24.36.01 – RULES OF THE IDAHO STATE BOARD OF PHARMACY

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, and 54-1755, Idaho Code. ( )

001. SCOPE.
These rules 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; and regulate and control the practice of pharmacy, pursuant to the Idaho Pharmacy Act, Title 54, Chapter 17, Idaho Code. ( )

002. DEFINITIONS AND ABBREVIATIONS.
The definitions set forth in Sections 54-1705 and 37-2701, Idaho Code, are applicable to these rules. In addition, the following terms have the meanings set forth below:

01. 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. ( )

02. DEA. United States Drug Enforcement Administration. ( )

03. DME – Durable Medical Equipment Outlet. A registered outlet that may hold for sale at retail durable medical equipment (DME) and the following prescription drugs: pure oxygen for human application, nitrous oxide, sterile sodium chloride, and sterile water for injection. ( )

04. Drug Outlet. Drug outlets include, but are not limited to, sterile product pharmacies, remote dispensing pharmacies, facilities operating narcotic treatment programs, DME outlets, prescriber drug outlets, outsourcing facilities, nuclear pharmacies, cognitive service pharmacies, correctional facilities, offsite ADSs for non-emergency dispensing, reverse distributors, mobile pharmacies, and analytical or research laboratories. ( )

05. FDA. United States Food and Drug Administration. ( )

06. Hazardous Drug. Any drug listed as such by the National Institute for Occupational Safety and Health or any drug identified by at least one (1) of the following criteria: carcinogenicity; teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low doses in humans or animals; genotoxicity; or new drugs that mimic existing hazardous drugs in structure or toxicity. ( )

07. HIPAA. Health Insurance Portability and Accountability Act of 1996. ( )

08. NDC. National Drug Code. ( )

09. Pharmaceutical Care Services. A broad range of services for patients performed independently or in collaboration with other health care professionals. Pharmaceutical care services are not limited to, but may include one (1) or more of the following: ( )

a. Diagnosing the patient's health status or condition; ( )

b. Reviewing or formulating a drug utilization plan; ( )

c. Monitoring and evaluating the patient's response to drug therapy; ( )

d. Ordering and interpreting laboratory tests and imaging; ( )

e. Performing drug product selection, substitution, medication administration, prescription adaptation, or refill authorization as provided in these rules; and ( )

f. Prescribing drugs and devices as provided in these rules. ( )

10. PDMP. Prescription Drug Monitoring Program. ( )

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

12. Reconstitution. The process of adding a diluent to a powdered medication to prepare a solution or suspension, according to the product's labeling or the manufacturer's instructions. ( )

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

003. -- 099. (RESERVED)

100. LICENSURE.

01. Licensure and Registration: Special Requirements.

a. Out-of-Practice. The Board may require any applicant who has both failed to maintain an active license in Idaho and has not practiced as a pharmacist for the preceding twelve (12) months or longer to take and pass an examination, complete intern hours, complete additional continuing education hours, or complete other requirements determined necessary to acquire or demonstrate professional competency. ( )

b. Cancellation and Registration. Failure to maintain the requirements for any registration will result in the cancellation of the registration. ( )

c. Reinstatement of License or Registration. Reinstatement applicants must provide satisfactory evidence of completion of a minimum of thirty (30) continuing education hours within the twenty-four (24) months prior to reinstatement and compliance with any direct orders of the Board. ( )

02. Pharmacist Continuing Education Requirement. To meet the standard of care, pharmacists are expected to complete sufficient continuing education germane to the practice of pharmacy to maintain their professional competence. At license renewal, every pharmacist shall attest that they have maintained competence through continuing education commensurate with their active practice setting. ( )

03. Determination of Need for Nonresident Licensure or Registration.

a. Independent Practice. Nonresident pharmacists must be licensed if engaged in the independent practice of pharmacy across state lines and not practicing for an Idaho registered drug outlet. ( )

b. Practice for an Idaho Registered Drug Outlet. A nonresident pharmacist serving as the PIC for an Idaho registered nonresident drug outlet must be registered to practice into Idaho. All other nonresident pharmacists who are employed by, or affiliated with, and practicing for the Idaho registered nonresident drug outlet, but who are not the PIC, are exempt from license and registration requirements for practice into Idaho. ( )

c. Multistate Pharmacists. Multistate pharmacists, as defined in Section 54-1723B, Idaho Code, are exempt from separate licensure or registration in Idaho. ( )

d. Exemption from Separate Practitioner Controlled Substance Registration. All pharmacists who manufacture, distribute, administer, dispense, or conduct research with any controlled substance in or into Idaho are exempt from obtaining a separate controlled substance registration, subject to compliance with all requirements of Title 37, Chapter 27, Idaho Code. This exemption does not apply to pharmacists who prescribe controlled substances in Idaho. ( )

04. Nonresident PIC Registration to Practice Pharmacy into Idaho. To be registered as a nonresident PIC, an applicant must submit an application on a Board form including, but not limited to: ( )

a. Individual License Information. Current pharmacist licensure information in all other states, including each state of licensure and each license number; ( )

b. Facility License Information. The license or registration number of the facility for which the applicant will be practicing. ( )

05. Pharmacist Intern Registration.

a. Registration Requirements. To be approved for and maintain registration as a pharmacist intern, the applicant must: ( )

i. Currently be enrolled and in good standing in an accredited school or college of pharmacy, pursuing a professional degree in pharmacy; or ( )

ii. Be a graduate of an accredited school or college of pharmacy within the United States and awaiting examination for pharmacist licensure; or ( )

iii. Be a graduate of a school or college of pharmacy located outside the United States, obtain certification by the FPGEC, and be awaiting finalization of pharmacist licensure. ( )

b. Renewal. ( )

i. Current Students. A pharmacist intern registration must be renewed biennially; however, the renewal fee will be waived, if renewed on time, for the duration of the student's enrollment in the school or college of pharmacy. Following graduation, if a pharmacist license application has been submitted, the pharmacist intern license will be extended at no cost for up to six (6) additional months from the date of application as a pharmacist, after which time the individual will need to submit a new application to continue to be a pharmacist intern. ( )

ii. Pharmacy Graduates. A graduate pharmacist intern registration may be obtained and renewed once within one (1) year from the date of issuance. The Board may, at its discretion, grant additional time to complete internship experience if unique circumstances present. ( )

06. Technician Exemption from Criminal Background Check. Technician candidates under the age of eighteen (18) are exempt from the fingerprint-based criminal history check requirement of Idaho Code. ( )

07. Practitioner Controlled Substance Registration. Any practitioner in Idaho who intends to prescribe, administer, dispense, or conduct research with a controlled substance must first obtain an Idaho practitioner controlled substance registration and: ( )

a. State License. Hold a valid license or registration to prescribe medications from a licensing entity established under Title 54, Idaho Code. ( )

b. DEA Registration. Obtain a valid federal DEA registration, if needed under federal law. Failure to obtain a federal DEA registration for any reason within forty-five (45) days of the issuance of the Idaho Practitioner Controlled Substance Registration will result in automatic cancellation. ( )

c. Idaho Practice Address. An Idaho practitioner controlled substance registration requires the applicant to establish an Idaho practice address, subject to inspection by the Board. This requirement does not apply to out-of-state practitioners who only prescribe into Idaho. ( )

08. Drug Outlet Licensure and Registration: General Requirements. A license or a certificate of registration is required for drug outlets prior to 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. ( )

a. New Drug Outlet Inspections. Following the issuance of a new license or registration, each drug outlet will be inspected to confirm that the facility is compliant with applicable law. A change of ownership of a currently registered pharmacy will not require an onsite inspection of a new pharmacy registration unless a change of location occurs. ( )

b. License and Registration Transferability. Drug outlet licenses and registrations are location and owner specific and are nontransferable as to person or place. ( )

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

d. Change of Location. At least ten (10) days prior to the event, the registrant must notify the Board of a drug outlet's change of location through the completion of an application for a new license or registration. When a licensee or registrant has made a timely and complete application for a new license or registration, the existing license does not expire until the application has been finally determined by the Board, and, in case the application is denied or the terms of the new license limited, until the last day for seeking review of the Board order. This does not preclude the Board from taking immediate action to protect the public interest. ( )

e. Change of Ownership. The registrant must notify the Board of any change to the operating legal entity's majority ownership of a drug outlet within thirty (30) days of the event. ( )

f. Permanent Closing. A registrant must notify the Board and the general public of the pharmacy's permanent closing at least ten (10) days prior to closing. The notice must include the proposed date of closure, and the new location of the prescription files. The notice to the board is to include the location where the closing inventory record of controlled substances is retained. ( )

g. Exemption from Separate Controlled Substance Registration. All drug outlets doing business in or into Idaho who hold a valid license or registration from the Board are exempt from obtaining a separate controlled substance registration, but are subject to compliance with all requirements under Title 37, Chapter 27, Idaho Code. ( )

09. Wholesaler Licensure and Registration.

a. Wholesaler Licensure. 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 on a Board form: ( )

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

ii. 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. ( )

b. Accreditation. The Board will recognize a wholesaler's accreditation by National Association of Boards of Pharmacy for purposes of reciprocity and satisfying the new drug outlet inspection requirements of these rules. ( )

c. Wholesaler Registration. Except when licensed pursuant to title 54, chapter 17, Idaho Code, and these rules, a wholesaler that engages in wholesale distribution of Durable Medical Equipment supplies, prescription medical devices, or products that contain pseudoephedrine in or into Idaho must be registered by the Board. ( )

10. Manufacturer Registration. Manufacturers that ship, mail, or deliver dispensed prescription drugs or devices to an Idaho resident must also register with the Board as a nonresident drug outlet. Those manufacturers

that only engage in the wholesale distribution of their own product are exempt from wholesale licensure. ( )

101. -- 199. (RESERVED)

200. PRACTICE STANDARDS

01. Scope of Practice. Subject to Idaho Code § 54-1705, pharmacists may perform pharmaceutical care services, as defined in these rules. ( )

02. Waivers or Variances. In the event of an emergency declared by the President of the United States, the Governor of the State of Idaho, or by any other person with legal authority to declare an emergency, the division administrator may waive any requirement of these rules for the duration of the emergency. ( )

03. Drug Outlets: Minimum Facility Standards.
A resident drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements: ( )

a. Security and Privacy. A drug outlet must be constructed and equipped with adequate security to protect its equipment, records and supply of drugs, devices and other restricted sale items from unauthorized access, acquisition or use. All protected health information must be stored and maintained in accordance with HIPAA. ( )

b. Controlled Substance Storage. Drug outlets must store controlled substances in accordance with federal law. ( )

c. Authorized Access to the Restricted Drug Storage Area. Access to the area where prescription drugs are prepared, compounded, distributed, dispensed, or stored must be limited to authorized personnel. ( )

d. Staffing. A drug outlet must be staffed sufficiently to allow for appropriate supervision, to otherwise operate safely and, if applicable, to remain open during the hours posted as open to the public for business. ( )

e. Electronic Recordkeeping System. A drug outlet that dispenses more than twenty (20) prescriptions per day must use an electronic recordkeeping system to establish and store patient medication records and prescription drug order, refill, transfer information, and other information necessary to provide safe and appropriate patient care. The electronic recordkeeping system must 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 prescriber responsible for the accuracy of these processes. ( )

04. Drug Outlets that Dispense Prescription Drugs: Minimum Prescription Filling Requirements. Unless exempted by these rules, each drug outlet that dispenses prescription drugs to patients in Idaho must meet the following minimum requirements either at the drug outlet or through offsite pharmacy services: ( )

a. Valid Prescription Drug Order. Prescription drugs may only be dispensed pursuant to a valid prescription drug order as set forth below in Rules 200.08 and 200.09. ( )

b. Prospective Drug Review. Prospective drug review must be provided. ( )

c. Labeling. Each drug must bear a complete and accurate label as set forth in these rules. ( )

d. Verification of Dispensing Accuracy. Verification of dispensing accuracy must be performed to compare the drug stock selected to the drug prescribed. If not performed by a pharmacist or prescriber, either an electronic verification system or verification by two (2) support persons must be used that confirms the drug stock selected to fill the prescription is the same as indicated on the prescription label. ( )

e. Patient Counseling. Counseling must be provided. ( )

05. Drug Outlets that Dispense Drugs to Patients without an Onsite Pharmacist or Prescriber. A drug outlet that dispenses drugs to patients in Idaho that does not have a pharmacist or prescriber onsite to perform or supervise pharmacy operations must comply with the following requirements: ( )

a. Security and Access. Maintain adequate video surveillance of the facility and retain a high quality recording for a minimum of thirty (30) days. ( )

b. Technology. The video or audio communication system used to counsel and interact with each patient or patient's caregiver, must be clear, secure, and HIPAA-compliant. ( )

c. Technical Limitation Closure. The drug outlet must be, or remain, closed to the public if any component of the surveillance or video and audio communication system is malfunctioning, until system corrections or repairs are completed. ( )

d. Exemptions. ( )

i. A self-service ADS that operates as a drug outlet is exempt from the video surveillance requirement of this rule. In addition, if counseling is provided by an onsite prescriber or pharmacist, a self-service ADS is exempt from the video and audio communication system requirements of this rule. ( )

ii. Veterinarians are exempt from this rule. ( )

06. Drugs Stored Outside of a Drug Outlet for Retrieval by a Licensed Health Professional. Drugs may be stored in an alternative designated area outside the drug outlet, including, but not limited to, in an emergency cabinet, in an emergency kit, or as emergency outpatient drug delivery from an emergency room at a registered institutional facility, provided the following conditions are met: ( )

a. Supervising Drug Outlet. Drugs stored in such a manner must remain under the control of, and be routinely monitored by, the supervising drug outlet. ( )

b. Secure Storage. The area is appropriately equipped to ensure security and protection from diversion or tampering. ( )

c. Controlled Substances. Controlled substances may only be stored in an alternative designated area as permitted by, and in accordance with, federal law. ( )

d. Stocking and Replenishing. Stocking or replenishing drugs in an alternative designated area may be performed by a pharmacist or prescriber, or by appropriate support personnel using either an electronic verification system or two (2) persons. ( )

07. Pharmacist Prescribing: General Requirements. In accordance with Section 54-1704, Idaho Code, a pharmacist may independently prescribe provided the following general requirements are met by the pharmacist: ( )

a. Education. Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained. ( )

b. Patient-Prescriber Relationship. Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code. ( )

c. Patient Assessment. Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence. ( )

d. Collaboration with Other Health Care Professionals. Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate. ( )

e. **Documentation**. Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan. ( )

f. **Prescribing Exemption**. The general requirements set forth in this section do not apply to the prescribing of devices and nonprescription drugs, prescribing under a collaborative pharmacy practice agreement, direct administration of a medication, or prescribing emergency drugs pursuant to Section 54-1735, Idaho Code. ( )

08. **Prescription Drug Order: Validity**. Prior to filling or dispensing a prescription drug order, a pharmacist must verify its validity. ( )

a. **Invalid Prescription Drug Orders**. A prescription drug order is invalid if not issued by a licensed prescriber for a legitimate medical purpose, and within the course and scope of the prescriber's professional practice and prescriptive authority. ( )

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

c. **Tampering**. A prescription drug order is invalid if, at the time of presentation, it shows evidence of alteration by any person other than the person who wrote it. ( )

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

e. **Digital Image Prescriptions**. A digital image of a prescription drug order is invalid if it is for a controlled substance or if the patient intends to pay cash for the drug in whole. ( )

09. **Prescription Drug Order: Minimum Requirements**. A prescription drug order must comply with applicable requirements of federal law and, except as differentiation is permitted for an institutional drug order, include at least the following: ( )

a. **Patient's Name**. The patient's or authorized entity's name and: ( )

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

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

b. **Date**. The date issued. ( )

c. **Drug Information**. The drug name, strength, and quantity. ( )

d. **Directions**. The directions for use. ( )

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

f. **Signature**. A signature sufficient to evidence a valid prescription of either the prescriber or, if a renewal of a previous prescription, the prescriber's agent, when authorized by the prescriber. ( )

g. **General Exemption.** A prescriber may omit drug information and directions and make an indication for the pharmacist to finalize the patient's drug therapy plan. ( )

10. **Filling Prescription Drug Orders: Practice Limitations**.

a. **Drug Product Selection**. Drug product selection is allowed only between therapeutic equivalent

drugs as published in the FDA's Orange Book or Green Book. If a prescriber orders by any means that a brand name drug must be dispensed, then no drug product selection is permitted. ( )

b. **Partial Filling**. A prescription drug order may be partially filled within the limits of federal law. The total quantity dispensed in partial fillings must not exceed the total quantity prescribed. ( )

c. **Refill Authorization**. A prescription drug order may be refilled when permitted by state and federal law and as specifically authorized by the prescriber. A pharmacist may also refill a prescription to ensure continuity of care. ( )

11. **Filling Prescription Drug Orders: Adaptation**. A pharmacist may adapt drugs as specified in this rule. ( )

a. **Change Quantity**. A pharmacist may change the quantity of medication prescribed if: ( )

i. The prescribed quantity or package size is not commercially available; ( )

ii. The change in quantity is related to a change in dosage form, strength, or therapeutic interchange; ( )

iii. The change is intended to dispense up to the total amount authorized by the prescriber including refills; or ( )

iv. The change extends a maintenance drug for the limited quantity necessary to coordinate a patient's refills in a medication synchronization program. ( )

b. **Change Dosage Form**. A pharmacist may change the dosage form of the prescription if it is in the best interest of patient care, so long as the prescriber's directions are also modified to equate to an equivalent amount of drug dispensed as prescribed. ( )

c. **Complete Missing Information**. A pharmacist may complete missing information on a prescription if there is evidence to support the change. ( )

d. **Documentation**. The adaption must be documented in the patient's record. ( )

12. **Filling Prescription Drug Orders: Drug Product Substitution**. Drug product substitutions in which a pharmacist dispenses a drug product other than that prescribed are allowed only as follows: ( )

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

b. **Institutional Facility**. At the direction of the quality assessment and assurance committee of an institutional facility; ( )

c. **Biosimilars**. A pharmacist may substitute an interchangeable biosimilar product for a prescribed biological product if: ( )

i. The biosimilar has been determined by the FDA to be interchangeable as published in the FDA's Purple Book; ( )

ii. The name of the drug and the manufacturer or the NDC number is documented in the patient medical record. ( )

d. **Therapeutic Interchange**. A pharmacist may substitute a drug with another drug in the same therapeutic class, provided the substitution lowers the cost to the patient or occurs during a drug shortage. ( )

13. Filling Prescription Drug Orders: Transfers. A prescription drug order may be transferred within the limits of federal law. Drug outlets using a common electronic file are exempt from transfer limits. ( )

14. Labeling Standards. All prescription drugs must be in an appropriate container and bear information that identifies the drug product, any additional components as appropriate, and the individual responsible for its final preparation. ( )

a. Standard Prescription Drug. A prescription drug for outpatient dispensing must be labeled in accordance with federal law. ( )

b. Parenteral Admixture. If one (1) or more drugs are added to a preparation of sterile products intended for administration by injection , the admixture's container must include the date and time of the addition or the beyond use date. ( )

c. Prepackaged Product. The containers of prepackaged drugs must include an expiration date that is the lesser of the manufacturer's original expiration date, one (1) year from the date the drug is prepackaged, or a shorter period if warranted. ( )

d. Repackaged Drug. If a previously dispensed drug is repackaged, it must contain the prescription number and contact information for the original dispensing pharmacy, as well as a statement that indicates that the drug has been repackaged, and the contact information of the repackaging pharmacy. ( )

e. Distributed Compounded Drug Product. Compounded and sterile prepackaged drug product distributed in the absence of a patient specific prescription must be labeled as follows: ( )

i. If from a pharmacy, the statement: “not for further dispensing or distribution.” ( )

ii. If from an outsourcing facility, the statements: “office use only” and “not for resale.” ( )

15. Prescription Delivery: Restrictions.

a. Acceptable Delivery. A drug outlet that dispenses drugs to patients in Idaho may deliver filled prescriptions in accordance with federal law, as long as appropriate measures are taken to ensure product integrity and safety. ( )

b. Pick-up or Return by Authorized Personnel. Filled prescriptions may be picked up for or returned from delivery by authorized personnel from a secured delivery area. ( )

16. Destruction or Return of Drugs or Devices: Restrictions. A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction in accordance with applicable federal law. Otherwise a dispensed drug or prescription device may only be accepted for return as follows: ( )

a. Potential Harm. When the pharmacist determines that harm could result if the drug is not returned. ( )

b. Did Not Reach Patient. Non-controlled drugs that have been maintained in the custody and control of the institutional facility, dispensing pharmacy, or their related clinical facilities may be returned if product integrity can be assured. Controlled substances may only be returned from a hospital daily delivery system under which a pharmacy dispenses no more than a seventy-two (72) hour supply for a drug order. ( )

c. Donation. Those that qualify for return under the provisions of the Idaho Legend Drug Donation Act as specified in Section 54-1762, Idaho Code. ( )

17. Recordkeeping: Maintenance and Inventory Requirements.

a. 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 and retained in a readily retrievable form and location for at least three (3) years from the date of the transaction. ( )

b. Prescription Retention. A prescription drug order must be retained in a readily retrievable manner by each drug outlet and maintained in accordance with federal law. ( )

c. Inventory Records. Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. A biennial inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law. ( )

d. 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. ( )

e. Drug Distributor Records. Wholesalers and other entities engaged in wholesale drug distribution must maintain inventories and records or transactions pertaining to the receipt and distribution or other disposition of drugs in accordance with federal law that include at least: ( )

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

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

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

iv. Controlled substance distribution invoices, in the form required by federal law. ( )

f. Central Records Storage. Records may be retained at a central location in compliance with federal law. ( )

g. Electronic Records Storage. Records may be electronically stored and maintained if they remain legible and are in a readily retrievable format, and if federal law does not require them to be kept in a hard copy format. ( )

18. Reporting Requirements.

a. Theft or Loss of Controlled Substances. 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. ( )

b. Criminal Convictions and Disciplinary Decisions. Licensees must report to the Board all felony convictions and any other criminal convictions involving any legend drug(s) within thirty (30) days of judgment. Licensees must also report to the Board all disciplinary decisions of any other licensing authority, or the surrender of a license in lieu of discipline, within thirty (30) days of the disciplinary order or the surrender. ( )

c. Adverse Event Reports. Outsourcing facilities must submit to the Board a copy of all adverse event reports submitted to the secretary of Health and Human Services in accordance with 21 CFR § 310.305. ( )

d. Individual and Outlet Information Changes. Changes in employment or changes to information provided on or with the initial or renewal application must be reported to the Board within ten (10) days of the change.

( )

e. Drug Distributor Monthly Reports. An authorized distributor must report to the Board specified data on controlled substances distributed in a form and manner prescribed by the Board. ( )

201. -- 299. (RESERVED)

300. DISCIPLINE

01. Unprofessional Conduct. The following acts or practices by any licensee or registrant are declared to be specifically, but not by way of limitation, unprofessional conduct and conduct contrary to the public interest. ( )

a. 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. ( )

b. 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. ( )

c. 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. ( )

d. 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. ( )

e. 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. ( )

f. Self-prescribing of Controlled Substances. Prescribing any drug legally classified as a controlled substance to himself or herself, or to a spouse, child, or stepchild. ( )

g. Prescription Drug Order Noncompliance. Failing to follow the instructions of the person writing, making, or ordering a prescription as to its refills, contents, or labeling except as provided in these rules. ( )

h. Failure to Confer. Failure to confer with the prescriber when necessary or appropriate. ( )

i. Excessive Provision of Controlled Substances. Providing an 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). ( )

j. Failure to Counsel or Offer Counseling. Failing to counsel or offer counseling, unless specifically exempted or refused. ( )

k. Substandard, Misbranded, Adulterated, or Expired Products. Manufacturing, compounding, delivering, distributing, dispensing, or permitting to be manufactured, compounded, delivered, distributed or dispensed substandard, misbranded, or adulterated drugs or preparations or those made using secret formulas. Failing to remove expired drugs from stock. ( )

l. 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. ( )

m. 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. ( )

n. 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. ( )

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

p. Use of False Information. Knowingly using false information in connection with the prescribing, delivering, administering, or dispensing of a controlled substance or other drug product. ( )

q. Standard of Care. Acts or omissions within the practice of pharmacy which fail to meet the standard provided by other qualified licensees or registrants in the same or similar setting. ( )

r. Unnecessary Services or Products. Directly promoting or inducing for the provisions of health care services or products that are unnecessary or not medically indicated. ( )

s. Controlled Substance Non-Compliance. Violating provisions of the federal Controlled Substances Act or Title 37, Chapter 27, Idaho Code. ( )

02. Board Inspections and Investigations.

a. 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. ( )

b. Inspections. Prior to the commencement of business, as applicable, and thereafter at regular intervals, 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. ( )

c. Inspection Deficiencies. Deficiencies noted must be promptly remedied, and if requested, the Board office notified of corrective measures. One (1) follow-up inspection may be performed by the Board at no cost. For additional follow-up inspections, the drug outlet will be charged actual travel and personnel costs incurred in the inspection to be paid within ninety (90) days of inspection. ( )

d. 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. ( )

e. Investigations. Licensees or registrants must fully cooperate with Board investigations conducted to confirm compliance with laws enforced by the Board, including audits of continuing education, to gather information pertinent to a complaint received by the Board or to enforce disciplinary actions. ( )

301. -- 399. (RESERVED)

400. FEES.
Nonrefundable fees are as follows:

01. Licenses and Registrations – Professionals.

License/Registration	Initial Fee	Annual Renewal Fee

Pharmacist License	$140	$130
Nonresident PIC Registration	$290	$290
Pharmacist Intern	$50	$50
Technician	$35	$35
Practitioner Controlled Substance Registration	$60	$60

( )

02. Certificates of Registration and Licensure – Facilities.

License/Registration	Initial Fee	Annual Renewal Fee
Drug Outlet (unless otherwise listed)	$100	$100
Wholesale License	$180	$180
Wholesale Registration	$150	$150
Central Drug Outlet (Nonresident)	$500	$250
Mail Service Pharmacy	$500	$250
Durable Medical Equipment Outlet	$50	$50
Outsourcing Facility (Nonresident)	$500	$250
Manufacturer	$150	$150
Veterinary Drug Outlet	$35	$35

( )

03. Administrative Services.

Category	Fee
Experiential hours certification	$25

( )

04. Fee Exemption for Controlled Substance Registrations. Persons exempt pursuant to federal law from fee requirements applicable to DEA registrations are also exempt from fees applicable to Idaho practitioner controlled substance registrations. ( )

401. -- 699. (RESERVED)

700. SAFE COMPOUNDING

01. Compounding Drug Preparations: General Provisions. Any compounding that is not permitted herein is considered manufacturing. ( )

a. Application. This rule applies to any person, including any business entity, authorized to engage in

the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho, except these rules do not apply to: ( )

i. The reconstitution of a non-sterile drug or a sterile drug for immediate administration; ( )

ii. The addition of a flavoring agent and/or a coloring agent to a drug product, so long as the agent is therapeutically inert and in the minimum quantity necessary; and ( )

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

b. General Compounding Standards. ( )

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

ii. Certificate of Analysis (COA). Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, a COA must be obtained for all active pharmaceutical ingredients procured for compounding and retained for a period of not less than three (3) years from the date the container is emptied, expired, returned, or disposed of. The following minimum information is necessary on the COA: product name, lot number, expiration date, and assay. ( )

iii. Equipment. Equipment and utensils must be of suitable design and composition and cleaned, sanitized, or sterilized as appropriate prior to use. ( )

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

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

d. Limited Compounding. ( )

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

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

a. It is medically warranted to provide an alternate ingredient, dosage form, or strength of significance; or ( )

b. The commercial product is not reasonably available in the market in time to meet the patient's needs. ( )

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

e. Drug Compounding Controls. Policies and procedures for the compounding or sterile prepackaging of drug products must ensure the safety, identity, strength, quality, and purity of the finished product.

To meet this standard, licensees and registrants will take into consideration the applicable provisions of USP Chapter 795 concerning pharmacy compounding of non-sterile preparations, USP Chapter 797 concerning sterile preparations, Chapter 1075 of the USP-NF concerning good compounding practices, and Chapter 1160 of the USP-NF concerning pharmaceutical calculations. ( )

02. Sterile Preparation.

a. Application. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Preparations, these rules apply to all persons, including any business entity, engaged in the practice of sterile compounding and sterile prepackaging in or into Idaho. ( )

b. Dosage Forms Requiring Sterility. The sterility of compounded diagnostics, drugs, nutrients, and radiopharmaceuticals must be maintained or the compounded drug preparation must be sterilized when prepared in the following dosage forms: ( )

i. Aqueous bronchial and nasal inhalations, except nasal dosage forms intended for local application; ( )

ii. Baths and soaks for live organs and tissues; ( )

iii. Injections (for example, colloidal dispersions, emulsions, solutions, suspensions); ( )

iv. Irrigations for internal body cavities; ( )

v. Ophthalmic drops and ointments; and ( )

vi. Tissue implants. ( )

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

i. Environmental Control Requirements. Except when prepared for immediate administration, the environment for the preparation of sterile preparations in a drug outlet must be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions. ( )

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

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

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

c. Audits appropriate for the risk of contamination for the particular sterile preparation including: ( )

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

ii. Periodic hand hygiene and garbing competency; ( )

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

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

v. Gloved fingertip sampling testing; ( )

vi. Sterility testing; ( )

d. Temperature, logged daily; ( )

e. Beyond use date and accuracy testing, when appropriate; and ( )

f. Measuring, mixing, sterilizing, and purification equipment inspection, monitoring, cleaning, and maintenance to ensure accuracy and effectiveness for their intended use. ( )

03. Hazardous Drugs Preparation. In addition to all other applicable rules in this chapter, including the rules governing Compounding Drug Preparations and Sterile Preparation, these rules apply to all persons, including any business entity, engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons must: ( )

a. Ventilation. Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove any airborne contaminants. ( )

b. Ventilated Cabinet. Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. ( )

i. Sterile hazardous drugs must be prepared in a dedicated Class II biological safety cabinet or a barrier isolator of appropriate design to meet the personnel exposure limits described in product material safety data sheets; ( )

ii. When asepsis is not required, a Class I BSC, powder containment hood or an isolator intended for containment applications may be sufficient. ( )

iii. A ventilated cabinet that re-circulates air inside the cabinet or exhausts air back into the room environment is prohibited, unless: ( )

a. The hazardous drugs in use will not volatilize while they are being handled; or ( )

b. Written documentation from the manufacturer attesting to the safety of such ventilation. ( )

c. Clear Identification. Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs. ( )

d. Labeling. Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills. ( )

e. Protective Equipment and Supplies. Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills and disposal. ( )

f. Contamination Prevention. Unpack, store, prepackage, and compound hazardous drugs separately from other inventory in a restricted area in a manner to prevent contamination and personnel exposure until hazardous drugs exist in their final unit-of-use packaging. ( )

g. Training. Ensure that personnel working with hazardous drugs are trained in hygiene, garbing, receipt, storage, handling, transporting, compounding, spill control, clean up, disposal, dispensing, medical

surveillance, and environmental quality and control. ( )

701. -- 799. (RESERVED)

800. PRESCRIPTION DRUG MONITORING PROGRAM.

01. Required Reporting. Specified data on controlled substances must be reported by the end of the business day by all drug outlets that dispense controlled substances in or into Idaho and prescribers that dispense controlled substances to humans. ( )

02. Online Access to PDMP. To obtain online access, a prescriber or pharmacist, or their delegate must complete and submit a registration application and agree to adhere to the access restrictions and limitations established by law. ( )

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

801. -- 999. (RESERVED)