education unit. ( )

18. **DEA**. United States Drug Enforcement Administration. ( )

19. **Distributor**. A supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer. ( )

20. **DME**. Durable medical equipment. ( )

21. **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. ( )

22. **Drug Product Selection**. The act of selecting either a brand name drug product or its therapeutically equivalent generic. ( )

23. **Drug Product Substitution**. Dispensing a drug product other than prescribed without the express permission of the prescriber and patient. ( )

24. **DTM -- Drug Therapy Management**. Selecting, initiating, or modifying drug treatment. ( )

25. **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. ( )

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

27. **FDA**. United States Food and Drug Administration. ( )

28. **Flavoring Agent**. An additive used in food or drugs when the additive: ( )

a. Is used in accordance with the principles of good pharmacy practices and in the minimum quantity required to produce its intended effect; ( )

b. Consists of one or more ingredients generally recognized as safe in food and drugs; ( )

c. Is not greater than five percent (5%) of the total weight of the product. ( )

29. 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. ( )

30. HIPAA. Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191). ( )

31. Hospital System. A hospital or hospitals and at least one (1) on-site institutional pharmacy under common ownership. A hospital system may also include a hospital or hospitals and one (1) or more COE pharmacies under common ownership. ( )

32. 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. ( )

33. Individually Identifiable Health Information. Information that is a subset of health information, including demographic information, collected from an individual and that: ( )

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

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: ( )

i. Identifies the individual; or ( )

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

34. Institution Engaged in The Practice of Telepharmacy Across State Lines. An institutional facility engaged in the practice of telepharmacy into Idaho that is an out-of-state hospital with an institutional pharmacy licensed or registered in another state or a COE pharmacy licensed or registered in another state that is part of a hospital system. ( )

35. Institutional Pharmacy. A pharmacy located in an institutional facility. ( )

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

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

02. MPJE. Multistate Pharmacy Jurisprudence Exam. ( )

03. 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: ( )

a. Medication therapy review; ( )

b. Personal medication record; ( )

c. Medication-related action plan; ( )

d. Intervention or referral, or both; ( )

e. Documentation and follow-up. ( )

04. NABP. National Association of Boards of Pharmacy. ( )

05. NAPLEX. North American Pharmacists Licensure Examination. ( )

06. NDC. National Drug Code. ( )

07. Non-Institutional Pharmacy. A pharmacy located in a drug outlet that is not an institutional facility. ( )

08. Parenteral Admixture. The preparation and labeling of sterile products intended for administration by injection. ( )

09. 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 MTM, pharmacotherapy, clinical pharmacy practice, pharmacist independent practice, and DTM under a collaborative practice agreement. 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: ( )

a. Performing or obtaining necessary assessments of the patient's health status; ( )

b. Reviewing, analyzing, evaluating, formulating or providing a drug utilization or treatment plan; ( )

c. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness; ( )

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

e. Documenting the care delivered; ( )

f. Communicating essential information or referring the patient to other care providers when necessary or appropriate; ( )

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; ( )

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

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

j. Identifying processes to improve continuity of care and patient outcomes; ( )

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

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

m. Other services as allowed by law. ( )

10. Pharmacist Extern. A person enrolled in an accredited school or college of pharmacy who is pursuing a professional degree in pharmacy and is obtaining practical experience under the supervision of a pharmacist. ( )

11. 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. ( )

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

13. PHI -- Protected Health Information. Individually identifiable health information that is: ( )

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

b. Maintained in electronic media; and ( )

c. Transmitted or maintained in any other form or medium. ( )

d. PHI excludes individually identifiable health information in: ( )

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

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

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. ( )

14. PIC. Pharmacist-in-charge. ( )

15. PMP. Prescription Monitoring Program. ( )

16. 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. ( )

17. Prescriber. An individual currently licensed, registered, or otherwise authorized to prescribe and administer drugs in the course of professional practice. ( )

18. 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. ( )

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

20. Relative Contraindication. A condition that renders a particular treatment or procedure inadvisable, but not prohibitive. ( )

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

22. Retail Non-Pharmacy Drug Outlet. A retail outlet that sells non-prescription drugs or devices

that is not a pharmacy. ( )

23. Retail Pharmacy. A community or other pharmacy that sells prescription drugs at retail and is open to the public for business. ( )

24. R.N. Registered nurse. ( )

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. ( )

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

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. ( )

04. Student Pharmacist. A term inclusive of pharmacist intern and pharmacist extern if differentiation is not needed. ( )

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. ( )

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

07. Therapeutic Equivalent Drugs. Products assigned an "A" code by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). ( )

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). ( )

09. USP. United States Pharmacopeia. ( )

10. USP-NF. United State Pharmacopeia-National Formulary. ( )

11. VAWD -- Verified Accredited Wholesale Distributor. An accreditation program for wholesale distributors offered through NABP. ( )

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

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

14. 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. ( )

15. VIS. Vaccine Information Statement. ( )

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: ( )

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

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

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; and ( )

d. The granting of the waiver or variance will afford substantially equal protection of public health, safety, and welfare intended by the particular rule for which the waiver or variance is requested. ( )

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: ( )

a. The name, address, and telephone number of the petitioner; ( )

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

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

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 ( )

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

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. ( )

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. ( )

05. Administrative Deadlines. A waiver or variance request that delays or cancels an administrative deadline will not be granted by the Board. ( )

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. ( )

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. ( )

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: ( )

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

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 ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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, expire annually on June 30 for pharmacists and on December 31 for all

other registrants. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

018. LICENSE OR 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. ( )

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. ( )

02. Additional Requirements. A pharmacist reinstatement applicant must provide evidence of completion of a minimum of thirty (30) CPEUs 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 CPEUs, or other requirements determined necessary to acquire or demonstrate professional competency. ( )

019. LICENSE AND REGISTRATION POSTING.
Licenses and registrations issued under the Idaho Pharmacy and the Uniform Controlled Substances Acts must be conspicuously posted at the licensed or registered location or at the drug outlet where the licensee or registrant is employed. ( )

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 and posted. ( )

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. ( )

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. ( )

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. ( )

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 revoked 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. ( )

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 that will not exceed one hundred dollars ($100). ( )

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. ( )

021. FEE SCHEDULE.

01. Licenses -- Professionals. ( )

a. Original pharmacist license: one hundred dollars ($100). ( )

b. Licensure by reciprocity: two hundred fifty dollars ($250). ( )

c. Pharmacist license annual renewal. ( )

i. Active: ninety dollars ($90). ( )

ii. Inactive: fifty dollars ($50). ( )

d. Late payment processing: fifty dollars ($50). ( )

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

02. Certificates of Registration -- Professionals. ( )

a. Pharmacist engaged in telepharmacy across state lines -- registration or annual renewal: two hundred fifty dollars ($250). ( )

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

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. ( )

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

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

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

03. Certificates of Registration and Licensure - Facilities. ( )

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

b. Institutional facility - registration or annual renewal. ( )

i. Hospital pharmacy: one hundred dollars ($100). ( )

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

iii. Hospital without a pharmacy: thirty-five dollars ($35). ( )

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

d. Wholesaler. ( )

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

ii. Registration or annual renewal: one hundred dollars ($100). ( )

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

f. Telepharmacy across state lines - registration or annual renewal: one hundred dollars ($100). ( )

g. Mail service pharmacy. ( )

i. Initial license: five hundred dollars ($500). ( )

ii. License annual renewal: two hundred fifty dollars ($250). ( )

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

i. Limited service pharmacy: one hundred dollars ($100). ( )

ii. Parenteral admixture pharmacy: one hundred dollars ($100). ( )

iii. Remote dispensing pharmacy: one hundred dollars ($100). ( )

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

v. Durable medical equipment outlet: fifty dollars ($50). ( )

vi. Prescriber drug outlet: thirty five dollars ($35). ( )

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

j. Retail non-pharmacy outlets - registration or annual renewal. ( )

i. "A" (Stocks more than fifty (50) drug items): sixty dollars ($60). ( )

ii. "B" (Stocks fifty (50) or fewer drug items): twenty-five dollars ($25). ( )

iii. "V" (Vending machines): ten dollars ($10) per machine. ( )

k. Supplemental facility registrations or annual renewals. ( )

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

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

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

04. Controlled Substance Registration. ( )

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

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

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

05. Administrative Services and Publications. ( )

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

b. Controlled substance inventory book: fifteen dollars ($15). ( )

c. Duplicate pharmacist certificate of licensure: thirty-five dollars ($35). ( )

d. Duplicate registration or license card: ten dollars ($10). ( )

e. Commercial lists. ( )

i. Pharmacy list: fifty dollars ($50). ( )

ii. Pharmacist list: fifty dollars ($50). ( )

iii. Controlled Substances Act ("CSA") registrant list: one hundred fifty dollars ($150). ( )

f. Official Idaho Register: fifteen dollars ($15). ( )

g. Idaho Pharmacy Laws and Rules book: thirty-five dollars ($35). ( )

h. Hearing transcript: five dollars ($5) per page. ( )

022. -- 029. (RESERVED)

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 a complete application for licensure by examination. ( )

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 by the Foreign Pharmacy Graduate Examination Committee (FPGEC), and certification of completion of a minimum of fifteen hundred (1500) experiential hours. ( )

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. ( )

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. ( )

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. ( )

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

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

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. ( )

034. PHARMACIST INACTIVE STATUS LICENSE.

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

a. Is a pharmacist in the state of Idaho licensed in good standing; ( )

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

c. Has submitted the required application. ( )

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. ( )

03. Return to Active Status. If an inactive status licensee wishes to return to active status, the licensee must complete a minimum of thirty (30) CPEUs and comply with the reinstatement requirements of these rules. ( )

035. PHARMACIST REGISTRATION FOR TELEPHARMACY ACROSS STATE LINES.
A pharmacist not licensed to practice pharmacy in the state of Idaho must satisfy the requirements of Section 54-

1723A, Idaho Code, and be registered by the Board to lawfully engage in the practice of telepharmacy across state lines into the state of Idaho. ( )

036. STUDENT PHARMACIST REGISTRATION.
Unless revoked or suspended by the Board, a pharmacist extern registration must be renewed annually on July 15; however, the renewal fee will be waived for the duration of the extern's enrollment in the school or college of pharmacy and until July 15 following graduation. ( )

037. -- 039. (RESERVED)

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

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

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; ( )

03. Personal Characteristics. Be of good moral character and temperate habits; and ( )

04. Certification. Have obtained and maintained certified pharmacy technician (CPhT) status through the Pharmacy Technician Certification Board (PTCB), the Institute for Certification of Pharmacy Technicians (ICPT), or their successors unless qualified for a continuous employment exemption. ( )

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. ( )

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. ( )

02. Renewal. The registration of a technician-in-training expires on June 30 and is renewable two times. ( )

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. ( )

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 correspondingly terminate on the date of employment termination. The person must thereafter satisfy the registration requirements of these rules to be lawfully employed as, or otherwise perform the duties of, a technician. ( )

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: ( )

01. Age. Be at least eighteen (18) years of age; ( )

02. Education. Be a high school graduate or the recipient of a high school equivalency diploma; and ( )

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

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. Application for approval will require provision of the following information: ( )

a. The name of provider or sponsor; ( )

b. The type of program offered; ( )

c. A description of the subject matter; ( )

d. The number of clock hours offered; ( )

e. The method of evaluating satisfactory completion of program; ( )

f. The dates and location of program; and ( )

g. The names and qualifications of instructors or other persons responsible for the delivery and content of the program. ( )

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

a. The socioeconomic and legal aspects of health care; ( )

b. The properties and actions of drugs and dosage forms; or ( )

c. The etiology, characteristics, and therapeutics of a disease state. ( )

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

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

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. ( )

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. ( )

052. CPE REQUIREMENTS.
Each pharmacist applicant for license renewal must annually complete the equivalent of one and one-half (1.5) CPE units (CPEU). One (1) CPEU is the equivalent of ten (10) clock hours of participation in programs approved by the

Board. ( )

01. ACPE or CME. At a minimum, eight (8) clock hours (0.8 CPEU) 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. ( )

02. Pharmacy Law. One (1) clock hour (0.1 CPEU) must be ACPE accredited or Board approved jurisprudence (pharmacy law) programs. ( )

03. Board Approved. A maximum of six (6) clock hours (0.6 CPEU) may be Board-approved programs not accredited through ACPE or CME. ( )

04. Live Attendance. Three (3) clock hours (0.3 CPEU) must be obtained by attendance at live or synchronous online CPE programs. ( )

05. Carryover of Certain Unused Units. Clock hours of CPEU accrued during June of a licensing period may be carried over into the next licensing period to the extent that a pharmacist's total clock hours of CPEU for the current licensing period exceed the total CPEUs required by these rules. ( )

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

053. CPE REQUIREMENTS FOR DUAL LICENSEES.

01. Idaho Licensee. An Idaho-licensed pharmacist residing in another state must meet Idaho CPE requirements to be granted an Idaho license renewal. ( )

02. Approval. 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. ( )

054. -- 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. ( )

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. ( )

02. Licenses and Registrations Nontransferable. Drug outlet licenses and registrations are location specific and are nontransferable as to person or place. If the ownership or location of an outlet changes, any registration or license issued to it by the Board is void. ( )

03. Reciprocity. The Board may license by reciprocity a drug outlet licensed under the laws of another state if the other state’s licensing standards are comparable to those in Idaho and acceptable to the Board, evidenced by an inspection report, and if the other state extends reciprocal licensure to Idaho drug outlets. ( )

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. ( )

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. ( )

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. ( )

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. ( )

071. TELEPHARMACY AND REMOTE DISPENSING SITE REGISTRATION.

01. Telepharmacy Practice Registration. Each location where drugs are dispensed through the practice of telepharmacy must be registered with the Board. ( )

02. 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. ( )

03. 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: ( )

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

b. The operating specifications; and ( )

c. An accurate scale drawing of the facility that illustrates: ( )

i. The layout and location of the systems; ( )

ii. The location of a patient counseling area; and ( )

iii. All access points to the electronic recordkeeping system and the ADS system. ( )

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. ( )

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. ( )

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. ( )

073. -- 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. ( )

a. The name of the owner and operator of the applicant, including: ( )

i. If a person, the name of the person; ( )

ii. If a partnership, the name of each partner, and the name of the partnership; ( )

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 ( )

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

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

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. ( )

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: ( )

a. The qualifications of the wholesaler's designated representative; ( )

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

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

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

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; ( )

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

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. ( )

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

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. ( )

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. ( )

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 an out-of-state mail service pharmacy pursuant to 54-1743, Idaho Code. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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

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

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. ( )

05. System Downtime. Pharmacies must have an auxiliary procedure for documentation of refills of prescription drug orders in the event of a system downtime that ensures: ( )

a. That refills are authorized by the original prescription drug order; ( )

b. That the maximum number of refills is not exceeded; and ( )

c. That the required data is retained for data entry as soon as the electronic recordkeeping system is restored. ( )

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. ( )

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

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. ( )

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: ( )

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

02. Prospective Drug Review Information. Information relevant to a prospective drug review; ( )

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

04. Other Information. Any other information that the pharmacist deems appropriate. ( )

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: ( )

a. The serial number, if any; ( )

b. The date of issuance; ( )

c. The date filled; ( )

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

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

f. The directions for use; ( )

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

h. The name of the prescriber; and ( )

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

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: ( )

a. The date of dispensing of each refill; ( )

b. The quantity dispensed; ( )

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

d. The total number of refills dispensed to date. ( )

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. ( )

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. ( )

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. ( )

01. Invalid Prescription Drug Orders. A prescription drug order is invalid if not issued: ( )

a. In good faith; ( )

b. For a legitimate medical purpose; ( )

c. By a licensed prescriber; ( )

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

e. Pursuant to a prescriber-patient relationship; and ( )

f. In the form and including the elements required by law. ( )

02. Antedating or Postdating. A prescription drug order is invalid if antedated or postdated. ( )

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. ( )

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

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. ( )

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: ( )

01. Patient's Name. The patient's name and: ( )

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

b. If for an animal, the species. ( )

02. Date. The date issued. ( )

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

04. Directions. The directions for use. ( )

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

06. Signature. If paper, the pre-printed, stamped, or hand-printed name and written signature of the prescriber, and if electronic, the prescriber's electronic signature. ( )

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

01. Patient's Name. The patient's name. ( )

02. Date. The date issued. ( )

03. Drug Information. The drug name, strength, and route of administration. ( )

04. Directions. The directions for use. ( )

05. Prescriber Information. The name of the prescriber. ( )

06. Signature. If written, the signature of the prescriber or the prescriber's agent. ( )

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: ( )

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

b. For a resident of an LTCF; and ( )

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

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. ( )

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. ( )

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. ( )

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

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." ( )

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

a. The date; ( )

b. The quantity dispensed; ( )

c. The remaining quantity authorized for dispensing; and ( )

d. The identification of the dispensing pharmacist. ( )

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: ( )

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

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

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

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. ( )

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. ( )

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

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: ( )

a. The name of the transferring pharmacist; ( )

b. The name of the receiving pharmacist; ( )

c. The name of the receiving pharmacy; ( )

d. The date of the transfer; ( )

e. The number of authorized refills available; and ( )

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

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: ( )

a. The name of the receiving pharmacist; ( )

b. The name of the transferring pharmacist; ( )

c. The name of the transferring pharmacy; ( )

d. The date of issuance of the original prescription drug order; ( )

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

f. The number of authorized refills available; and ( )

g. If written for a controlled substance: ( )

i. The dates and locations of the original dispensing and previous refills; and ( )

ii. The name, address, DEA registration number, and assigned prescription number of the transferring pharmacy for each dispensing and of the pharmacy that originally filled the prescription, if different. ( )

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. ( )

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

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. ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

02. Emergency Prescription Refills. A pharmacist may refill a prescription for a patient when 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. ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

119. PRESCRIPTION DRUG ORDER -- INSPECTION AND COPYING.

01. Prescriber Inspection. A prescription drug order must be made available for inspection by the issuing prescriber upon request. ( )

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." ( )

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)." ( )

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: ( )

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. ( )

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

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

a. The client's name and address; ( )

b. The animal species; ( )

c. The date issued; ( )

d. The name, strength, and quantity of product; ( )

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

f. The name, license number, and signature of the prescribing veterinarian. ( )

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: ( )

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. ( )

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

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

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. ( )

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. ( )

a. Refilling or reprocessing of veterinary drug orders is prohibited. ( )

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. ( )

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

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

e. Compounding by a VDT is prohibited. ( )

121. -- 129. (RESERVED)

130. DRUG PRODUCT SUBSTITUTION.
Drug product substitutions are allowed only in situations requiring compliance with a formulary or drug list prepared by the pharmacy and therapeutics committee of a hospital or the quality assessment and assurance committee of a skilled nursing facility consisting of the director of nursing services, a physician designated by the facility, and at least three (3) other members of the facility's staff. ( )

131. DRUG PRODUCT SELECTION.
Drug product selection is allowed only between therapeutic equivalent drugs. ( )

01. Method of Drug Product Selection. A branded product must be dispensed only if "BRAND ONLY" is specified by the prescriber on the electronic prescription drug order or on the face of a paper prescription drug order by a "BRAND ONLY" check box or a handwritten notation. ( )

02. Drug Product Selection 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. ( )

132. -- 134. (RESERVED)

135. DRUG PRODUCT FLAVORING.
A flavoring agent may be added to a drug product on request by the prescriber, the patient, or the patient's agent. ( )

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: ( )

01. Dispenser Information. The name, address, and telephone number of the dispenser (person or business); ( )

02. Prescription Number. The prescription serial number; ( )

03. Date. The date the prescription is filled; ( )

04. Prescriber. The name of the prescriber; ( )

05. Patient. The name of the patient, and if the patient is an animal, the species; ( )

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); ( )

07. Quantity. The quantity of item dispensed; ( )

08. Directions. The directions for use; ( )

09. Cautionary Information. Cautionary information as required or deemed appropriate for proper use and patient safety; ( )

10. Expiration. An expiration date that is the lesser of: ( )

a. One (1) year from the date of dispensing; ( )

b. The manufacturer's original expiration date; ( )

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

d. A shorter period if warranted; and ( )

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

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 an institutional facility must be dispensed in an appropriate container that bears at least the following information: ( )

a. The date filled; ( )

b. The name of the patient; ( )

c. The name and strength of the drug; ( )

d. The quantity of item dispensed; ( )

e. The directions for use, including the route of administration; ( )

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

g. The expiration or beyond use date, if appropriate; and ( )

h. The initials or other unique identifier of the dispensing pharmacist. ( )

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. ( )

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: ( )

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

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

03. Preparer Identification. The initials or other unique identifier of the person who added the drug or drugs; ( )

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

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

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: ( )

01. Drug Name and Strength. The name and strength of the drug; ( )

02. Expiration Date. An expiration date that is the lesser of: ( )

a. The manufacturer's original expiration date; ( )

b. One (1) year from the date the drug is prepackaged; or ( )

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.); ( )

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. ( )

144. (RESERVED)

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. ( )

146. -- 199. (RESERVED)

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

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

a. The prescription will be paid for, in whole or in part, by an insurer; or ( )

b. The pharmacy is part of the institutional facility where the patient is being treated. ( )

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: ( )

a. The recipient's name (if other than the patient); ( )

b. A notation indicating that the recipient was known to the pharmacy staff; and ( )

c. The identity of the pharmacy staff member making the personal identification. ( )

03. Acceptable Identification. The identification presented must include an unaltered photograph and signature and acceptable forms include a valid state or military driver's license or identification card and a valid passport. ( )

04. Identification Documentation. Documentation of the recipient's identification must be permanently linked to the record of the dispensed prescription and must include: ( )

a. A copy of the identification presented; or ( )

b. A record that includes: ( )

i. The recipient's name; ( )

ii. A notation of the type of identification presented; ( )

iii. The state, military branch, or other government entity that issued the identification; and ( )

iv. The identification number of the driver's license, identification card, or passport. ( )

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. ( )

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

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

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

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

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

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. ( )

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. ( )

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. ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

02. Restricted Quantity. No more than 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. ( )

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

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. ( )

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: ( )

a. The name and address of the purchaser; ( )

b. The name and quantity of the controlled substance purchased; ( )

c. The date of the purchase; ( )

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

e. The signature of the purchaser. ( )

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

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 and prescribers that dispense controlled substances. Data on controlled substance prescription drug samples does not need to be reported. ( )

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: ( )

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

b. Obtain Board approval for access; and ( )

c. Be issued a user account, login name, and password. ( )

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. ( )

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. ( )

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. ( )

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. ( )

206. CONTROLLED SUBSTANCES -- INVENTORIES.

01. Annual Inventory of Stocks of Controlled Substances. Each registrant must conduct an inventory of controlled substances on hand at least every twelve (12) months in a form and manner that satisfies the inventory requirements of federal law. ( )

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

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

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. ( )

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. ( )

06. Annual Inventory Compliance. Complete inventories conducted as otherwise required by these rules may also be considered in complying with the annual inventory requirement. ( )

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

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. ( )

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. ( )

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: ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

210. -- 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. ( )

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

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 ( )

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. ( )

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. ( )

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. ( )

01. Administration of Investigational Drugs. Nurses may administer investigational drugs only after completion of appropriate education and training by the clinician on relevant pharmacologic information about investigational drugs. ( )

02. Information on Investigational Drugs. Essential information resources regarding investigational drugs must be readily available. ( )

231. -- 239. (RESERVED)

240. STERILE PRODUCT PREPARATION.

01. Environmental Controls. The environment for the preparation of sterile products must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. ( )

a. Hoods and aseptic environmental control devices must be certified for operational efficiency as often as recommended by the manufacturer or at least every twelve (12) months or if relocated. ( )

b. Prefilters must be inspected and replaced in accordance with the manufacturer's recommendations. ( )

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

a. Protective apparel including non-vinyl gloves, gowns, and masks; ( )

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

c. A refrigerator for proper storage of additives and finished sterile products prior to delivery when

necessary; ( )

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

e. A separate vertical flow biohazard safety hood, if hazardous materials are prepared; and ( )

f. Supplies necessary for handling both hazardous and biohazardous spills and disposal of wastes must be available and maintained in the area at all times. ( )

03. Cytotoxic Drugs. A drug outlet in which cytotoxic drugs are prepared must also: ( )

a. Be equipped with and prepare the drugs in a vented 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; ( )

b. Require appropriate containment techniques; ( )

c. Clearly identify prepared doses of cytotoxic drugs, label them with proper precautions, and dispense them in a manner to minimize risk of cytotoxic spills; ( )

d. Comply with applicable local, state, and federal laws in the disposal of cytotoxic waste; and ( )

e. Include procedures for handling cytotoxic spills in the policies and procedures manual. ( )

04. Documentation Requirements. The following documentation must also be maintained by a drug outlet in which sterile products are prepared: ( )

a. Justification of expiration dates chosen; ( )

b. Employee training records; ( )

c. Technique audits; and ( )

d. Equipment inspection, monitoring, and maintenance. ( )

05. Policies and Procedures. Policies and procedures appropriate to the practice setting must be adopted by a drug outlet compounding sterile pharmaceutical products and must: ( )

a. Be designed and sufficiently detailed to protect the health and safety of persons preparing or receiving sterile products; and ( )

b. Include a continuous quality improvement program for monitoring personnel qualifications and training in sterile technique, product storage, stability standards, and infection control. ( )

241. -- 259. (RESERVED)

260. DRUG PRODUCT STORAGE.
Prescription drugs, controlled substances, or other items restricted to sale, dispensing, or administration by, or under the supervision of, a pharmacist or other registrant 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. ( )

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. ( )

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. ( )

03. Adulterated Drug Reporting Required. A licensee or registrant must report to the Board any adulteration of a prescription drug. ( )

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. ( )

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: ( )

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 ( )

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 ( )

c. Those for which the following conditions are satisfied: ( )

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; ( )

ii. The drug is returned in an unopened manufacturer-sealed container or with other tamper-evident packaging intact; ( )

iii. In the professional judgment of the pharmacist, the safety and efficacy of the drug has not been compromised; and ( )

iv. A system is in place to track the restocked drug for purposes of a recall. ( )

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. ( )

03. Consulting Pharmacy and PIC Responsibilities. The pharmacy and its PIC are responsible for consulting with an institutional facility from which returns will be accepted and must ensure that the institutional facility has an employee trained and knowledgeable in the proper storage, use, and administration of drugs and devices at the institutional facility. ( )

263. -- 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. ( )

a. The drug name, strength, lot number, and expiration date must appear on the package or label. ( )

b. The drug must be FDA-approved and: ( )

i. Be in the original unit dose packaging; or ( )

ii. Be an oral or parenteral drug in a sealed, single dose container approved by the FDA; or ( )

iii. Be a topical or inhalant drug in a sealed, unit-of-use container approved by the FDA; or ( )

iv. Be a parenteral drug in a sealed, multiple dose container approved by the FDA from which no doses have been withdrawn. ( )

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. ( )

d. The drug must not require storage temperatures other than normal room temperature as specified by the manufacturer or the USP. ( )

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. ( )

02. Donation Standards. ( )

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. ( )

b. Donating nursing homes may only donate drugs that appear on the formulary. ( )

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: ( )

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; ( )

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; ( )

iii. Attests that the donated drugs are those qualified for donation by their inclusion in the qualifying charitable clinic or center's formulary; ( )

iv. Attests that the donation is fully compliant with these rules; ( )

v. Attests that all PHI has been removed or redacted from the package; ( )

vi. Lists the name of the donating nursing home and the name of the receiving qualifying charitable clinic or center; and ( )

vii. Lists the name, strength, expiration date, lot number, and quantity of each prescription drug donated. ( )

d. A copy of the manifest must be delivered to the qualifying charitable clinic or center with the donated drugs. ( )

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. ( )

04. Verification of Received Drugs. ( )

a. Each donated drug must be verified against the donation manifest by an individual authorized to receive the drugs. ( )

b. If all PHI has not been removed by the donating entity, the information must be removed or redacted prior to dispensing. ( )

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: ( )

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; ( )

ii. Verify that the name and strength indicated on the label of each donated drug unit is correct; and ( )

iii. Determine for each donated drug that it is not adulterated or misbranded and is safe to dispense. ( )

d. Donated drugs that do not meet the criteria of these rules must be destroyed and documentation of the destruction retained. ( )

05. Storage of Donated Drugs. ( )

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. ( )

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. ( )

c. The drug storage area must be secured at all times and accessible only to persons authorized to handle donated drugs. ( )

06. Dispensing Donated Drugs. ( )

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. ( )

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: ( )

i. Use an appropriate container; ( )

ii. Label the container as required by these rules except that the expiration date must be the same as on the original container; and ( )

iii. Initial the prescription label. ( )

c. A qualifying charitable clinic or center must retain records for each donated drug dispensed. ( )

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. ( )

07. Miscellaneous. ( )

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. ( )

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. ( )

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. ( )

d. Nothing in these rules precludes a qualifying charitable clinic or center from charging a dispensing fee. ( )

266. -- 269. (RESERVED)

270. EMERGENCY DRUG DISTRIBUTION BY A DISPENSER.
For an emergency medical reason, pursuant to Section 54-1752(16), Idaho Code, a dispenser may distribute (without obtaining a wholesale distribution registration) a drug to another dispenser, as follows: ( )

01. Emergency. For purposes of this rule, an emergency medical reason is a situation where a quantity of a drug is needed by a dispenser without an alternative source for the drug reasonably available and the drug is unavailable through a normal distribution channel in sufficient time to prevent risk of harm to a patient that would result from a delay in obtaining the drug. ( )

02. Allowable Amount. The amount of drug distributed must not reasonably exceed the amount required for immediate dispensing. ( )

03. Controlled Substance Distribution. For controlled substances, each dispenser must retain a signed receipt of the distribution that includes at least: ( )

a. The date of the transaction; ( )

b. The name, address, and DEA registration number of the distributing dispenser; ( )

c. The name, address, and DEA registration number of the receiving dispenser; ( )

d. The drug name, strength, and quantity for each product distributed; and ( )

e. The signature of the person receiving the drugs. ( )

271. -- 289. (RESERVED)

290. ADS SYSTEM -- MINIMUM STANDARDS.
This rule establishes the minimum standards for the use of an ADS system to dispense and store drugs and devices. ( )

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: ( )

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; ( )

b. In a prescriber drug outlet; and ( )

c. In an institutional facility. ( )

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: ( )

a. The manufacturer's name and model of the ADS system; ( )

b. The state and, if applicable, federal ADS system registrations; and ( )

c. The name, address, and specific location where the ADS system is operational. ( )

03. System Access, Monitoring, and Control. Access to the ADS system must be controlled as follows: ( )

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, or director; ( )

b. The prescriber, PIC, or director must be able to stop or change access at any time; ( )

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; and ( )

d. Review of user access reports must be conducted periodically to ensure that access by persons no longer employed has been appropriately disabled. ( )

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. ( )

05. System Filling, Stocking, Replenishing. The filling, stocking, or replenishing of drugs into the ADS system must be accomplished by a pharmacist, technician, prescriber, 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. ( )

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: ( )

a. The date; ( )

b. The drug name; ( )

c. The dosage form; ( )

d. The strength; ( )

e. The quantity; ( )

f. The drug expiration; ( )

g. The identity of the ADS system; and ( )

h. The name or initials of the authorized individual filling the ADS system and, if applicable, the verifying pharmacist or prescriber. ( )

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: ( )

a. The identity of the system and, if applicable, the component accessed; ( )

b. The name or other identification (e.g., electronic signature or unique identifier) of the person conducting the transaction; ( )

c. The type of transaction; ( )

d. The date and time of transaction; ( )

e. The name, strength, dosage form, and quantity of the drug or description of the medical device accessed; and ( )

f. If applicable, the name of the patient for whom the drug was ordered. ( )

08. Supervising Pharmacy Documentation. The supervising pharmacy of a remote dispensing site must retain separate records of transactions and prescriptions processed by each ADS system utilized. ( )

09. 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. ( )

10. 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: ( )

a. A pharmacist has verified the proper filling and labeling of the cartridge or container; ( )

b. The individual cartridges or containers are transported to the ADS system in a secure, tamper-evident container; and ( )

c. The ADS system utilizes technologies to ensure that the cartridges or containers are accurately loaded. ( )

11. Self-Service ADS System. An ADS system may be used for self-service delivery of prescriptions if in compliance with this rule. ( )

a. Products that are temperature sensitive must not be provided unless the system is able to maintain required storage conditions. ( )

b. Controlled substances and products that require additional preparation to be ready for patient use must not be provided. ( )

c. The system must be physically attached to the pharmacy or prescriber drug outlet in a manner that access to areas used to stock the device are only accessible through the pharmacy or prescriber drug outlet by authorized personnel. ( )

d. The system must be operational only during the operating hours of the pharmacy or prescriber drug outlet. ( )

e. A self-service ADS system must not be used to deliver new prescriptions outside of a prescriber

drug outlet. ( )

f. Prescribers utilizing a self-service ADS system to deliver new prescriptions must provide patient counseling on all new medications. ( )

g. The use of a self-service ADS system for prescription refills must comply with laws applicable to the provision of refills by a pharmacy and must provide a patient notification with information about how counseling may be obtained. ( )

12. 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 and are subject to inspection by the Board upon reasonable notice. ( )

291. ADS SYSTEMS -- INSTITUTIONAL FACILITIES.
Institutional facilities utilizing one or more ADS systems must ensure compliance with the ADS system minimum standards, as applicable, and the requirements of this rule. ( )

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: ( )

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 ( )

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. ( )

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: ( )

a. The system is being used as an after-hours cabinet for drug dispensing in the absence of a pharmacist. ( )

b. The system is being used in place of an emergency kit. ( )

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. ( )

d. The drug is a subsequent dose from a previously reviewed drug order. Any change made to the drug order requires a new approval by a pharmacist prior to removing the drug. ( )

03. Product Returns. The ADS system must provide a mechanism for securing and accounting for drugs removed from and subsequently returned to the system (e.g., a return bin). ( )

a. A drug removed but not administered to a patient must be returned to the pharmacy immediately or maintained in a manner that prevents access to the returned drug except to return it to the pharmacy and except: ( )

i. Items that are too large or bulky to be inserted into the system's return bin; ( )

ii. Items requiring refrigeration; or ( )

iii. Limited critical care items for which inaccessibility would compromise patient care. ( )

b. A removed drug or device must not be returned directly to the system for immediate reissue or reuse. ( )

c. Once removed, a drug or device must not be reused or reissued except: ( )

i. Drugs stored after dispensing under the drug storage conditions required by these rules; ( )

ii. As supervised by the pharmacist; and ( )

iii. In unopened, sealed, intact, and unaltered containers. ( )

04. Wasted and Discarded Drugs. The ADS system must provide a mechanism for securing and accounting for wasted or discarded drugs. Waste documentation must include at least the following: ( )

a. Date and time of transaction; ( )

b. Patient name and location; ( )

c. Drug and dose; ( )

d. Quantity of transaction; ( )

e. Wasted amount; ( )

f. Beginning and ending count (for controlled substances only); ( )

g. Nurse identification; and ( )

h. Witness identification, if needed. ( )

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. ( )

292. -- 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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

a. The function is routine; ( )

b. The function is one for which the technician is adequately trained; ( )

c. The function is performed under a pharmacist's supervision; and ( )

d. The function does not require the use of a pharmacist's professional judgment. ( )

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. ( )

304. PHARMACIST -- AUTHORIZED PHARMACY ENTRANCE.
A pharmacist must not permit a person other than a pharmacist, student pharmacist, or technician to 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. ( )

305. -- 309. (RESERVED)

310. PHARMACIST COLLABORATIVE PHARMACY PRACTICE.
Pharmacists 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. ( )

01. Agreement Elements. The collaborative pharmacy practice agreement must include: ( )

a. Identification of the parties to the agreement; ( )

b. The establishment of each pharmacist's scope of practice authorized by the agreement, including a description of the types of permitted activities and decisions; ( )

c. The drug name, class, or category and protocol, formulary, or clinical guidelines that describe or limit a pharmacist's authority to perform DTM; ( )

d. A described method for a prescriber to monitor compliance with the agreement and clinical outcomes of patients and to intercede where necessary; ( )

e. A provision documenting a prescriber's right to override a collaborative practice decision made by a pharmacist whenever deemed necessary or appropriate; ( )

f. A provision allowing any party to cancel the agreement by written notification; ( )

g. An effective date; and ( )

h. Signatures of the parties to the agreement and dates of signing. ( )

i. Amendments to a collaborative pharmacy practice agreement must be documented, signed, and

dated. ( )

02. Board Review. The original collaborative pharmacy practice agreement and any subsequent revisions must be made available to the Board upon request. ( )

03. Agreement Review. The collaborative pharmacy practice agreement must be reviewed and renewed annually and revised when necessary or appropriate. ( )

04. Documentation of Pharmacist Activities. The patient care provided pursuant to the agreement must be documented in the patient's permanent record in a manner that allows it to be readily available to other healthcare professionals providing care to the patient. ( )

311. -- 319. (RESERVED)

320. PHARMACIST INDEPENDENT PRACTICE.
A pharmacist may provide pharmaceutical care services outside of a pharmacy or institutional facility if the following conditions are met: ( )

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; ( )

02. Information Protected from Unauthorized Use. Access to the information required by these rules is protected from unauthorized access and use; and ( )

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. ( )

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. ( )

02. Pharmacist Qualifications. To qualify to administer immunizations, a pharmacist must first: ( )

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: ( )

i. Basic immunology, vaccine, and immunization protection; ( )

ii. Diseases that may be prevented by vaccination or immunization; ( )

iii. Current recommended immunization schedules; ( )

iv. Vaccine and immunization storage and management; ( )

v. Informed consent; ( )

vi. Physiology and techniques for administration of immunizations; ( )

vii. Pre-immunization and post-immunization assessment and counseling; ( )

viii. Immunization reporting and records management; and ( )

ix. Identification response, documentation, and reporting of adverse events. ( )

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. ( )

03. Maintaining Qualification. To maintain qualification to administer immunizations, a pharmacist must annually complete a minimum of one (1) clock hour (0.1 CPEU) of ACPE-approved CPE related to vaccines, immunizations, or their administration, which may also be applied to the general CPE requirements of these rules. ( )

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. ( )

05. Waste Disposal. An immunizing pharmacist must properly dispose of used or contaminated supplies. ( )

06. Required Reports. An immunizing pharmacist must report: ( )

a. Adverse events to the healthcare provider identified by the patient, if any, and to the Vaccine Adverse Event Reporting System (VAERS); and ( )

b. Administration of immunizations to the Idaho Immunization Reminder Information System (IRIS), as required. ( )

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. ( )

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. ( )

09. Recordkeeping. For each administered immunization, the following information must be collected and maintained in the patient profile: ( )

a. The patient's name, address, date of birth, and known allergies; ( )

b. The date of administration; ( )

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

d. Documentation identifying the VIS provided; ( )

e. The site and route of administration and, if applicable, the dose in a series (e.g. one (1) of three (3)); ( )

f. The name of the patient's healthcare provider, if any; ( )

g. The name of the immunizing pharmacist and of the student pharmacist, if any; ( )

h. Adverse events observed or reported, if any, and documentation including at least the dates of any subsequent required reporting; and ( )

i. Completed informed consent forms. ( )

10. Emergencies. ( )

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

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

331. -- 349. (RESERVED)

350. STUDENT PHARMACIST UTILIZATION AND PRACTICE LIMITATIONS.

01. Activities. A student pharmacist may engage in the practice activities of a pharmacist if: ( )

a. The activity is not specifically required to be performed only by a pharmacist; ( )

b. The activity is commensurate with the education and skill of the student pharmacist and performed under the supervision of a pharmacist; ( )

c. Any activity of a compounding, dispensing, or interpretive nature is checked by a pharmacist; and ( )

d. Any recording activity that requires the initial or signature of a pharmacist is countersigned by a pharmacist. ( )

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. ( )

03. Identification of Student Pharmacists. ( )

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. ( )

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. ( )

351. -- 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. ( )

02. Unlawful Performance. A technician must not perform tasks or functions connected with pharmacy operations that: ( )

a. Are not routine; ( )

b. The technician is not adequately trained to perform; ( )

c. The technician has inadequate pharmacist supervision to perform; or ( )

d. Requires the use of a pharmacist's professional judgment. ( )

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: ( )

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; ( )

b. Consult with the prescriber prior to filling if clarification of information is needed regarding a patient or the prescription drug order; ( )

c. Perform prospective drug review or interpret clinical data in a patient's medication record (e.g., contraindications, drug interactions, etc.); ( )

d. Perform professional consultation with a prescriber, nurse, or other healthcare professional; ( )

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; ( )

f. Provide patient consultation on a new or refilled prescription or on over-the-counter drugs or supplements; and ( )

g. Supervise the pharmacy operations activities of student pharmacists and technicians. ( )

04. Technician Identification. ( )

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. ( )

b. Technicians must identify themselves as a technician on any phone calls initiated or received while on duty. ( )

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. ( )

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: ( )

a. The name of the pharmacist assigned as the coordinator of the verification technician program; ( )

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; ( )

c. A description of the duties of technicians designated to perform the functions of verifying the work of other technicians; ( )

d. Identification of the types of drugs verification technicians are authorized to verify; ( )

e. A description of the specialized and advanced training that must be provided to each verification

technician; and ( )

f. A description of the monitoring and evaluation processes used by the institutional pharmacy to ensure the ongoing competency of each verification technician. ( )

02. Program Requirements. Each institutional pharmacy utilizing a verification technician program must comply with the following requirements: ( )

a. A technician must neither be designated to perform, nor may the technician perform, verification functions without competently completing the required training. ( )

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. ( )

c. The institutional pharmacy must conduct ongoing monitoring and evaluation of each verification technician to ensure the ongoing competency of the technician. ( )

d. For each verification technician, an institutional pharmacy utilizing a verification technician program must maintain records containing: ( )

i. The date the technician was designated; ( )

ii. The date the technician completed the required training; ( )

iii. The dates and results of each competency evaluation; and ( )

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. ( )

e. While on duty, each verification technician must wear identification that includes the title, "Verification Technician." ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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). ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

14. Failure to Follow Board Order. Failure to follow an order of the Board. ( )

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. ( )

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. ( )

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, or to the hospital or other institutional facility in which the patient is convalescing. ( )

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. ( )

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. ( )

505. -- 599. (RESERVED)

SUBCHAPTER E -- DRUG OUTLET PRACTICE STANDARDS
(Rules 600 through 699 -- Drug Outlet Practice Standards)

600. PHARMACY REGISTRANT AND PIC OR DIRECTOR.

01. Designated PIC or Director Required. A pharmacy must not be without a designated PIC or director for more than thirty (30) sequential days. ( )

02. Corresponding and Individual Responsibility. The pharmacy registrant 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. ( )

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. ( )

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. ( )

03. Additional Retail Pharmacy Requirements. A retail pharmacy that is new or remodeled after the effective date of this rule must: ( )

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 prescription preparation or drug storage areas, and is compliant with the Americans with Disabilities Act; and ( )

b. Include a lavatory facility in the pharmacy restricted to pharmacy staff. ( )

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. ( )

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. ( )

03. Separate Telephone. A pharmacy 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. ( )

603. PHARMACY REFERENCES.

Required pharmacy references include the latest hard copy or electronic editions and supplements of the following: ( )

01. Pharmacy Laws and Rules. Idaho Pharmacy Laws and Rules. ( )

02. Current Pharmacy Reference. One (1) of the following current pharmacy references: ( )

a. Facts and Comparisons; ( )

b. Clinical Pharmacology; ( )

c. Micromedex; or ( )

d. Lexicomp. ( )

03. Additional Current Pharmacy Reference. One (1) additional current pharmacy reference relevant to the practice setting. ( )

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 as allowed by these rules for emergency access to an institutional pharmacy. 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. ( )

605. PHARMACY SECURITY.

01. Basic Security Standards. A pharmacy must be constructed and equipped with adequate security, and at least while closed, 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. Pharmacies without an alarm or other monitoring system as of the effective date of this rule must comply with this rule upon completion of a structural remodel. ( )

02. Non-Institutional Pharmacy Security During Pharmacist Absence. A non-institutional pharmacy must be closed for business and secured during all times a pharmacist is not present except for temporary pharmacist absences for on-premises rest breaks or to perform professional services in the peripheral areas immediately outside of the pharmacy. ( )

03. Structural Security Requirements. If a pharmacy is located within an establishment that is open to the public for business at times when a pharmacist is not present, the pharmacy 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. ( )

a. Pharmacy walls must extend to the roof or the pharmacy must be similarly secured from unauthorized entry. ( )

b. Solid core or metal doors are required. ( )

c. Doors and other access points must be constructed in a manner that the hinge hardware is accessible only from inside of the pharmacy and must be equipped with locking devices. ( )

d. 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. ( )

04. Restricted Access to the Pharmacy. No one must be allowed entrance to the closed and secured pharmacy unless under the direct supervision of a pharmacist or except as permitted by these rules for an institutional pharmacy. ( )

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. ( )

02. Notification of Change of Business Hours. The Board 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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

a. The name and address of the pharmacy to be sold or closed; ( )

b. The date of sale or closure; ( )

c. The name and address of the business acquiring the prescription inventory; and ( )

d. The name and address of the pharmacy acquiring the prescription files and patient profiles in compliance with the records retention requirement. ( )

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. ( )

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. ( )

04. Transfer or Other Disposition of Drugs and Prescription Files. The PIC of a pharmacy that ceases operation must adequately secure and protect the drug product inventory from diversion, deterioration, or other damage until lawful transfer or disposition and must retain a closing inventory of controlled substances. ( )

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. ( )

610. -- 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 within institutional facilities or by persons employed by them. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

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. ( )

02. Formulary or Drug List Development. The participation in any development of a formulary or drug list for the facility. ( )

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. ( )

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: ( )

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; ( )

b. Ensuring that outdated or other unusable drugs are identified and stored in a manner that prevents their distribution or administration prior to disposition; ( )

c. Ensuring that emergency drugs are in adequate and proper supply at designated locations; ( )

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; ( )

e. Ensuring accurate filling and labeling of containers from which drugs are to be administered or dispensed; ( )

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 ( )

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. ( )

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. ( )

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. ( )

07. Records Maintenance. The maintenance of records of institutional pharmacy transactions required by law. ( )

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. ( )

09. Continuous Quality Improvement Program. The development and implementation of a continuous quality improvement program to review and evaluate pharmaceutical services and recommend improvements. ( )

623. -- 629. (RESERVED).

630. INSTITUTIONAL FACILITY -- GENERAL STANDARDS FOR ADMINISTRATION AND CONTROL OF DRUGS AND DEVICES.

01. Drugs and Devices Dispensed for Administration or Use Within an Institutional Facility. Within an institutional facility, drugs and devices may be dispensed for administration to, or for self-administration or use by, a patient while in the institutional facility only as permitted by applicable law and these rules consistent with usual and customary standards of good medical practice, as follows: ( )

a. Upon the drug orders of licensed facility prescribers; ( )

b. Pursuant to an emergency protocol for the administration of drugs without an order in life or death situations; and ( )

c. By 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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

05. Suspected Adverse Drug Reaction Reporting. Suspected adverse drug reactions must be communicated in a timely manner to the pharmacy. ( )

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. ( )

631. INSTITUTIONAL FACILITY -- EMERGENCY DRUG ACCESS AND PHARMACIST ABSENCE. 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. ( )

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: ( )

a. One (1) R.N. may be designated per shift for emergency access to the pharmacy; ( )

b. Access may only occur if controlled substances are secured in a locked cabinet or other appropriate means to prevent unauthorized access; and ( )

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. ( )

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: ( )

a. The emergency cabinet must be accessible only by key, combination, or otherwise sufficiently

secured to deny access to unauthorized persons; and ( )

b. Drugs stocked in the emergency cabinet must be approved, prepared, stored, and handled as specified by these rules for emergency drug supplies. ( )

03. Emergency Drug Access Conditions and Documentation. Emergency access by an R.N. to an institutional pharmacy or an emergency cabinet or similar enclosure must be documented as follows: ( )

a. Removal of a drug must be pursuant to a valid drug order; ( )

b. Removal of a drug must be documented in a record that includes at least: ( )

i. The patient's name and location; ( )

ii. The name and strength of the drug; ( )

iii. The amount; ( )

iv. The date and time; and ( )

v. The signature of the designated nurse. ( )

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. ( )

04. 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: ( )

a. No other person may be allowed access or entrance to the pharmacy; ( )

b. Drugs or devices may not leave the pharmacy except if requested by, and immediately delivered to, the pharmacist; and ( )

c. Neither student pharmacists nor technicians may remain in the pharmacy during periods of pharmacist absence from the institutional facility. ( )

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: ( )

01. Prepackaged Amounts. The drugs must be prepackaged in amounts sufficient to satisfy immediate therapeutic requirements only; ( )

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; ( )

03. Access Documentation. Access to the emergency drugs must be documented by drug orders and, if applicable, proofs of use; ( )

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 ( )

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. ( )

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. ( )

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. ( )

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: ( )

a. The name, strength, and quantity of each drug; ( )

b. The expiration date of the first expiring drug; and ( )

c. The name, address, and telephone number of the supplying pharmacist, if applicable. ( )

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. ( )

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. ( )

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. ( )

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**.** ( )

01. Provider Pharmacy Documentation. The nursing home must document the pharmacy retained in writing. ( )

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. ( )

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: ( )

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. ( )

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. ( )

03. Controlled Substances. Emergency kits supplied to home health or hospice agencies must not include controlled substances. ( )

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. ( )

01. Pharmacist Routine Monitoring. Floor stock drugs must be routinely monitored by a pharmacist to ensure appropriate use and storage. ( )

02. Prescription Drugs. Prescription drugs included in floor stock must be in unit dose or unit-of-use packaging. ( )

03. Controlled Substances. For controlled substances included in the floor stock formulary, the director must ensure that: ( )

a. The floor stock contains appropriate controlled substances that are prepackaged in amounts sufficient for only immediate therapeutic requirements; ( )

b. Controlled substances maintained as floor stock are accessible only by key, combination, or otherwise sufficiently secured to deny access to unauthorized persons; ( )

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: ( )

i. The patient's name and location; ( )

ii. The name and strength of the drug; ( )

iii. The amount; ( )

iv. The date and time; and ( )

v. The signature or electronic personal verification of the person delivering the drug; and ( )

d. Controlled substances are inventoried at least weekly. ( )

637. INSTITUTIONAL FACILITY -- EMERGENCY OUTPATIENT DRUG DELIVERY BY HOSPITAL EMERGENCY ROOMS.
A limited supply of drugs, not including Schedule II controlled substances, may be approved for delivery to outpatients receiving hospital emergency room treatment if stored in the emergency room pursuant to applicable law and these rules pertaining to emergency drug product storage and if accessed and delivered as permitted or restricted by this rule. ( )

01. 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. ( )

02. Documentation. Delivery must occur only pursuant to a valid drug order and must be documented as required by these rules for institutional facility emergency drug access. ( )

03. Labeling. A label must be affixed to the container with the information required by these rules for outpatient dispensing. ( )

04. R.N. Staff Personnel Only. This rule does not authorize any person other than an R.N. on a hospital's emergency room staff to prepare or deliver prescription drugs to outpatients receiving emergency

treatment. ( )

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. ( )

02. Written Agreement. The arrangements must be made in writing and must, at a minimum, specify that: ( )

a. An offsite pharmacist will act in the capacity of a part-time director; ( )

b. For nursing homes, on-call services by a pharmacist will be available at all times; ( )

c. The pharmacy will provide adequate storage facilities for drugs; and ( )

d. Drugs housed in an LTCF must be labeled as required by the general provisions of these rules and, unless maintained in an electronic record, must include a lot number for administration of recalls. ( )

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 with these rules. ( )

642. -- 649. (RESERVED)

650. INSTITUTIONAL FACILITY -- CENTRALIZED PHARMACY SERVICES.
An institutional pharmacy may centralize prescription drug order processing or filling services if: ( )

01. Limited Purpose. The centralizing of prescription drug order processing or filling services is 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; ( )

02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility to centralize prescription drug order processing or filling services for its patients and residents; ( )

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 ( )

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. ( )

651. INSTITUTIONAL FACILITY -- PRACTICE OF TELEPHARMACY.

01. Contracted Telepharmacy Services. An institutional pharmacy may centralize pharmacy services through the practice of telepharmacy if: ( )

a. The central pharmacy provides a training and orientation program that ensures that pharmacists who are providing telepharmacy services are competent to review and approve drug orders; ( )

b. Appropriate video, telecommunications, or other systems allow the pharmacist within the central pharmacy to readily communicate with the prescribers within the institutional facility; ( )

c. The parties share a common electronic file or utilize other technology that allows access by the central pharmacy to information required to fill or refill a prescription drug order; and ( )

d. The parties implement and maintain a continuous quality improvement program for telepharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems. ( )

02. Policies and Procedures. An institutional pharmacy and its contracted central pharmacy that provides telepharmacy services must adopt policies and procedures and retain documentation that evidences at least the following: ( )

a. A copy of the approval required by these rules; ( )

b. A copy of the contract required by these rules; ( )

c. Identification of the director of the central pharmacy and of the institutional pharmacy; ( )

d. The maintenance of appropriate records to identify the pharmacists providing centralized prescription drug order processing or filling services; ( )

e. The protocol for ensuring that the central pharmacy maintains sufficient Board licensed or registered pharmacists to meet the centralized pharmacy services needs of the institutional facility; ( )

f. The maintenance of a mechanism for tracking the prescription drug order during each step in the dispensing process; ( )

g. The documentation and protocols demonstrating adequate security to protect the privacy of PHI; ( )

h. The protocol for accessing prescription drugs in the institutional pharmacy contracting with the central pharmacy and for maintaining the security of the drugs; ( )

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

j. The protocol for the central pharmacy to perform a review of the patient's profile, including but not limited to performing a prospective drug review. ( )

652. -- 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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

a. Controlled substances listed in Schedules I through V of either the state or federal Controlled Substances Acts; ( )

b. Euthanasia drugs or products; ( )

c. Tranquilizer drugs or products; ( )

d. Curare, succinylcholine, or other neuromuscular paralyzing drugs; and ( )

e. General anesthesia drugs or products. ( )

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. ( )

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. ( )

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. ( )

675. -- 679. (RESERVED)

680. TELEPHARMACY ACROSS STATE LINES.
The practice of telepharmacy across state lines is permitted only for institutions engaged in the practice of telepharmacy across state lines, as defined, and their pharmacists if both are registered or licensed as required by the Board. ( )

681. -- 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: ( )

01. Description of Services. A description of the type and method of specialized services to be provided; ( )

02. Times of Operation. The days and hours of operation; ( )

03. Drug Information. The types and schedules of drugs to be stored, distributed, or dispensed; and ( )

04. Equipment and Supplies. The equipment and supplies to be used. ( )

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: ( )

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. ( )

a. Information justifying the need for the remote dispensing site must be submitted with the initial registration application. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

b. The contract must be retained by the supervising pharmacy. ( )

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. ( )

04. Remote Dispensing Site Limitations. The Board may limit the number of remote dispensing sites under the supervision and management of a single pharmacy. ( )

05. Technician Staffing. A remote dispensing site must be staffed by one or more certified technicians 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. ( )

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: ( )

a. Electronic records must be available to, and accessible from, both the supervising pharmacy and the remote dispensing site; and ( )

b. Prescriptions dispensed at the remote dispensing site must be distinguishable from those dispensed

from the supervising pharmacy. ( )

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. ( )

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 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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

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. ( )

12. Returns Prohibited. The technician at a remote dispensing site must not accept drugs returned by a patient or patient's agent. ( )

13. Patient Counseling. A remote dispensing site must include an appropriate area for patient counseling. ( )

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. ( )

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. ( )

14. Remote Dispensing Site Sign. A remote dispensing site must display a sign, easily visible to the public, that informs patients that: ( )

a. The location is a remote dispensing site providing telepharmacy services supervised by a pharmacist located in another pharmacy; ( )

b. Identifies the city or township where the supervising pharmacy is located; and ( )

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. ( )

15. 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. ( )

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: ( )

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. ( )

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. ( )

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. ( )

c. Except when prohibited by law for controlled substances, the technician may also transmit the prescription drug order to the supervising pharmacist by fax. ( )

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. ( )

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. ( )

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. ( )

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. ( )

712. RETAIL TELEPHARMACY WITH REMOTE DISPENSING SITES -- POLICIES AND PROCEDURES.
A supervising pharmacy commencing telepharmacy operations with a remote dispensing site after August 23, 2011, must adopt policies and procedures that address each of the following areas prior to engaging in the practice of telepharmacy. ( )

01. Minimum Standards. The establishment of minimum standards and practices necessary to ensure safety, accuracy, security, sanitation, recordkeeping, and patient confidentiality, including at least: ( )

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; ( )

b. Procedures for the procurement of drugs and devices to the remote site and into any ADS systems used; and ( )

c. The criteria for monthly in-person pharmacist inspections of the remote dispensing site and appropriate documentation. ( )

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. ( )

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: ( )

a. Procedures for response while the communication or electronic recordkeeping systems are experiencing downtime or for an ADS system malfunction; and ( )

b. Procedures for the maintenance and testing of the written plan for recovery. ( )

713. -- 749. (RESERVED)

750. DME OUTLET STANDARDS.

01. Policies and Procedures. A DME outlet must adopt policies and procedures that establish: ( )

a. Operational procedures for the appropriate provision and delivery of equipment; ( )

b. Operational procedures for maintenance and repair of equipment; and ( )

c. Recordkeeping requirements for documenting the acquisition and provision of products. ( )

02. DME Outlet Sale of Specified Prescription Drugs. Registered DME outlets may hold for sale at retail the following prescription drugs: ( )

a. Pure oxygen for human application; ( )

b. Nitrous oxide; ( )

c. Sterile sodium chloride; and ( )

d. Sterile water for injection. ( )

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. ( )

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. ( )

801. WHOLESALER FACILITY REQUIREMENTS.
Facilities where drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution must: ( )

01. Minimum Physical Standards. Be of suitable size, construction, and location to accommodate cleaning, maintenance, and proper operations; ( )

02. Minimum Environmental Standards. Have adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; ( )

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; ( )

04. Maintenance Requirements. Be maintained in a clean and orderly condition; and ( )

05. Pest Controls. Be free from infestation by insects, rodents, birds, or vermin of any kind. ( )

802. WHOLESALER FACILITY SECURITY.
Facilities used for wholesale drug distribution must be secure from unauthorized entry, as follows: ( )

01. Access from Outside. Access from outside the premises must be kept to a minimum and well controlled; ( )

02. Perimeter Lighting. The outside perimeter of the premises must be well lighted; ( )

03. Authorized Entry. Entry into areas where drugs are held must be limited to authorized personnel; ( )

04. Alarm Systems. Facilities must be equipped with an alarm systems to detect entry after hours; and ( )

05. Security Systems. Facilities must be equipped with security systems sufficient to protect against theft, diversion, and record tampering. ( )

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. ( )

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. ( )

02. Outgoing Shipment Inspections. Outgoing shipments must be inspected to verify the accuracy and product integrity of the shipment contents. ( )

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. ( )

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. ( )

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. ( )

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. ( )

01. Record Contents. The records must include at least: ( )

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; ( )

b. The identity and quantity of the drugs received and distributed or disposed of; and ( )

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

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. ( )

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. ( )

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. ( )

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. ( )

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: ( )

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. ( )

02. Recalls and Withdrawals. Drugs must be recalled or withdrawn upon: ( )

a. A request by the FDA or other local, state, or federal law enforcement or other government agency, including the Board; ( )

b. A voluntary action by a manufacturer to remove defective or potentially defective drugs from the market; or ( )

c. An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or a new package design. ( )

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. ( )

809. PRESCRIPTION DRUG PEDIGREES.
Each person, including repackagers but excluding the original manufacturer of the finished form of the prescription drug, engaged in wholesale distribution of prescription drugs that leave or have left the normal distribution channel must tender a pedigree to the person receiving the drug upon delivery. A retail pharmacy or chain pharmacy warehouse must comply with these pedigree requirements only if engaging in wholesale distribution. ( )

01. Pedigree Contents. A pedigree for each prescription drug must contain the following information: ( )

a. The proprietary and established name of the drug; ( )

b. The container size; ( )

c. The number of containers; ( )

d. The dosage form; ( )

e. The dosage strength; ( )

f. The lot number with expiration dates and the NDC; ( )

g. The name of the manufacturer and repackager, if applicable, of the finished product; ( )

h. The name, address, telephone number, and, if available, the e-mail address, of each owner and each wholesale distributor of the drug; ( )

i. The name and address of each location from which the drug was shipped, if different from the owner's; ( )

j. The dates of each transaction; ( )

k. A certification that each recipient has authenticated the pedigree; and ( )

l. The name and address of each recipient. ( )

02. Authentication. Each person engaged in wholesale distribution who is provided a pedigree must affirmatively verify each listed transaction before further wholesale distribution may occur. ( )

03. Availability of Records for Inspection. Pedigrees must be retained and made available to the

Board upon request. ( )

810. -- 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.
( )

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. ( )

901. DRUG MANUFACTURER STANDARDS.
A manufacturer must ensure compliance with the federal "Current Good Manufacturing Practice" requirements.
( )

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.
( )

903. -- 999. (RESERVED)