LEGISLATURE OF THE STATE OF IDAHO

Sixty-eighth Legislature

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First Regular Session - 2025

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 200

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACISTS; AMENDING SECTION 54-1702, IDAHO CODE, TO REVISE PROVISIONS REGARDING A LEGISLATIVE DECLARATION; REPEALING SECTION 54-1703, IDAHO CODE, REGARDING A STATEMENT OF PURPOSE; AMENDING SEC-TION 54-1704, IDAHO CODE, TO DEFINE TERMS AND TO REVISE DEFINITIONS; AMENDING SECTION 54-1705, IDAHO CODE, TO REMOVE A PROVISION REGARDING RULES OF THE BOARD OF PHARMACY; AMENDING SECTION 54-1706, IDAHO CODE, TO REVISE PROVISIONS REGARDING THE STATE BOARD OF PHARMACY; REPEALING SECTION 54-1714, IDAHO CODE, RELATING TO COMPENSATION OF BOARD MEMBERS; AMENDING SECTION 54-1718, IDAHO CODE, TO REVISE PROVISIONS REGARDING LICENSURE AND DISCIPLINE; AMENDING SECTION 54-1719, IDAHO CODE, TO REVISE PROVISIONS REGARDING THE DUTIES, POWERS, AND AUTHORITY OF THE BOARD OF PHARMACY; REPEALING SECTION 54-1720, IDAHO CODE, RELATING TO OTHER DUTIES, POWERS, AND AUTHORITY OF THE BOARD OF PHARMACY; AMEND-ING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1720, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING LICENSING FEES; AMENDING SECTION 54-1721, IDAHO CODE, TO REVISE PROVISIONS REGARDING UNLAWFUL PRACTICE; AMENDING SECTION 54-1722, IDAHO CODE, TO PROVIDE FOR CERTAIN FEES; AMENDING SECTION 54-1723, IDAHO CODE, TO PROVIDE FOR CER-TAIN FEES AND TO REVISE PROVISIONS REGARDING LICENSURE BY RECIPROCITY; AMENDING SECTION 54-1723A, IDAHO CODE, TO REVISE PROVISIONS REGARD-ING CERTIFICATION TO PRACTICE INTO IDAHO; AMENDING SECTION 54-1723B, IDAHO CODE, TO REMOVE A PROVISION REGARDING RULES; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1723C, IDAHO CODE, TO PROVIDE A REQUIREMENT FOR RENEWAL OF A PHARMACIST LI-CENSE; REPEALING SECTION 54-1725, IDAHO CODE, RELATING TO CONTINUING PHARMACY EDUCATION; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1725, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING PHARMACIST INTERN RENEWAL REQUIREMENTS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1725A, IDAHO CODE, TO PROVIDE FOR PRACTITIONER CONTROLLED SUBSTANCE REGISTRATION; AMENDING SECTION 54-1726, IDAHO CODE, TO REVISE PROVISIONS REGARDING GROUNDS FOR DISCIPLINE; AMENDING SECTION 54-1728, IDAHO CODE, TO REVISE A PROVISION REGARDING VIOLATIONS AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1729, IDAHO CODE, TO REVISE PROVISIONS REGARDING REGISTRATION AND LICENSURE OF FACILITIES; AMENDING SECTION 54-1729A, IDAHO CODE, TO REVISE PROVISIONS REGARDING WHOLESALE DRUG DISTRIBUTOR LICENSURE; REPEALING SECTION 54-1730, IDAHO CODE, RELATING TO DRUG OUT-LET APPLICATION PROCEDURES; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1730, IDAHO CODE, TO ESTABLISH DRUG OUTLET MINIMUM FACILITY STANDARDS; REPEALING SECTION 54-1731, IDAHO CODE, RELATING TO NOTIFICATIONS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1731, IDAHO CODE, TO ESTAB-LISH DRUG OUTLET AND LICENSEE REPORTING REQUIREMENTS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1731A,

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IDAHO CODE, TO ESTABLISH MINIMUM REQUIREMENTS FOR CERTAIN DRUG OUTLETS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SEC-TION 54-1731B, IDAHO CODE, TO PROVIDE FOR DRUG OUTLETS WITH ALTERNATIVE DISPENSING MODELS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1731C, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING DRUG OUTLET RECORDKEEPING REQUIREMENTS; AMENDING SECTION 54-1732, IDAHO CODE, TO REVISE PROVISIONS REGARDING VIOLATIONS AND PENALTIES; AMENDING SECTION 54-1733, IDAHO CODE, TO REVISE PROVISIONS REGARDING THE VALIDITY OF PRESCRIPTION DRUG ORDERS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1733A, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING PRESCRIPTION DRUG ORDER MINIMUM REQUIREMENTS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1733B, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING LIMITATIONS ON THE FILLING OF PRESCRIPTION DRUG ORDERS; RE-PEALING SECTION 54-1734, IDAHO CODE, RELATING TO THE TRANSMISSION OF PRESCRIPTION DRUG ORDERS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1734, IDAHO CODE, TO ESTABLISH PROVI-SIONS REGARDING GENERAL REQUIREMENTS FOR PHARMACIST PRESCRIBING; RE-PEALING SECTION 54-1736, IDAHO CODE, RELATING TO A DECLARATION OF COM-MON NUISANCE; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1736, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING PRESCRIPTION DRUG LABELING STANDARDS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1736A, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING PRESCRIPTION DRUG DELIVERY AND RETURN; AMENDING SECTION 54-1738, IDAHO CODE, TO PROVIDE FOR A CERTAIN COMMON NUISANCE; REPEALING SECTION 54-1739, IDAHO CODE, RELATING TO PROSPEC-TIVE DRUG REVIEW AND COUNSELING; AMENDING SECTION 54-1760, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1765, IDAHO CODE, TO PRO-VIDE FOR GENERAL PROVISIONS REGARDING COMPOUNDING DRUG PREPARATIONS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SEC-TION 54-1766, IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING STERILE PREPARATION; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1767, IDAHO CODE, TO ESTABLISH PROVISIONS REGARD-ING HAZARDOUS DRUG PREPARATION; REPEALING SECTION 54-1771, IDAHO CODE, RELATING TO SEVERABILITY; AMENDING SECTION 37-2716, IDAHO CODE, TO RE-VISE PROVISIONS REGARDING REGISTRATION REQUIREMENTS; AMENDING SECTION 37-2730A, IDAHO CODE, TO PROVIDE FOR THE REPORTING OF CERTAIN DATA; AMENDING SECTION 54-5705, IDAHO CODE, TO PROVIDE A CORRECT CODE REFER-ENCE; PROVIDING THAT CERTAIN RULES CONTAINED IN IDAPA 24.36.01 SHALL BE NULL, VOID, AND OF NO FORCE AND EFFECT; AND DECLARING AN EMERGENCY AND PROVIDING AN EFFECTIVE DATE.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Section 54-1702, Idaho Code, be, and the same is hereby amended to read as follows:

54-1702. LEGISLATIVE DECLARATION. The practice of pharmacy in the state of Idaho is declared a professional practice affecting the health, safety and welfare of the public and is subject to regulation and control in

the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, merits and receives the confidence of the public and that only qualified persons be permitted to engage in the practice of pharmacy in or into the state of Idaho. This chapter shall be liberally construed to carry out these objects and purposes. Only qualified persons shall be permitted to engage in the practice of pharmacy in or into the state of Idaho.

SECTION 2. That Section 54-1703, Idaho Code, be, and the same is hereby repealed.

SECTION 3. That Section 54-1704, Idaho Code, be, and the same is hereby amended to read as follows:

54-1704. DEFINITIONS. In this chapter:

- (1) "Accredited school or college of pharmacy" means a school or college that meets the minimum standards of the accreditation council for pharmacy education and appears on its list of accredited schools or colleges of pharmacy.
- (2) "Board of pharmacy" or "board" means the Idaho state board of pharmacy.
- (3) "Certificate" means a license or registration issued by the board unless specifically stated.
- (4) "Chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control.
- (5) "Colicensed partner or product" means an instance where two (2) or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the federal food and drug administration's implementation of the prescription drug marketing act.
- (6) "Collaborative pharmacy practice" means a pharmacy practice where one (1) or more pharmacists or pharmacies jointly agree to work under a protocol authorized by one (1) or more prescribers to provide patient care and drug therapy management services not otherwise permitted to be performed by a pharmacist under specified conditions.
- (7) "Compounding" means the practice in which a pharmacist, a prescriber, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.
- (8) "Counseling" or "counsel" means the effective communication by the pharmacist of information, as set out in this chapter, to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices.
- (9) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.
- (10) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article, including any component part or accessory that is:

- (a) Recognized in the official United States Pharmacopoeia or official National Formulary, other drug compendia or any supplement to them;
- (b) Intended for use in the diagnosis of disease or other conditions or the cure, mitigation, treatment or prevention of disease in man or other animal;
- (c) Intended to affect the structure or any function of the body of man or other animal, does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animal, and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
- (11) "Dispense" or "dispensing" means the preparation and delivery of a drug pursuant to a lawful prescription drug order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription.
- (12) "Distribute" means the delivery of a drug other than by administering or dispensing.
- (13) "Distributor" means a supplier of drugs manufactured, produced, or prepared by others to persons other than the ultimate consumer.
 - (14) "Donation repository" means:
 - (a) A community health center as defined in section 39-3203, Idaho Code;
 - (b) A free medical clinic as defined in section 39-7702, Idaho Code;
 - (c) A designated regional behavioral health center as described in chapter 31, title 39, Idaho Code;
 - (d) A state charitable institution as described in chapter 1, title 66, Idaho Code; or
 - (e) A drug outlet as defined in this section.
 - (15) "Drug" means:

- (a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them;
- (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animal;
- (c) Articles, other than food, intended to affect the structure or any function of the body of man or other animal; and
- (d) Articles intended for use as a component of any articles specified in paragraph (a), (b) or (c) of this subsection.
- $\underline{\text{(16)}}$ "Drug enforcement administration" or "DEA" means the United States drug enforcement administration.
- (16) (17) "Drug outlet" means a resident or nonresident pharmacy, business entity or other facility subject to registration by the board, pursuant to section 54-1729, Idaho Code, where employees or personnel are engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, delivering, distributing or manufacturing of drugs or devices in or into Idaho, including limited service outlets.
- (17) (18) "Drug therapy management" means selecting, initiating, or modifying drug treatment pursuant to a collaborative pharmacy practice agreement.
- (18) "Epinephrine auto-injector" means a single-use device for the automatic injection of a premeasured dose of epinephrine into the human body.

 $\underline{\text{(19)}}$ "Food and drug administration" or "FDA" means the United States food and drug administration.

- (20) "Hazardous drug" means 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.
- (19) (21) "Institutional drug order" means 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 as defined in rule. Unless specifically differentiated, state law applicable to a prescription drug order is also applicable to an institutional drug order.
- (20) [22] "Institutional facility" means a facility whose primary purpose is to provide a physical environment for patients to obtain health care services and in which patients spend a majority of their time, as may be further defined by board rule.
- (21) "Internship" means a practical experience program under the supervision of a preceptor.
- $\frac{(22)}{(23)}$ "Investigational or new drug" means any drug limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.
- (23) <u>(24)</u> "Labeling" means the process of preparing and affixing a label to any drug container, exclusive however of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or device. Any such label shall include all information required by federal and state law.
- (24) (25) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for his own use or the preparation, compounding, packaging or labeling of a drug:
 - (a) By a pharmacist or practitioner as an incident to his administering, dispensing, or, as authorized by board rule, distributing of a drug in the course of his professional practice; or
 - (b) By a practitioner or by his authorization under his supervision for the purpose of or as an incident to research, teaching, or chemical analysis and not for sale.
- (25) (26) "Manufacturer" means a person who is licensed or approved by the federal food and drug administration to engage in the manufacture of drugs, including a colicensed partner or affiliate of that person, who compounds, cultivates, derives, harvests, mixes, or by other process produces or prepares legend drugs and includes persons who prepare such drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process, or who packages or repackages such drugs, but does not include pharmacists or practitioners in the practice of their profession.

- (26) "Medically indigent patient" means a resident of Idaho who:
- (a) Is not eligible for medicaid or medicare;

- (b) Cannot afford private prescription drug insurance; or
- (c) Does not have income and other resources available sufficient to pay for a legend drug.
- (27) "Multistate license" means a license, registration, or other credential for the practice of pharmacy issued by the pharmacy licensing agency of a state.
- (28) "Multistate licensee" means a multistate pharmacist, multistate pharmacist intern, or multistate technician.
- (29) "Multistate pharmacist" means a nonresident pharmacist who is licensed by a party state and is not otherwise licensed by the board.
- (30) "Multistate pharmacist intern" means a nonresident pharmacist intern who is registered by a party state and is not otherwise licensed by the board.
- (31) "Multistate practice of pharmacy" means the practice of pharmacy in or into Idaho for a patient located in Idaho by a multistate licensee pursuant to the requirements of this section and the terms of a mutual recognition agreement.
- (32) "Multistate technician" means a nonresident technician who is licensed by a party state and is not otherwise registered by the board.
- (33) (29) "Mutual recognition agreement" means a written agreement entered into between the board and a party state allowing for the multistate practice of pharmacy, subject to the requirements of this section and any other reasonable and supplemental contract terms negotiated by the board and the party state.
- (34) (30) "Nonprescription drugs" means medicines or drugs that may be sold without a prescription drug order and that are prepackaged for use by the consumer and labeled in accordance with state and federal law.
- (35) (31) "Nonresident" means a person or business entity located in the District of Columbia or a state or territory other than Idaho that practices pharmacy including, but not limited to, pharmaceutical care services into Idaho.
- (36) (32) "Off-site pharmacy services" means services provided by a central drug outlet or an off-site pharmacist or technician. Services may include, but are not limited to: processing a request from another pharmacy to fill, refill or dispense a prescription drug order; performance of processing functions; or providing cognitive or pharmaceutical care services. Each function may be performed by the same or different persons and at the same or different locations.
- $\frac{(37)}{(33)}$ "Opioid antagonist" means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal food and drug administration for the treatment of drug overdose.
- (38) (34) "Outsourcing facility" means a pharmacy or facility that is registered by the federal food and drug administration pursuant to 21 U.S.C. 353b and either registered or endorsed by the board.
- $\frac{(39)}{(35)}$ "Party state" means any pharmacy licensing agency of a state that has entered into a mutual recognition agreement with the board.
- (40) (36) "Person" means an individual, corporation, partnership, association or any other legal entity.

(41) "Person in charge" or "PIC" means a person whose qualifications, responsibilities, and reporting requirements are defined in rule.

- (42) (37) "Pharmaceutical care" means drug therapy and other pharmaceutical patient care services provided by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board.
- (43) (38) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist registered by this state who is located in another state, territory or the District of Columbia and is engaged in the practice of pharmacy into Idaho, unless exempted.
- (44) (39) "Pharmacist intern" means a person who is enrolled in or who has completed a course of study at an accredited school or college of pharmacy and is registered with the board as a pharmacist intern prior to commencement of an internship.:
 - (a) Is enrolled in and in good standing in an accredited school or college of pharmacy;
 - (b) Has completed a course of study at an accredited school or college of pharmacy; or
 - (c) Is certified by the foreign pharmacy graduate examination committee (FPGEC) and awaiting final pharmacist licensure.
- $\overline{(40)}$ "Pharmacy" means any drug outlet, facility, department, or other place where prescription drug orders are filled or compounded and where prescriptions are sold, dispensed, offered, or displayed for sale and that has, as its principal purpose, the dispensing of drug and health supplies intended for the general health, welfare, and safety of the public.
- (46) (41) "Practice of pharmacy" means the safe interpretation, evaluation, compounding, administration, and dispensing of prescription drug orders, patient counseling, collaborative pharmacy practice, provision of pharmaceutical care services, proper storage of drugs and devices, and prescribing of drugs and devices as may be further defined in this chapter.
- (47) (42) "Practitioner" means a person licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.
- (48) "Preceptor" means a pharmacist or other health professional licensed and in good standing who supervises the internship training of a registered pharmacist intern.
- (49) "Precursor" means a substance, other than a legend drug, that is an immediate chemical intermediate that can be processed or synthesized into a legend drug and is used or produced primarily for use in the manufacture of a legend drug.
- (50) (43) "Prepackaging" means 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.
- (51) (44) "Prescriber" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.
- $\frac{(52)}{(45)}$ "Prescriber drug outlet" means 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, patient assistance program drugs, or investigational drugs as permitted in chapter 94, title 39, Idaho Code.

(53) (46) "Prescription drug or legend drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with one (1) of the following statements:

- (a) "Caution: Federal law prohibits dispensing without a prescription"; or
- (b) "Rx Only"; or

(c) "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian";

or a drug that is required by any applicable federal or state law or rule to be dispensed on prescription drug order only or is restricted to use by practitioners only.

 $\frac{(54)}{(47)}$ "Prescription drug order" means a valid order of a prescriber for a drug or device for an ultimate user of the drug or device.

(55) (48) "Primary state of residence" means the multistate licensee's declared primary state of residence as evidenced by a valid state or federal identification card with a home address or another form of identification accepted by the board.

(56) "Prospective drug review" includes, but is not limited to, the following activities:

- (a) Evaluation of the prescription drug order for known allergies, rational therapy contraindications, reasonable dose and route of administration, and reasonable directions for use;
- (b) Evaluation of the prescription drug order for duplication of therapy;
- (c) Evaluation of the prescription drug order for drug, food, or disease interactions; and
- (d) Evaluation of the prescription drug order for proper utilization.
- (57) (49) "Qualified donor" means:
- (a) Any entity that meets the definition of "donation repository" as provided in this section; or
- (b) Any member of the public in accordance with section 54-1762, Idaho Code.
- (50) "Reconstitution" means 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.
- (58) (51) "Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records or other written indicia, documents or objects that are used in any way in connection with the purchase, sale or handling of any drug or device.
- (59) (52) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding such actions when completed by the pharmacist responsible for dispensing product to the patient.
- (60) (53) "Reverse distributor" means a drug outlet that receives nonsalable prescription drugs from persons or their agents, who may lawfully

possess prescription drugs without being issued a valid prescription drug order, and that processes for credit or disposes of such prescription drugs.

(61) (54) "Sale" means every sale and includes:

- (a) Manufacturing, processing, transporting, handling, packaging or any other production, preparation or repackaging;
- (b) Exposure, offer, or any other proffer;

- (c) Holding, storing or any other possession;
- (d) Dispensing, giving, delivering or any other supplying; and
- (e) Applying, administering or any other usage.
- $\frac{(62)}{(55)}$ "Technician" means an individual authorized by registration with the board to perform pharmacy support services under the direction of a pharmacist.
- $\frac{(63)}{(56)}$ "Ultimate user" means a person who lawfully possesses a drug for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.
 - (64) (57) "USP" means United States pharmacopoeia.
- $\frac{(65)}{(58)}$ "Veterinary drug outlet" means a prescriber drug outlet that dispenses drugs or devices intended for animal patients.
- (66) (59) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
 - (a) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23;
 - (b) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
 - (c) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when such common carrier does not store, warehouse, or take legal ownership of the prescription drug; or
 - (d) The sale or transfer from a community pharmacy or chain pharmacy warehouse of expired, damaged, mispicked, returned, or recalled prescription drugs to the original manufacturer, original wholesaler, or third-party returns processor, including a reverse distributor.
- (60) "Wholesaler" means a person who, in the usual course of business, lawfully distributes drugs or devices in or into Idaho to persons other than the ultimate user.
- SECTION 4. That Section 54-1705, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1705. PRACTICE OF PHARMACY -- GENERAL APPROACH. To evaluate whether a specific act is within the practice of pharmacy in or into Idaho, or whether an act can be delegated to other individuals under his supervision, a licensee or registrant of the board of pharmacy shall independently determine whether:
 - (1) The act is expressly prohibited by:
 - (a) This chapter;
 - (b) The uniform controlled substances act, chapter 27, title 37, Idaho Code; $\underline{\text{or}}$
 - (c) The rules of the board of pharmacy; or
 - (d) (c) Any other applicable state or federal laws or regulations;

(2) The act is consistent with the individual's education, training, and experience; and

- (3) Performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent individual with similar education, training, and experience.
- SECTION 5. That Section 54-1706, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1706. STATE BOARD OF PHARMACY ESTABLISHED. There is hereby established in the division of occupational and professional licenses a state board of pharmacy whose responsibilities shall be to enforce the provisions of this act. The board that shall have all of the duties, powers, and authority specifically granted by and necessary to the enforcement of this act, as well as such other duties, powers and authority as it may be granted from time to time by appropriate statute chapter.
- SECTION 6. That Section 54-1714, Idaho Code, be, and the same is hereby repealed.
 - SECTION 7. That Section 54-1718, Idaho Code, be, and the same is hereby amended to read as follows:
 - 54-1718. LICENSURE AND DISCIPLINE. (1) The board of pharmacy shall be responsible for the control and regulation of the practice of pharmacy in this state, including but not limited to the following:
 - (a) The licensing by examination or by reciprocity of applicants who are qualified to engage in the practice of pharmacy under the provisions of this chapter;
 - (b) The renewal of licenses to engage in the practice of pharmacy;
 - (c) The enforcement of the provisions of this chapter relating to the conduct or competence of pharmacists practicing in this state and the suspension, revocation or restriction of licenses to practice pharmacy; and
 - (d) The regulation of the training, qualifications and employment of pharmacist interns. pharmacist interns and technicians;
 - (e) The cancellation of certificates that fail to maintain the requirements of this chapter; and
 - (f) The reinstatement of licenses following the completion of thirty (30) hours of continuing education within twenty-four (24) months and compliance with any prior board orders.
 - (2) The board of pharmacy shall require the following applicants <u>over</u> the age of eighteen (18) to submit to a fingerprint-based criminal history check in accordance with section 67-9411A, Idaho Code:
 - (a) Original applicants for a certificate, unless exempted by board rule; and
 - (b) Applicants for reinstatement of a certificate.
- SECTION 8. That Section 54-1719, Idaho Code, be, and the same is hereby amended to read as follows:

- 54-1719. MEDICATIONS -- DRUGS -- DEVICES -- OTHER MATERIALS <u>DUTIES -- POWERS -- AUTHORITY</u>. (1) The board of pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:
 - (1) (a) The regulation of the sale at retail and the dispensing of medications, drugs, devices and other materials, including the method of dispensing in institutional facilities and including the right to seize such drugs, devices and other materials found to be detrimental to the public health and welfare by the board after appropriate hearing as required under the administrative procedure act;
- (2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, dispensing and distribution of such medications, drugs, devices and other materials within the practice of pharmacy;
 - $\frac{(3)}{(b)}$ The control of the purity and quality of such medications, drugs, devices and other materials within the practice of pharmacy; and $\frac{(4)}{(c)}$ The issuance and renewal of certificates of drug outlets for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs.
- (2) The board may solicit and receive from parties other than the state grants, moneys, donations, and gifts of tangible and intangible property for any purpose consistent with the provisions of this chapter, which purposes may be specified as a condition of any grants, moneys, donations, or gifts.
- (3) The board or its authorized representatives shall have power to investigate and gather evidence concerning alleged violations of the provisions of this chapter. All records required under this chapter shall be made available for inspection upon request by the board or its authorized agents.
- (4) The board shall inspect drug outlets prior to the commencement of business, if applicable, and at regular intervals.
- SECTION 9. That Section $\underline{54-1720}$, Idaho Code, be, and the same is hereby repealed.
- SECTION 10. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1720, Idaho Code, and to read as follows:
- 54-1720. LICENSING FEES. Non-refundable fees shall be posted by the division and shall not exceed the amounts specified as follows:
 - (1) Individual certificates:

39 40	Certificate	Initial fee, not to exceed	Annual renewal fee, not to exceed
41	Pharmacist license	\$140	\$130
42 43	Nonresident person in charge	\$290	\$290
44	Pharmacist intern	\$50	\$50

1	Technician	\$35	\$35
2 3	Practitioner controlled substance		
4	registration	\$60	\$60

(2) Drug outlet certificates:

6 7	Certificate	Initial fee, not to exceed	Annual renewal fee, not to exceed
8 9	Drug outlet (unless otherwise listed)	\$100	\$100
10	Wholesale license	\$180	\$180
11	Wholesale registration	\$150	\$150
12 13	Central drug outlet (nonresident)	\$500	\$250
14	Mail service pharmacy	\$500	\$250
15 16	Durable medical equipment outlet	\$50	\$50
17 18	Outsourcing facility (nonresident)	\$500	\$250
19	Manufacturer	\$150	\$150
20	Veterinary drug outlet	\$35	\$35

SECTION 11. That Section 54-1721, Idaho Code, be, and the same is hereby amended to read as follows:

54-1721. UNLAWFUL PRACTICE. (1) It shall be unlawful for any person or business entity to engage in the practice of pharmacy including, but not limited to, pharmaceutical care services in or into Idaho unless licensed or registered to so practice under the provisions of this chapter, except as provided in this subsection:

- (a) Practitioners who are licensed under the laws of this state and their agents or employees may deliver and administer prescription drugs to their patients in the practice of their respective professions where specifically authorized to do so by statute of this state;
- (b) Nonresident pharmacists who are actively licensed in their state of residence may practice pharmacy into Idaho if employed by or affiliated with and practicing for an Idaho-registered nonresident drug outlet. Only the PIC of a registered nonresident facility must be registered to practice into Idaho Only the person in charge of a registered nonresident facility shall be registered to practice into Idaho. All other nonresident pharmacists who are affiliated with and practicing from a nonresident facility are exempt from license and registration requirements for practice into Idaho;

- (c) Multistate licensees permitted to engage in the multistate practice of pharmacy in or into Idaho pursuant to section 54-1723B, Idaho Code;
- (d) A veterinary drug outlet, as defined in section 54-1704, Idaho Code, does not need to register with the board if the outlet does not dispense for outpatient use any controlled substances listed in chapter 27, title 37, Idaho Code, euthanasia drugs, tranquilizer drugs, neuromuscular paralyzing drugs or general anesthesia drugs;
- (e) Employees of the public health districts established under section 39-408, Idaho Code, shall be permitted to engage in the labeling and delivery of prepackaged items pursuant to a valid prescription drug order and in accordance with a formulary established by the district health director; and
- (f) Researchers may possess legend drugs for use in their usual and lawful research projects.
- (2) It shall be unlawful for any person not legally licensed as a pharmacist to take, use or exhibit the title of pharmacist or any other title or description of like import.
- (3) Any person who shall be found to have unlawfully engaged in the practice of pharmacy shall be subject to a fine not to exceed three thousand dollars (\$3,000) for each offense. Each such violation of this chapter Θ the rules promulgated hereunder pertaining to unlawfully engaging in the practice of pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this state.
- SECTION 12. That Section 54-1722, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1722. QUALIFICATIONS FOR <u>PHARMACIST</u> LICENSURE BY EXAMINATION. (1) To obtain a license to engage in the practice of pharmacy, an applicant for licensure by examination shall:
 - (a) Submit a written application in the form prescribed by the board of pharmacy;
 - (b) Graduate and receive the first professional degree from an accredited school or college of pharmacy;
 - (c) Pass the North American pharmacist licensure examination by the national association of boards of pharmacy or submit a passing score transfer into Idaho within ninety (90) days after application; and
 - (d) Pay the fees specified by the board of pharmacy for examination and issuance of license this chapter.
- (2) Any applicant who is a graduate of a school or college of pharmacy located outside of the United States may substitute the following for subsection (1)(b) of this section:
 - (a) Graduate from a school or college of pharmacy located outside of the United States;
 - (b) Submit certification by the foreign pharmacy graduate examination committee; and
 - (c) Complete a minimum of one thousand seven hundred forty (1,740) experiential hours as verified on an employer's affidavit, signed by a pharmacist licensed and practicing in the United States.

SECTION 13. That Section 54-1723, Idaho Code, be, and the same is hereby amended to read as follows:

- 54-1723. QUALIFICATIONS FOR <u>PHARMACIST</u> LICENSURE BY RECIPROCITY. (1) To obtain a license as a pharmacist by reciprocity, an applicant for licensure shall:
- $\frac{\text{(a)}}{\text{(1)}}$ Submit a written application in the form prescribed by the board of pharmacy;
- $\frac{\text{(b)}}{\text{(2)}}$ Possess at the time of initial licensure as a pharmacist such other qualifications necessary to have been eligible for licensure at that time in this state;
- (c) (3) Present to the board proof of initial licensure by examination and proof that such license and any other certificate granted to the applicant by any other state or states is not at the time of application suspended, revoked, canceled or otherwise restricted in a manner preventing the applicant from practicing as a pharmacist for any reason except nonrenewal or the failure to obtain required continuing education credits in any state where the applicant is licensed but not engaged in the practice of pharmacy; and
- $\frac{\text{(d)}}{\text{(d)}}$ Pay the fees specified by the board of pharmacy for issuance of a license this chapter.
- (2) Eligibility. No applicant shall be eligible for licensure by reciprocity unless the state in which the applicant was initially licensed as a pharmacist also grants reciprocal licensure to pharmacists duly licensed by examination in this state, under like circumstances and conditions.
- SECTION 14. That Section 54-1723A, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1723A. CERTIFICATE TO ENGAGE IN THE PRACTICE OF PHARMACY INTO IDAHO. (1) To obtain a certificate to practice as a pharmacist into the state of Idaho, the applicant shall:
 - (a) Be licensed and in good standing in the state from which the applicant practices pharmacy;
 - (b) Submit a written application in the form prescribed by the board; and
 - (c) Pay the fee(s) specified by the board for the issuance of the certificate; and
 - (d) Comply with all other requirements of the board.
- (2) A successful applicant for a certificate under this section shall be subject to the disciplinary provisions of section 54-1726, Idaho Code, and the penalty provisions of section 54-1728, Idaho Code, and the rules of the board.
- (3) A successful applicant for a certificate under this section shall comply with the board's laws and rules \underline{laws} of this state unless compliance would violate the laws or rules in the state in which the applicant is located.
- (4) Renewal shall be required biennially and submitted to the board no later than the applicant's birthday. The board shall specify by rule the procedures to be followed and the fees to be paid for renewal of the certificate.

(5) An applicant who has failed to maintain an Idaho license and who has not practiced as a pharmacist for the preceding twenty-four (24) months or longer may, at the board's discretion, be subject to requirements necessary to demonstrate professional competency.

- SECTION 15. That Section 54-1723B, Idaho Code, be, and the same is hereby amended to read as follows:
- 54--1723B. MULTISTATE PRACTICE OF PHARMACY. Notwithstanding any provision of law to the contrary:
- (1) The board may enter into mutual recognition agreements with one (1) or more party states provided that each party state:
 - (a) Has substantially similar requirements for drug outlet registration as required in section 54-1730, Idaho Code, pharmacist licensure, as required in section 54-1722, Idaho Code, or pharmacist intern and technician registration, as required by board rule, or both;
 - (b) Requires a fingerprint-based criminal history check prior to licensure that is substantially similar to the requirement in section 54-1718, Idaho Code; and
 - (c) Grants the same multistate practice privileges to Idaho drug outlets, pharmacists, pharmacist interns, or technicians as Idaho grants to the party state's drug outlets, pharmacists, pharmacist interns, or technicians under like circumstances and conditions.
- (2) A drug outlet, pharmacist, pharmacist intern, or technician license issued by a party state will be recognized by the board as permitting the multistate practice of pharmacy in or into Idaho without a license issued by the board provided the following conditions are met:
 - (a) The party state is the primary state of residence for the multistate licensee;
 - (b) The multistate licensee holds an active license issued by a party state that is not currently suspended, revoked, canceled, or otherwise restricted or conditioned in any manner; and
 - (c) The requirements specified in paragraph (a) or (b) of this subsection shall be met at all times by any multistate licensee engaged in the multistate practice of pharmacy in or into Idaho.
 - (i) If such a multistate licensee no longer meets the requirements in paragraph (a) of this subsection, the multistate licensee shall apply for licensure in the new primary state of residence prior to relocating to the new primary state of residence. If the pharmacist, pharmacist intern, or technician's new primary state of residence is either Idaho or another party state, the pharmacist, pharmacist intern, or technician may continue to practice until a new license is issued in the new primary state of residence.
 - (ii) If a multistate licensee no longer meets the requirements in paragraph (b) of this subsection, the multistate licensee shall immediately cease engaging in the multistate practice of pharmacy in or into Idaho, unless the multistate licensee obtains a license issued by the board.

(3) A multistate licensee engaged in the multistate practice of pharmacy in or into Idaho shall comply with all laws governing the practice of pharmacy in the state of Idaho.

- (4) If the board finds grounds for discipline exist, as set forth in section 54-1726 or 37-2718, Idaho Code, the board may impose upon the multistate practice privileges of a multistate licensee any of the penalties set forth in section 54-1728 or 37-2718, Idaho Code. The board's imposition of any penalties shall be limited to the multistate practice privileges of a multistate licensee. Only the party state shall have the power to revoke, suspend, or otherwise discipline a license issued by the party state.
- (5) The board shall promptly notify a party state of any board action taken against the multistate practice privileges of a multistate licensee licensed by the party state. The party state shall give the same priority and effect to reported conduct received from the board as it would if such conduct had occurred within the party state.
- SECTION 16. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1723C, Idaho Code, and to read as follows:
- 54-1723C. RENEWAL OF PHARMACIST LICENSE. 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 he has maintained competence through continuing education commensurate with the pharmacist's active practice setting.
- SECTION 17. That Section 54-1725, Idaho Code, be, and the same is hereby repealed.
 - SECTION 18. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1725, Idaho Code, and to read as follows:
 - 54-1725. PHARMACIST INTERN RENEWAL REQUIREMENTS. (1) A pharmacist intern registration shall be obtained prior to commencement of an internship and shall be renewed biennially. No renewal fee shall be charged if the pharmacist intern renews the registration annually by July 15.
 - (2) After graduation, a pharmacist intern application may be extended for up to twelve (12) months at no cost from the date of application as a pharmacist. Following an extension, the individual may register as a technician or petition the board for more time as a pharmacist intern if exceptional circumstances are present.
 - SECTION 19. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1725A, Idaho Code, and to read as follows:
 - 54-1725A. PRACTITIONER CONTROLLED SUBSTANCE REGISTRATION. Any person needing a controlled substance registration as provided in section 37-2716, Idaho Code, shall:

(1) Hold a valid state license or registration to prescribe medications from a licensing authority established under this title;

- (2) Obtain a valid DEA registration if required pursuant to federal law. Failure to obtain such registration, if required, within forty-five (45) days after issuance of an Idaho controlled substance registration shall result in automatic cancellation; and
- (3) Have an Idaho practice address subject to inspection by the board. The provisions of this subsection shall not apply to nonresident prescribers who only prescribe into Idaho.

SECTION 20. That Section 54-1726, Idaho Code, be, and the same is hereby amended to read as follows:

- 54-1726. GROUNDS FOR DISCIPLINE. (1) The board of pharmacy may penalize as set forth in section 54-1728, Idaho Code, a certificate of any person, pursuant to the procedures set forth in chapter 52, title 67, Idaho Code, upon one (1) or more of the following grounds:
 - (a) Unprofessional conduct as that term is defined by the rules of the board; including but not limited to:
 - (i) Unethical conduct, including fraud, misrepresentation, negligence, concealment, using false information, or breaching the public trust;
 - (ii) A lack of fitness for professional practice due to incompetency, personal habits, drug or alcohol dependence, on-duty intoxication or impairment, or any other cause that endangers the public;
 - (iii) Diversion of drug products and devices, unlawful possession or use of drugs, excessive provision of controlled substances, or violating provisions of the federal or state controlled substances laws;
 - (iv) Failing to follow the instructions of the person ordering a prescription, except as provided in this chapter;
 - (v) Providing substandard, misbranded, or adulterated drugs or drugs made using secret formulas;
 - (vi) Acts or omissions within the practice of pharmacy that fail to meet the standard of care provided by other licensees or registrants in the same or similar setting;
 - (vii) Directly promoting or inducing health care services or products that are unnecessary or not medically indicated; or
 - (viii) Failure to follow an order of the board, comply with an inspection or investigation, or promptly remediate inspection deficiencies;
 - (b) Incapacity of a nature that prevents a person from engaging in the practice of pharmacy with reasonable skill, competence and safety to the public;
 - (c) Being found guilty, convicted or having received a withheld judgment or suspended sentence by a court of competent jurisdiction in this state or any other state of one (1) or more of the following:
 - (i) Any crime deemed relevant in accordance with section 67-9411(1), Idaho Code;

- (ii) Any act related to the qualifications, functions or duties of a licensee or registrant; or
- (iii) Violations of the pharmacy or drug laws of this state or rules pertaining thereto, or of statutes, rules or regulations of any other state, or of the federal government;
- (d) Fraud or intentional misrepresentation by a licensee or registrant in securing the issuance or renewal of a certificate;
- (e) Engaging or aiding and abetting an individual to engage in the practice of pharmacy without a certificate or falsely using the title of pharmacist; and
- (f) Being found by the board to be in violation of any of the provisions of this chapter, $\underline{\text{or}}$ chapter 27, title 37, Idaho Code, or rules adopted pursuant to either chapter.
- (2) Nonresident licensees and registrants shall be held accountable to the board for violations by its agents and employees and subject to the same grounds for discipline and penalties for their actions as set forth herein.
- SECTION 21. That Section 54-1728, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1728. PENALTIES AND REINSTATEMENT INTERVALS. (1) Upon the finding of the existence of grounds for discipline of any person or business entity holding, seeking, or renewing a certificate under the provisions of this chapter, the board of pharmacy may impose any of the following penalties:
 - (a) Suspension of the offender's certificate for a term to be determined by the board;
 - (b) Revocation of the offender's certificate;

- (c) Restriction of the offender's certificate to prohibit the offender from performing certain acts or from engaging in the practice of pharmacy in a particular manner for a term to be determined by the board;
- (d) Refusal to issue or renew the offender's certificate;
- (e) Placement of the offender on probation and supervision by the board for a period to be determined by the board; or
- (f) Imposition of an administrative fine not to exceed two thousand dollars (\$2,000) for each occurrence providing a basis for discipline.
- (2) Whenever it appears that grounds for discipline exist under this chapter and the board finds that there is an immediate danger to the public health, safety, or welfare, the board is authorized to commence emergency proceedings to suspend, revoke, or restrict the certificate. Such proceedings shall be promptly instituted and processed. Any person whose certificate has been disciplined pursuant to this subsection can contest the emergency proceedings and appeal under the applicable provisions of chapter 52, title 67, Idaho Code.
- (3) The board may take any action against a nonresident licensee or registrant that the board can take against a resident licensee or registrant for violation of the laws of this state or the state in which it resides.
- (4) The board may report any violation by a nonresident licensee or registrant, or its agent or employee, of the laws and rules of this state, the state in which it resides or the United States to any appropriate state or federal regulatory or licensing agency including, but not limited to, the

regulatory agency of the state in which the nonresident licensee or registrant is a resident.

- (5) The suspension, revocation, restriction or other action taken against a licensee or registrant by a state licensing board with authority over a licensee's or registrant's professional certificate or by the drug enforcement administration may result in the board's issuance of an order likewise suspending, revoking, restricting or otherwise affecting the certificate in this state, without further proceeding, but subject to the effect of any modification or reversal by the issuing state or the drug enforcement administration.
- (6) The assessment of costs and fees incurred in the investigation and prosecution or defense of a person holding, seeking, or renewing a certificate under this chapter shall be governed by the provisions of section 12-117(5), Idaho Code.
- (7) Any person or business entity whose certificate to practice pharmacy in this state has been suspended, revoked, or restricted pursuant to this chapter, whether voluntarily or by action of the board, shall have the right, at reasonable intervals, to petition the board for reinstatement of such certificate. Such petition shall be made in writing and in the form prescribed by the board. Upon investigation and hearing, the board may in its discretion grant or deny such petition, or it may modify its original finding to reflect any circumstances which that have changed sufficiently to warrant such modifications.
- (8) Nothing herein shall be construed as barring criminal prosecutions for violations of the act where such violations are deemed as criminal offenses in other statutes of this state or of the United States.
- (9) All final decisions by the board shall be subject to judicial review pursuant to the procedures of the administrative procedure act.
- SECTION 22. That Section 54-1729, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1729. REGISTRATION AND LICENSURE OF FACILITIES. (1) All drug or device outlets doing business in or into Idaho shall:
 - (a) If a nonresident, be licensed or registered and in good standing in the applicant's state of residence and, if a pharmacy, have a PIC who is registered by the board person in charge who is licensed and in good standing in the nonresident state and registered by the board on a form approved by the board;
 - (b) Submit a written application in the form prescribed by the board with information about ownership and location; and
 - (c) Pay the fee or fees specified by the board for the issuance of the certificate this chapter.
- (2) Each drug or device outlet shall apply for a certificate in one (1) of the following classifications prior to doing business in or into Idaho:
 - (a) Resident drug outlet;
 - (b) Nonresident drug outlet;
 - (c) Manufacturer;

- (d) Wholesaler; or
- (e) Prescriber drug outlet.

(3) The board shall establish by rule under the powers granted to it under sections 54-1718 and 54-1719, Idaho Code, the criteria that each outlet with employees or personnel engaged in the practice of pharmacy must meet to qualify for registration or licensure in each classification designated in subsection (2) of this section. The board may issue various types of certificates with varying restrictions to such outlets designated in subsection (2) of this section where the board deems it necessary by reason of the type of outlet requesting a certificate.

- (4) (3) It shall be lawful for any outlet or facility to sell and distribute nonprescription drugs. Outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule will be adopted by the board under this chapter that requires the sale of nonprescription drugs by a pharmacist or under the supervision of a pharmacist or otherwise applies to or interferes with the sale and distribution of such medicines.
- (4) Following the issuance of a new license or registration, each facility shall be inspected to confirm that the facility is compliant with applicable law.
- (5) If the regulatory board or licensing authority of the state in which a nonresident outlet is located fails or refuses to conduct an inspection or fails to obtain records or reports required by the board, upon reasonable notice to the nonresident outlet, the board may conduct an inspection. Nonresident outlets shall also pay the actual costs of the out-of-state inspection of the outlet, including the transportation, lodging and related expenses of the board's inspector.
- (6) A successful applicant for a certificate under the provisions of this section shall be subject to the disciplinary provisions of section 54-1726, Idaho Code, and the penalty provisions of section 54-1728, Idaho Code, and the rules of the board.
- (7) A successful applicant for a certificate under the provisions of this section shall comply with the board's laws and the rules of this state unless compliance would violate the laws, regulations, or rules in the state in which the licensee or registrant is located.
- (8) Renewal shall be required biennially and submitted to the board in accordance with the provisions of section 67-2614, Idaho Code. The board shall specify by rule the procedures to be followed and the fees to be paid for renewal of a certificate.
- SECTION 23. That Section 54-1729A, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1729A. WHOLESALE DRUG DISTRIBUTOR -- LICENSURE. (1) In addition to meeting federal requirements, every business entity that engages in the wholesale distribution of prescription drugs, durable medical equipment, or pseudoephedrine products in or into Idaho must shall be licensed by the board as a wholesale distributor, except:
 - (a) Manufacturers distributing their own federal food and drug administration-approved drugs and devices, including distribution of prescription drug samples by manufacturers' representatives and intracompany sales, meaning any transaction or transfer between any division, subsidiary, parent, or affiliated or related company under

 common ownership and control of a corporate entity or any transfer between colicensees of a colicensed product, unless particular requirements are deemed necessary and appropriate following rulemaking;

- (b) An entity that donates prescription drugs, when conducted in accordance with sections 54-1760 through 54-1765, Idaho Code;
- (c) A pharmacy distributing in accordance with section 54-1732, Idaho Code; and
- (d) Persons selling, purchasing, distributing, trading, or transferring a prescription drug for emergency medical reasons.
- (2) The board shall not issue a wholesale distributor license to an applicant unless the board determines that the designated representative meets the following qualifications:
 - (a) Is actively involved in and aware of the actual daily operation of the wholesale distributor; and
 - (b) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including but not limited to sick leave and vacation leave—; and
 - (c) Has disclosed under oath any felony convictions, any conviction of the applicant related to wholesale or retail prescription drug distribution, or any discipline by a state regulatory agency related to wholesale or retail prescription drug distribution.
- (3) All applicant-designated representatives shall submit to a fingerprint-based criminal history check in accordance with section 67-9411A, Idaho Code.
- (4) A wholesale distributor shall have adequate processes in place for monitoring purchase activity of customers and identifying suspicious ordering patterns that indicate potential diversion or criminal activity related to controlled substances such as orders of unusual size, orders deviating substantially from a normal pattern, orders for drugs that are outside of the prescriber's scope of practice, or orders of unusual frequency.
- (5) The board may adopt rules to approve an accreditation body to evaluate a wholesaler's operations to determine compliance with professional standards and any other applicable laws and to perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesaler.
- (5) The board shall recognize a wholesaler's accreditation by the national association of boards of pharmacy for purposes of reciprocity and satisfying the new drug outlet inspection required by this chapter.
- SECTION 24. That Section $\underline{54-1730}$, Idaho Code, be, and the same is hereby repealed.
- SECTION 25. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1730, Idaho Code, and to read as follows:
- 54-1730. DRUG OUTLET MINIMUM FACILITY STANDARDS. Each resident drug outlet shall meet the following minimum facility standards:

- (1) 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;
 - (2) Store controlled substances in accordance with federal law;

- (3) Restrict access to the area where prescription drugs are prepared, compounded, distributed, dispensed, or stored to authorized personnel;
- (4) Maintain staff sufficient to operate safely and remain open during the hours posted to the public; and
- (5) If dispensing more than twenty (20) prescriptions per day, maintain an electronic recordkeeping system to store patient medication records. Such system shall have audit trail functionality that documents the identity of each individual involved in each step of processing, filling, and dispensing or, alternatively, the identity of the pharmacist or prescriber responsible for the accuracy of such processes.
- SECTION 26. That Section 54-1731, Idaho Code, be, and the same is hereby repealed.
- SECTION 27. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1731, Idaho Code, and to read as follows:
- 54-1731. DRUG OUTLET AND LICENSEE REPORTING REQUIREMENTS. (1) All drug outlets shall report to the board of pharmacy:
 - (a) At least ten (10) days prior, the occurrence of a change of location or permanent closing, including notice of the proposed new location of prescription files and the location where the closing inventory record of controlled substances will be retained;
 - (b) As soon as possible, the occurrence of any disaster, accident, or emergency that affects safe and continued operation;
 - (c) On the same day as such report is made to the DEA, any theft or loss of controlled substances; and
 - (d) Within thirty (30) days, a change of the operating legal entity's majority ownership.
- (2) Authorized distributors shall report specified data on controlled substances each month in a form and manner prescribed by the board.
- (3) All licensees shall report changes in information provided on or with renewal application forms within thirty (30) days of such changes.
- (4) All licensees shall report the following within thirty (30) days after the final action:
 - (a) All felony and other criminal convictions involving any legend drug;
 - (b) Any disciplinary action from any other licensing authority; and
 - (c) The surrender of a license in lieu of discipline from any other licensing authority.

SECTION 28. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1731A, Idaho Code, and to read as follows:

54-1731A. DRUG OUTLETS THAT DISPENSE PRESCRIPTION DRUGS -- MINIMUM REQUIREMENTS. All drug outlets shall:

- (1) Dispense prescription drugs only pursuant to a valid prescription drug order as set forth in this chapter;
- (2) Provide prospective drug review that shall include evaluation of a prescription drug order for known allergies, rational therapy contraindications, reasonable dose and route of administration, reasonable directions for use, duplication of therapy, drug interactions, and proper utilization;
 - (3) Provide a complete and accurate label as set forth in this chapter;
- (4) Verify the accuracy of the drug stock selected relative to the drug prescribed. If not performed by a pharmacist, an electronic verification system or verification by two (2) support persons shall be necessary; and
- (5) Provide counseling for new medications. For refills or renewed prescriptions an offer to counsel the patient or caregiver shall be extended. Nothing in this section shall require a pharmacist to provide counseling when a patient or caregiver refuses such counseling, when counseling is otherwise impossible, or for inpatients of a hospital or institutional facility if a licensed health care professional administers the medication.
- SECTION 29. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1731B, Idaho Code, and to read as follows:
- 54-1731B. DRUG OUTLETS WITH ALTERNATIVE DISPENSING MODELS. (1) A drug outlet that dispenses prescription drugs to human patients that does not have a pharmacist or other prescriber on site to supervise pharmacy operations shall:
 - (a) Maintain adequate video surveillance and retain a recording for a minimum of thirty (30) days. Provided, however, that self-service automated dispensing systems shall be excluded from the requirements of this paragraph;
 - (b) Use an audio communication system to counsel and interact with each patient or patient's caregiver; and
 - (c) Remain closed to the public if either of the systems required pursuant to paragraphs (a) or (b) of this subsection are not functioning properly.
- (2) A drug outlet that stores drugs outside of a drug outlet for retrieval by a licensed health care professional shall comply with the following:
 - (a) Drugs shall remain under the control of, and be routinely monitored and inventoried by, the supervising drug outlet; and
 - (b) The storage area shall be appropriately equipped to ensure security and prevent diversion or tampering;
- (3) Stocking and replenishing of a drug outlet that stores drugs outside of a drug outlet for retrieval by a licensed health care professional may be performed by a pharmacist or prescriber or an appropriate support person if using an electronic verification system or a verification by two support persons.

SECTION 30. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1731C, Idaho Code, and to read as follows:

- 54-1731C. DRUG OUTLET RECORDKEEPING REQUIREMENTS. (1) Unless otherwise provided for in this chapter, prescription records and any other records required by this chapter shall be maintained for at least three (3) years after the date of a transaction. Prescription records may be retained at a central location or may be stored and maintained electronically provided that such records remain legible. All records shall be produced within seventy-two (72) hours.
- (2) Each drug outlet shall 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. Pursuant to the requirements of this subsection:
 - (a) A biennial inventory shall be conducted at each registered location not 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; and
 - (b) Evidence of an amount of a controlled substance that differs from the amount reflected on a record or inventory shall create a rebuttable presumption that the registrant has failed to keep records or maintain inventories pursuant to the requirements of this chapter.
- (3) Wholesalers and other entities engaged in wholesale drug distribution shall maintain inventories and records that include, at a minimum:
 - (a) The source of 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, quantity, and dates of receipt and distribution of drugs received and distributed or disposed of; and
 - (c) Controlled substance distribution invoices.
- SECTION 31. That Section 54-1732, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1732. VIOLATIONS AND PENALTIES. (1) No drug outlet designated in section 54-1729, Idaho Code, shall be operated until a certificate has been issued to said facility by the board. Upon the finding of a violation of this subsection, the board may impose one (1) or more of the penalties enumerated in section 54-1728, Idaho Code.
- (2) Reinstatement of a certificate that has been suspended, revoked or restricted by the board may be granted in accordance with the procedures specified in section 54-1728(7), Idaho Code.
- (3) The following acts, or the failure to act, and the causing of any such act or failure are unlawful:
 - (a) The sale, delivery or administration of any prescription drug or legend drug, except an emergency medication pursuant to section 54-1735, Idaho Code, unless:
 - (i) Such legend drug is dispensed or delivered by a pharmacist or prescriber upon an original prescription, drug order or prescription drug order by a practitioner in good faith in the course of his

practice. Any person violating the provisions of this subparagraph shall be guilty of a felony and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years, or punished by a fine of not more than five thousand dollars (\$5,000), or by both such fine and imprisonment; or

- (ii) In the case of a legend drug dispensed to a person, there is a label affixed to the immediate container in which such drug is dispensed. Any person violating this subparagraph shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than five hundred dollars (\$500). Nothing in this subparagraph prohibits a practitioner from delivering professional samples of legend drugs in their original containers in the course of his practice when oral directions for use are given at the time of such delivery.
- (b) The refilling of any prescription or drug order for a legend drug, except as designated on the prescription or drug order or by the authorization of the practitioner, or in accordance with board rule. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year or punished by a fine of not more than one thousand dollars (\$1,000), or by both such fine and incarceration.
- (c) The possession or use of a legend drug or a precursor, except an emergency medication pursuant to section 54-1735, Idaho Code, by any person unless such person obtains such drug on the prescription or drug order of a practitioner. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year or punished by a fine of not more than one thousand dollars (\$1,000), or by both such fine and incarceration.
- (d) The wholesale distribution of drugs or devices by a pharmacy except for:
 - (i) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets;
 - (ii) The sale of minimal quantities of prescription drugs to practitioners for office use or to dispensing drug outlets for a specific patient need;
 - (iii) The sale of a prescription drug for emergency medical reasons, but never to a wholesale distributor;
 - (iv) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between colicensees or a colicensed product, but never to a wholesale distributor; or
 - (v) Other exemptions as permitted by federal law.
- (e) The failure to keep records as required by the board this chapter. Any person guilty of violating the provisions of this paragraph shall be

- guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year or punished by a fine of not more than one thousand dollars (\$1,000), or by both such fine and incarceration.
- (f) The refusal to make available and to accord full opportunity to check any record, as required by the board. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year or punished by a fine of not more than one thousand dollars (\$1,000), or by both such fine and incarceration.
- (g) It is unlawful to:

- (i) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug: by fraud, deceit, misrepresentation or subterfuge; by the forgery or alteration of a prescription, drug order, or of any written order; by the concealment of a material fact; or by the use of a false name or the giving of a false address;
- (ii) Communicate information to a practitioner in an effort unlawfully to procure a legend drug, or unlawfully to procure the administration of any such drug. Any such communication shall not be deemed a privileged communication;
- (iii) Intentionally make a false statement in any prescription, drug order, order, report or record required by this chapter;
- (iv) For the purpose of obtaining a legend drug to falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, dispenser, prescriber, or other person;
- (v) Make or utter any false or forged prescription or false drug order or forged written order;
- (vi) Affix any false or forged label to a package or receptacle containing legend drugs. This subparagraph does not apply to law enforcement agencies or their representatives while engaged in enforcing state and federal drug laws; or
- (vii) Wholesale or retail any prescription or legend drug to any person in this state not entitled by law to deliver such drug to another.

Every violation of paragraph (g) (i) through (vi) of this subsection shall be a misdemeanor, and any person convicted thereof shall be incarcerated in the county jail for a term not to exceed one (1) year or fined not more than one thousand dollars (\$1,000), or punished by both such fine and imprisonment. Any person violating paragraph (g) (vii) of this subsection is guilty of a felony and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years or punished by a fine of not more than five thousand dollars (\$5,000), or by both such fine and imprisonment.

(4) The ultimate user of a legend drug who has lawfully obtained such legend drug may deliver, without being registered, the legend drug to another person for the purpose of disposal of the legend drug if the person receiving the legend drug for purposes of disposal is authorized under a state or federal law or regulation to engage in such activity.

SECTION 32. That Section 54-1733, Idaho Code, be, and the same is hereby amended to read as follows:

- 54-1733. VALIDITY OF PRESCRIPTION DRUG ORDERS. (1) A prescription drug order for a legend drug is valid only if it is issued by a prescriber for a legitimate medical purpose arising from a prescriber-patient relationship that includes a documented patient evaluation adequate to establish diagnoses, if applicable, and identify underlying conditions and/or contraindications to the treatment. A valid prescriber-patient relationship may be established through virtual care technologies, provided that the applicable Idaho community standard of care must be satisfied.
- (2) A valid prescription may not be antedated or postdated or have evidence of alteration by any person other than the person who wrote it.
- (2) (3) A prescriber who is otherwise authorized to perform any of the activities listed in this section may prescribe or perform any of the following activities for a patient with whom the prescriber does not have a prescriber-patient relationship under the following circumstances:
 - (a) Writing initial admission orders for a newly hospitalized patient;
 - (b) Writing a prescription drug order for a patient of another prescriber for whom the prescriber is taking call;
 - (c) Writing a prescription drug order for a patient examined by a physician assistant, advanced practice registered nurse or other licensed practitioner with whom the prescriber has a supervisory or collaborative relationship;
 - (d) Writing a prescription drug order for a medication on a short-term basis for a new patient prior to the patient's first appointment;
 - (e) Writing a prescription for an emergency medication pursuant to section 54-1735, Idaho Code;
 - (f) In emergency situations where the life or health of the patient is in imminent danger;
 - (g) In emergencies that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak; and
 - (h) If a prescriber makes a diagnosis of an infectious disease in a patient, prescribe or dispense antimicrobials to an individual who has been exposed to the infectious person in accordance with clinical guidelines.
- $\frac{(3)}{(4)}$ Treatment, including issuing a prescription drug order, based solely on a static online questionnaire does not constitute a legitimate medical purpose.
- $\underline{\mbox{(4)}}\underline{\mbox{(5)}}$ A prescription drug order shall be issued only by a prescriber including a prescriber who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to prescribe legend drugs in the course of his professional practice as long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription drug order.
 - (5) (6) (a) The following acts shall be unlawful:
 - (a) (i) To knowingly issue an invalid prescription drug order for a legend drug;

(b) (ii) To knowingly dispense a legend drug pursuant to an invalid prescription drug order; or

- (c) (iii) To prescribe drugs to individuals without a prescriber-patient relationship, unless excepted in this section.; or
- (iv) To issue a controlled substance prescription for the prescriber's own use.
- (b) Such acts shall constitute unprofessional conduct and the prescriber or dispenser shall be subject to discipline according to the provisions of the Idaho Code chapter pursuant to which the prescriber or dispenser is licensed, certified or registered.
- SECTION 33. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1733A, Idaho Code, and to read as follows:
- 54-1733A. PRESCRIPTION DRUG ORDER MINIMUM REQUIREMENTS. (1) A prescription drug order may be transmitted by delivery of the original signed written prescription or a digital image of the order, or by a prescriber, prescriber's agent, or representative of a state-licensed or federally certified provider community either electronically, verbally, or via facsimile.
 - (2) Each prescription drug order shall include at least the following:
 - (a) The name of the patient or authorized entity, and, if for an animal, the species;
 - (b) If a controlled substance, the patient's address;
 - (c) The date issued;

- (d) The drug name, strength, and quantity;
- (e) Directions for use;
- (f) The name of the prescriber, and, if a controlled substance, the address and DEA registration number; and
- (g) The signature of the prescriber or, if a renewal of a previous prescription, the prescriber's authorized agent.
- (3) A provider may omit drug information and directions and, instead, make an indication for the pharmacist to finalize the patient's drug therapy plan.
- SECTION 34. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1733B, Idaho Code, and to read as follows:
- 54-1733B. FILLING PRESCRIPTION DRUG ORDERS -- LIMITATIONS. (1) Drug product selection is only allowed between therapeutic equivalent drugs as published in the FDA orange book or green book. If a prescriber orders that a brand name drug shall be dispensed, then no drug product selection is permitted.
- (2) Partial fillings shall be allowed as long as the total quantity dispensed does not exceed the total quantity prescribed.
- (3) A prescription drug order may be refilled as authorized by the prescriber and within the limits of federal law. A pharmacist may also refill a prescription to ensure continuity of care.
 - (4) A pharmacist may:

- (a) Change the quantity of medication prescribed if any of the following apply: the quantity or package size is not commercially available, the change is related to a change in dosage form, strength or therapeutic interchange, the change is intended to synchronize a patient's medications, or if it is to dispense the total amount authorized by the prescriber;
- (b) Change the dosage form if it is in the best interest of patient care, as long as the directions are also modified to equate to an equivalent amount of the drug dispensed as prescribed; and
- (c) Complete missing information on the prescription if there is evidence to support the change.
- (5) Drug product substitutions in which a pharmacist dispenses a drug product other than that prescribed are only allowed as follows:
 - (a) Pursuant to a formulary or drug list of a pharmacy and therapeutics committee of a hospital;
 - (b) At the direction of the quality assessment and assurance committee of an institutional facility;
 - (c) For interchangeable biosimilar products published in the FDA purple book, if the name of the drug and the manufacturer or the national drug code number is documented in the patient's medical record; and
 - (d) Therapeutic interchange within the same therapeutic class is allowed if the substitution lowers the cost to the patient or occurs during a drug shortage.
- SECTION 35. That Section 54-1734, Idaho Code, be, and the same is hereby repealed.
- SECTION 36. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1734, Idaho Code, and to read as follows:
- 54-1734. PHARMACIST PRESCRIBING -- GENERAL REQUIREMENTS. (1) A pharmacist may independently prescribe if such pharmacist:
 - (a) Only prescribes drugs for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained;
 - (b) Only issues a prescription for a legitimate medical purpose arising from a patient-prescriber relationship;
 - (c) Obtains 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) Recognizes the limits of the pharmacist's own knowledge and experience and consults with and refers to other health care professionals as appropriate; and
 - (e) Maintains documentation adequate to justify the care provided, including but not limited to the information collected as part of the patient assessment, diagnosis, prescription record, provider notification, and follow-up care plan.
- (2) The general requirements provided for 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 authorized under this chapter.

 SECTION 37. That Section 54-1736, Idaho Code, be, and the same is hereby repealed.

- SECTION 38. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1736, Idaho Code, and to read as follows:
- 54-1736. PRESCRIPTION DRUG LABELING STANDARDS. (1) All prescription drugs shall be in an appropriate container bearing a label in conformance with federal law.
- (2) For parenteral admixtures, the label shall include the date and time of the addition or the beyond use date.
- (3) For prepackaged products, the label shall 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.
- (4) For repackaged drugs, the label shall include the prescription number and contact information for the original dispensing pharmacy, a statement indicating that the drug has been repackaged, and contact information for the repackager.
- SECTION 39. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1736A, Idaho Code, and to read as follows:
- 54-1736A. PRESCRIPTION DRUG DELIVERY AND RETURN. (1) Delivery of filled prescriptions shall be allowed if appropriate measures are taken to ensure product integrity and safety. Prescriptions may be picked up for or returned from delivery by authorized personnel from a secured delivery area.
- (2) A drug outlet registered with the DEA as a collector may collect controlled and non-controlled drugs for destruction. Otherwise a dispensed drug or device may only be accepted for return as follows:
 - (a) When the pharmacist determines that harm could result if the drug or device is not returned;
 - (b) If it is a legend drug for donation pursuant to sections 54-1760 through 54-1764, Idaho Code; and
 - (c) The drug did not reach the patient and has been maintained in the custody and control of the drug outlet and the drug outlet is able to assure that product integrity has been maintained.
- SECTION 40. That Section 54-1738, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1738. PROOF THAT A DRUG IS A PRESCRIPTION DRUG OR LEGEND DRUG -- COMMON NUISANCE. (1) The following shall constitute prima facie evidence in any criminal or civil proceeding in this state that a drug is a prescription drug or legend drug:

(1) (a) In the case of a drug for which a new drug application was submitted to the United States food and drug administration, the affidavit of an officer having legal custody of the official records of the United States food and drug administration stating that such records show that the new drug application was approved, setting forth the date of approval, and further stating that the records show that proposed labeling for the drug which includes the legend "Caution: Federal law prohibits dispensing without a prescription" was approved. The affidavit shall be accompanied by a certificate that such officer has the custody. (2) (b) In the case of a drug for which the United States food and drug administration does not require an approved new drug application as a condition for marketing the drug, the affidavit of an officer having legal custody of the official records of the United States food and drug administration stating that such records reflect that the drug meets the criteria of federal law to be regarded as a prescription drug and is required to bear the legend "Caution: Federal law prohibits dispensing without a prescription." The affidavit shall be accompanied by a certificate that such officer has the custody.

(3) (c) In the case of a drug designated a prescription drug by action of the state board of pharmacy, independently of federal law, the affidavit of an officer having legal custody of the records of the state board of pharmacy stating that such records show that the drug has been denominated a prescription drug, to which shall be attached a copy of the official document evidencing such action. The affidavit shall be accompanied by a certificate that such officer has the custody.

(4) (2) This section does not prevent proof that a drug is a prescription or legend drug by any method authorized by any applicable statute, rule of procedure or rule of evidence.

(3) Any store, shop, warehouse, dwelling house, apartment, building, vehicle, boat, aircraft, or any place whatsoever used by any person for the purpose of unlawfully using any legend drug, or used for the unlawful keeping or selling of the same, is a common nuisance. No person shall keep or maintain such a common nuisance or frequent or visit such place knowing that it is used for any such purpose.

SECTION 41. That Section 54-1739, Idaho Code, be, and the same is hereby repealed.

SECTION 42. That Section 54-1760, Idaho Code, be, and the same is hereby amended to read as follows:

54-1760. SHORT TITLE. Sections 54-1760 through $\frac{54-1765}{54-1764}$, Idaho Code, shall be known and may be cited as the "Idaho Legend Drug Donation Act."

SECTION 43. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1765, Idaho Code, and to read as follows:

54-1765. COMPOUNDING DRUG PREPARATIONS -- GENERAL PROVISIONS. (1) Any compounding that is not permitted pursuant to the provisions of this chapter is considered manufacturing.

(2) The provisions of subsections (3) through (7) of this section apply to any person authorized to engage in the practice of non-sterile compounding, sterile compounding, and sterile prepackaging of drug products in or into Idaho but shall not apply to:

- (a) The reconstitution of a non-sterile drug or sterile drug for immediate administration;
- (b) The addition of a flavoring agent or coloring agent to a drug product, as long as the agent is therapeutically inert and in the minimum quantity necessary; or
- (c) Product preparation of a non-sterile, non-hazardous drug according to the manufacturer's FDA approved labeling.
- (3) Any person engaging in compounding pursuant to this section shall:
- (a) Obtain all active pharmaceutical ingredients from an FDA registered manufacturer;
- (b) Unless the active pharmaceutical ingredient complies with the standards of an applicable USP-NF monograph, obtain a certificate of analysis 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 certificate shall contain the product name, lot number, expiration date, and assay;
- (c) Use equipment and utensils of suitable design and composition and that are cleaned, sanitized, or sterilized as appropriate prior to use; and
- (d) Remove unknown or questionable products from stock and isolate such products for return, reclamation, or destruction.
- (4) Compounding any drug products for human use that the FDA has identified as presenting demonstrable difficulties in compounding or has withdrawn or removed from the market is prohibited.
- (5) A drug product that is commercially available may only be compounded if not compounded regularly or in inordinate amounts or if the commercial product is not reasonably available in the market in time to meet a patient's needs.
- (6) Limited quantities of a drug 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 product.
- (7) Policies and procedures for the compounding or sterile prepackaging of drug products shall ensure the safety, identity, strength, quality, and purity of the finished product. To meet this standard, licensees and registrants shall take into consideration the applicable provisions of USP chapters 795 and 797, and USP-NF chapters 1075 and 1160.
- SECTION 44. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1766, Idaho Code, and to read as follows:
- 54-1766. STERILE PREPARATION. (1) The sterility of compounded diagnostics, drugs, nutrients, and radiopharmaceuticals shall be maintained or the compounded drug preparation shall be sterilized when prepared in the following dosage forms:

- (a) Aqueous bronchial and nasal inhalations, except nasal dosage forms intended for application;
- (b) Baths and soaks for live organs and tissues;
- (c) Injections such as colloidal dispersions, emulsions, solutions, and suspensions;
- (d) Irrigations for internal body cavities;
- (e) Ophthalmic drops and ointments; and
- (f) Tissue implants.

- (2) 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.
- (3) Except when provided for immediate administration, the environment for the preparation of sterile preparations in a drug outlet shall be in an isolated area, designed to avoid unnecessary traffic and airflow disturbances, and equipped to accommodate aseptic techniques and conditions.
- (4) The following shall be documented with respect to any sterile preparation:
 - (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 visual inspection, periodic hand hygiene and garbing competency, gloved fingertip sampling testing, sterility testing, media-fill test procedures, competency evaluation at least annually for each compounder, and environmental sampling testing at least upon registration of a new drug outlet, upon the servicing or re-certification of facilities and equipment, in response to identified problems, or every six (6) months;
 - (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.

SECTION 45. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underbrace{\text{NEW SECTION}}_{\text{Log}}$, to be known and designated as Section 54-1767, Idaho Code, and to read as follows:

- 54-1767. HAZARDOUS DRUG PREPARATION. This section shall apply to all persons engaged in the practice of compounding or sterile prepackaging with hazardous drugs. Such persons shall:
- (1) Ensure the storage and compounding areas have sufficient general exhaust ventilation to dilute and remove airborne contaminants;
- (2) Utilize a ventilated cabinet designed to reduce worker exposures while preparing hazardous drugs. Sterile hazardous drugs shall 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. When asepsis is not required, a class I

biological safety cabinet, powder containment hood or an isolator intended for containment applications may be sufficient. 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 is provided attesting to the safety of such ventilation.
- (3) Clearly identify storage areas, compounding areas, containers, and prepared doses of hazardous drugs;
- (4) Label hazardous drugs with proper precautions, and dispense them in a manner to minimize risk of hazardous spills;
- (5) Provide and maintain appropriate personal protective equipment and supplies necessary for handling hazardous drugs, spills, and disposal;
- (6) 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 unity-of-use packaging; and
- (7) 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.

SECTION 46. That Section 54-1771, Idaho Code, be, and the same is hereby repealed.

SECTION 47. That Section 37-2716, Idaho Code, be, and the same is hereby amended to read as follows:

- 37-2716. REGISTRATION REQUIREMENTS. (a) Every person who manufactures, distributes, prescribes, administers, dispenses, or conducts research with any controlled substance within this state shall obtain annually a registration issued by the board in accordance with this chapter and its rules. Idaho law. All drug outlets with a valid license or registration under chapter 17, title 54, Idaho Code, are exempt from obtaining a separate controlled substance registration.
- (b) Every prescriber, except veterinarians, shall also register with the division to obtain online access to the controlled substances prescriptions database.
- (c) Persons registered by the board under this chapter may possess, manufacture, distribute, dispense, prescribe, administer, or conduct research with those substances to the extent authorized by their registration and licensing entity and in conformity with the other provisions of this chapter.
- (d) The following persons need not register and may lawfully possess controlled substances under this chapter:
 - (1) An agent or employee of any person registered pursuant to this chapter, if he is acting in the usual course of his business or employment;
 - (2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled substance is in the usual course of business or employment;

- (3) An ultimate user or a person in possession of any controlled substance pursuant to a lawful order of a practitioner or in lawful possession of a schedule V substance.
- (e) The board may waive by rule the requirement for registration of certain persons if it finds it consistent with the public health and safety.

- (f) (e) A separate registration is required at each principal place of business or professional practice where the applicant manufactures, distributes, administers, dispenses, or conducts research with controlled substances, except a separate registration is not required under this chapter for practitioners engaging in research with nonnarcotic controlled substances in schedules II through IV where the practitioner is already registered under this chapter in another capacity.
- $\frac{\text{(g)}}{\text{(f)}}$ Practitioners registered under federal law to conduct research with schedule I substances may conduct research with schedule I substances within this state upon registering in Idaho and furnishing the board with evidence of the practitioner's federal registration.
- $\underline{\mbox{ (h) }}\underline{\mbox{ (g)}}$ The board may inspect the establishment of a registrant or applicant for registration in accordance with this chapter and board rule Idaho law.
- SECTION 48. That Section 37-2730A, Idaho Code, be, and the same is hereby amended to read as follows:
- 37-2730A. PRESCRIPTION TRACKING PROGRAM. (1) The division shall maintain a program to track the prescriptions for controlled substances that are filed with the division under section 37-2726, Idaho Code, for the purpose of assisting in identifying illegal activity related to the dispensing of controlled substances and for the purpose of assisting the division in providing information to patients, practitioners and pharmacists to assist in avoiding inappropriate use of controlled substances. The tracking program and any data created thereby shall be administered by the division. Data collected pursuant to this subsection shall be reported by the end of the business day by all drug outlets that dispense controlled substances in or into Idaho for human patients.
- (2) The division shall use the information obtained through the tracking program in identifying activity it reasonably suspects may be in violation of this chapter or medical assistance law. The division shall report this information to the individuals and persons set forth in section 37-2726(2), Idaho Code. The division may release unsolicited information to pharmacists and practitioners when the release of information may be of assistance in preventing or avoiding inappropriate use of controlled substances. The division may provide the appropriate law enforcement agency, medicaid or medicare agency, or licensing board with the relevant information in the division's possession, including information obtained from the tracking program, for further investigation or other appropriate law enforcement or administrative enforcement use.
- (3) Information that does not identify individual patients, practitioners, or dispensing pharmacists or pharmacies may be released by the division for educational, research, or public information purposes.

(4) Nothing herein shall prevent a pharmacist or practitioner from furnishing another pharmacist or practitioner information obtained pursuant to and in compliance with this chapter.

- (5) Unless there is shown malice or criminal intent or gross negligence or reckless, willful and wanton conduct as defined in section 6-904C, Idaho Code, the state of Idaho, the division, any other state agency, or any person or entity in proper possession of information as herein provided shall not be subject to any liability or action for money damages or other legal or equitable relief by reason of any of the following:
 - (a) The furnishing of information under the conditions herein provided;
 - (b) The receiving and use of, or reliance on, such information;
 - (c) The fact that any such information was not furnished; or
 - (d) The fact that such information was factually incorrect or was released by the division to the wrong person or entity.
- (6) The division may apply for any available grants and accept any gifts, grants or donations to assist in developing and maintaining the program required by this section.
- SECTION 49. That Section 54-5705, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-5705. PROVIDER-PATIENT RELATIONSHIP. A provider may provide virtual care to a patient if such provider has first established a provider-patient relationship with the patient, the patient has a provider-patient relationship with another provider in the provider group, the provider is covering calls for a provider with an established relationship with the patient, or the provider is performing any activities set forth in section $54-1733\frac{(2)}{(3)}$, Idaho Code. A provider-patient relationship may be established by use of virtual care technologies, provided that the applicable Idaho community standard of care is satisfied.
- SECTION 50. The rules contained in IDAPA 24.36.01, Division of Occupational and Professional Licenses, Rules of the Idaho State Board of Pharmacy, shall be null, void, and of no force and effect on and after July 1, 2025.
- 34 SECTION 51. An emergency existing therefor, which emergency is hereby 35 declared to exist, this act shall be in full force and effect on and after 36 July 1, 2025.