



LEGISLATURE OF THE STATE OF IDAHO



Sixty-third Legislature

First Regular Session - 2015

IN THE \_\_\_\_\_

BILL NO. \_\_\_\_\_

BY \_\_\_\_\_

AN ACT

1 RELATING TO PHARMACISTS; AMENDING SECTION 54-1705, IDAHO CODE, TO RE-  
 2 VISE DEFINITIONS AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION  
 3 54-1732, IDAHO CODE, TO PROHIBIT WHOLESALE DISTRIBUTION OF DRUGS OR  
 4 DEVICES BY PHARMACIES, WITH CERTAIN EXCEPTIONS AND TO PROVIDE CORRECT  
 5 CODE REFERENCES; AMENDING SECTION 54-1734, IDAHO CODE, TO PROVIDE THAT  
 6 CERTAIN PERSONS MAY POSSESS LEGEND DRUGS; AMENDING SECTION 54-1735,  
 7 IDAHO CODE, TO PROVIDE THAT PHARMACISTS KEEP PATIENT RECORDS; AMENDING  
 8 SECTION 54-1752, IDAHO CODE, TO REVISE DEFINITIONS; AMENDING SECTION  
 9 54-1753, IDAHO CODE, TO REVISE AND CLARIFY LICENSURE REQUIREMENTS, TO  
 10 REQUIRE THAT WHOLESALE DISTRIBUTORS MONITOR AND IDENTIFY CERTAIN DRUG  
 11 ORDERS AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1754,  
 12 IDAHO CODE, TO REMOVE LANGUAGE RELATING TO RETURNS OR EXCHANGES OF  
 13 PRESCRIPTION DRUGS AND TO PROHIBIT CERTAIN WHOLESALE DISTRIBUTIONS;  
 14 AMENDING SECTION 54-1758, IDAHO CODE, TO REMOVE LANGUAGE RELATING TO  
 15 PROHIBITED ACTS, TO PROVIDE CORRECT CODE REFERENCES AND TO MAKE TECH-  
 16 NICAL CORRECTIONS; REPEALING SECTION 54-1755, IDAHO CODE, RELATING TO  
 17 PEDIGREE; REPEALING SECTION 54-1756, IDAHO CODE, RELATING TO ENFORCE-  
 18 MENT ORDERS; AND AMENDING SECTIONS 37-3201, 54-1759, 54-1761, 54-4702  
 19 AND 54-5110, IDAHO CODE, TO PROVIDE CORRECT CODE REFERENCES.  
 20

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

22 SECTION 1. That Section 54-1705, Idaho Code, be, and the same is hereby  
 23 amended to read as follows:

24 54-1705. DEFINITIONS. In this chapter:

25 (1) "Board of pharmacy" or "board" means the Idaho state board of phar-  
 26 macy.

27 (2) "Central drug outlet" means a resident or nonresident pharmacy,  
 28 drug outlet, or business entity employing or contracting pharmacists to  
 29 perform centralized pharmacy services.

30 (3) "Central pharmacist" means a pharmacist performing centralized  
 31 pharmacy services.

32 (4) "Centralized pharmacy services" means the processing by a central  
 33 drug outlet or central pharmacist of a request from another pharmacy to fill,  
 34 refill, or dispense a prescription drug order, perform processing functions  
 35 or provide cognitive or pharmaceutical care services. Each function may be  
 36 performed by the same or different persons and at the same or different loca-  
 37 tions.

38 (5) "Compounding" means the act of incorporating two (2) or more sub-  
 39 stances to create practice in which a pharmacist, a prescriber, or, in the  
 40 case of an outsourcing facility, a person under the supervision of a phar-  
 41 macist, combines, mixes or alters ingredients of a finished drug product to  
 42 create a medication tailored to the needs of an individual patient.

1 (6) "Counseling" or "counsel" means the effective communication by the  
2 pharmacist of information as set out in this chapter, to the patient or care-  
3 giver, in order to improve therapeutic outcomes by maximizing proper use of  
4 prescription drugs and devices. Specific areas of counseling shall include,  
5 but are not limited to:

6 (a) Name and strength and description of the drug;

7 (b) Route of administration, dosage, dosage form, continuity of ther-  
8 apy and refill information;

9 (c) Special directions and precautions for preparation, administra-  
10 tion, storage and use by the patient as deemed necessary by the pharma-  
11 cist;

12 (d) Side effects or adverse effects and interactions and therapeutic  
13 contraindications that may be encountered, including their avoidance,  
14 which may interfere with the proper use of the drug or device as was in-  
15 tended by the prescriber, and the action required if they occur;

16 (e) Techniques for self-monitoring drug therapy; and

17 (f) Action to be taken in the event of a missed dose.

18 (7) "Deliver" or "delivery" means the actual, constructive or at-  
19 tempted transfer of a drug or device from one (1) person to another, whether  
20 or not for a consideration.

21 (8) "Device" means an instrument, apparatus, implement, machine, con-  
22 trivance, implant, in vitro reagent or other similar related article includ-  
23 ing any component part or accessory which is:

24 (a) Recognized in the official United States Pharmacopoeia or official  
25 National Formulary, other drug compendia or any supplement to them;

26 (b) Intended for use in the diagnosis of disease or other conditions, or  
27 the cure, mitigation, treatment or prevention of disease in man or other  
28 animal;

29 (c) Intended to affect the structure or any function of the body of man  
30 or other animal, and which does not achieve any of its principal in-  
31 tended purposes through chemical action within or on the body of man or  
32 other animal, and which is not dependent upon being metabolized for the  
33 achievement of any of its principal intended purposes.

34 (9) "Dispense" or "dispensing" means the preparation and delivery of  
35 a drug pursuant to a lawful prescription drug order of a practitioner in a  
36 suitable container appropriately labeled for subsequent administration to  
37 or use by a patient or other individual entitled to receive the prescription.

38 (10) "Distribute" means the delivery of a drug other than by administer-  
39 ing or dispensing.

40 (11) "Drug" means:

41 (a) Articles recognized as drugs in the official United States Phar-  
42 macopoeia, official National Formulary, official Homeopathic Pharma-  
43 copoeia, other drug compendia or any supplement to any of them;

44 (b) Articles intended for use in the diagnosis, cure, mitigation,  
45 treatment or prevention of disease in man or other animal;

46 (c) Articles, other than food, intended to affect the structure or any  
47 function of the body of man or other animals; and

48 (d) Articles intended for use as a component of any articles specified  
49 in paragraph (a), (b) or (c) of this subsection.

1 (12) "Drug order" means a prescription drug order issued in the unique  
2 form and manner permitted for a patient or resident of an institutional  
3 facility or as permitted for other purposes as defined in rules. Unless  
4 specifically differentiated, state law applicable to a prescription drug  
5 order is also applicable to a drug order.

6 (13) "Drug outlets" means all resident or nonresident pharmacies,  
7 business entities and other facilities where employees or personnel are en-  
8 gaged in the practice of pharmacy, in the provision of pharmaceutical care,  
9 or in the dispensing, delivering, distributing or manufacturing of drugs or  
10 devices in or into Idaho.

11 (14) "Extern" means a bona fide student enrolled in an approved school  
12 or college of pharmacy who has not received his first professional degree in  
13 pharmacy.

14 (15) "Externship" means a structured practical experience program in  
15 pharmacy administered by a school or college of pharmacy.

16 (16) "Institutional facility" means a facility for which its primary  
17 purpose is to provide a physical environment for patients to obtain health  
18 care services and in which patients spend a majority of their time, as may be  
19 further defined by board rules.

20 (17) "Intern" means any person who has completed a course of study at  
21 an approved school or college of pharmacy, received the first professional  
22 degree in pharmacy and is registered with the board as a pharmacist intern.  
23 Interns must register with the board prior to commencement of an internship  
24 program.

25 (18) "Internship" means a postgraduate practical experience program  
26 under the supervision of a preceptor.

27 (19) "Investigational or new drug" means any drug which is limited by  
28 state or federal law to use under professional supervision of a practitioner  
29 authorized by law to prescribe or administer such drug.

30 (20) "Labeling" means the process of preparing and affixing of a label  
31 to any drug container, exclusive however, of the labeling by a manufacturer,  
32 packer or distributor of a nonprescription drug or commercially packaged  
33 legend drug or device. Any such label shall include all information required  
34 by federal and state law.

35 (21) "Limited service outlet" means a resident or nonresident facility  
36 or business entity that is subject to registration by the board, pursuant  
37 to section 54-1729, Idaho Code, and has employees or personnel engaged in  
38 the practice of pharmacy, in the provision of pharmaceutical care, or in the  
39 dispensing, delivering, distributing or manufacturing of drugs or devices  
40 but is not a retail pharmacy, institutional facility, manufacturer, whole-  
41 saler, veterinary drug outlet, nonresident central drug outlet or mail ser-  
42 vice pharmacy.

43 (22) "Mail service pharmacy" means a nonresident pharmacy that ships,  
44 mails or delivers by any lawful means a dispensed legend drug to residents  
45 in this state pursuant to a legally issued prescription drug order and en-  
46 sures the provision of corresponding related pharmaceutical care services  
47 required by law.

48 (23) "Manufacture" means the production, preparation, propagation,  
49 compounding, conversion or processing of a device or a drug, either directly  
50 or indirectly by extraction from substances of natural origin or indepen-

1 dently by means of chemical synthesis or by a combination of extraction and  
2 chemical synthesis and includes any packaging or repackaging of the sub-  
3 stance or labeling or relabeling of its container, except that this term does  
4 not include the preparation or compounding of a drug by an individual for his  
5 own use or the preparation, compounding, packaging or labeling of a drug:

6 (a) By a pharmacist or practitioner as an incident to his administer-  
7 ing, dispensing or, as authorized by board rule, distributing of a drug  
8 in the course of his professional practice; or

9 (b) By a practitioner or by his authorization under his supervision for  
10 the purpose of or as an incident to research, teaching or chemical anal-  
11 ysis and not for sale.

12 (24) "Manufacturer" means a person who by compounding, cultivating,  
13 harvesting, mixing or other process, produces or prepares legend drugs,  
14 and includes persons who prepare such drugs in dosage forms by mixing, com-  
15 pounding, encapsulating, entableting, or other process, or who packages or  
16 repackages such drugs, but does not include pharmacists or practitioners in  
17 the practice of their profession.

18 (25) "Nonprescription drugs" means medicines or drugs which may be sold  
19 without a prescription drug order and which are prepackaged for use by the  
20 consumer and labeled in accordance with state and federal law.

21 (26) "Nonresident" means a person or business entity located in the Dis-  
22 trict of Columbia or a state other than Idaho that practices pharmacy includ-  
23 ing, but not limited to, pharmaceutical care services into Idaho.

24 (27) "Outsourcing facility" means a facility that is registered by the  
25 United States food and drug administration pursuant to 21 U.S.C. section  
26 353b and either registered or endorsed by the board.

27 (28) "Person" means an individual, corporation, partnership, associa-  
28 tion or any other legal entity.

29 (289) "Pharmaceutical care" means drug therapy and other pharmaceuti-  
30 cal patient care services intended to achieve outcomes related to the cure or  
31 prevention of a disease, elimination or reduction of a patient's symptoms,  
32 or arresting or slowing of a disease process as defined in the rules of the  
33 board.

34 (2930) "Pharmacist" means an individual licensed by this state to en-  
35 gage in the practice of pharmacy or a pharmacist registered by this state who  
36 is located in another state or the District of Columbia and is engaged in the  
37 practice of pharmacy into Idaho, unless exempted.

38 (301) "Pharmacist-in-charge" (PIC) means a pharmacist whose qualifica-  
39 tions, responsibilities and reporting requirements are defined in rule.

40 (312) "Pharmacy" means any facility, department or other place where  
41 prescription drug orders are filled or compounded and prescriptions are  
42 sold, dispensed, offered or displayed for sale, which has, as its principal  
43 purpose, the dispensing of drug and health supplies intended for the general  
44 health, welfare and safety of the public.

45 (323) "Practitioner" means a person licensed in this state and permit-  
46 ted by such license to dispense, conduct research with respect to or adminis-  
47 ter drugs in the course of professional practice or research in this state.

48 (334) "Precursor" means a substance, other than a legend drug, which is  
49 an immediate chemical intermediate that can be processed or synthesized into  
50 a legend drug, and is used or produced primarily for use in the manufacture

1 of a legend drug by persons other than persons licensed to manufacture such  
2 legend drugs by the Idaho board of pharmacy, registered by the state board  
3 of health and welfare, or licensed to practice pharmacy by the Idaho board of  
4 pharmacy.

5 (345) "Preceptor" means a pharmacist licensed and in good standing who  
6 supervises the internship or externship training of a registered student  
7 pharmacist. The preceptor shall be actively engaged in the practice of phar-  
8 macy on a full-time employment basis.

9 (356) "Prescriber" means an individual currently licensed, registered  
10 or otherwise authorized to prescribe and administer drugs in the course of  
11 professional practice.

12 (367) "Prescription drug or legend drug" means a drug ~~which~~, that under  
13 federal law is required, prior to being dispensed or delivered, to be labeled  
14 with one (1) of the following statements:

15 (a) "Caution: Federal law prohibits dispensing without a prescrip-  
16 tion"; or

17 (b) "Rx Only"; or

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

20 or a drug which is required by any applicable federal or state law or regula-  
21 tion to be dispensed on prescription drug order only or is restricted to use  
22 by practitioners only.

23 (378) "Prescription drug order" means a valid order of a practitioner  
24 for a drug or device for an ultimate user of the drug or device.

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

27 (a) Evaluation of the prescription drug order for:

28 (i) Known allergies;

29 (ii) Rational therapy contraindications;

30 (iii) Reasonable dose and route of administration; and

31 (iv) Reasonable directions for use.

32 (b) Evaluation of the prescription drug order for duplication of ther-  
33 apy.

34 (c) Evaluation of the prescription drug order for interactions:

35 (i) Drug-drug;

36 (ii) Drug-food; and

37 (iii) Drug-disease.

38 (d) Evaluation of the prescription drug order for proper utilization:

39 (i) Over or under utilization; and

40 (ii) Abuse/misuse.

41 (3940) "Record" means all papers, letters, memoranda, notes, prescrip-  
42 tions, drug orders, invoices, statements, patient medication charts or  
43 files, computerized records or other written indicia, documents or objects  
44 which are used in any way in connection with the purchase, sale or handling of  
45 any drug or device.

46 (401) "Sale" means every sale and includes:

47 (a) Manufacturing, processing, transporting, handling, packaging or  
48 any other production, preparation or repackaging;

49 (b) Exposure, offer, or any other proffer;

50 (c) Holding, storing or any other possession;

1 (d) Dispensing, giving, delivering or any other supplying; and

2 (e) Applying, administering or any other usage.

3 ~~(412) "Warehouseman" means a person who stores legend drugs for others~~  
4 ~~and who has no control over the disposition of such drugs except for the pur-~~  
5 ~~pose of such storage~~ "Ultimate user" means a person who lawfully possesses a  
6 drug for his own use or for the use of a member of his household or for admin-  
7 istering to an animal owned by him or by a member of his household.

8 ~~(423) "Wholesaler" means a person engaged who in the usual course of~~  
9 ~~business of distributing legend~~ lawfully distributes drugs that he himself  
10 has not produced or prepared, devices in or into Idaho to persons included  
11 in any of other than the classes named in subsection (2)(a) through (f) of  
12 section 54-1734, Idaho Code ultimate user.

13 SECTION 2. That Section 54-1732, Idaho Code, be, and the same is hereby  
14 amended to read as follows:

15 54-1732. VIOLATIONS AND PENALTIES. (1) No drug outlet designated in  
16 section 54-1729, Idaho Code, shall be operated until a certificate of reg-  
17 istration has been issued to said facility by the board. Upon the finding of  
18 a violation of this subsection, the board may impose one (1) or more of the  
19 penalties enumerated in section 54-1728, Idaho Code.

20 (2) Reinstatement of a certificate that has been suspended, revoked  
21 or restricted by the board may be granted in accordance with the procedures  
22 specified in section 54-1728(6), Idaho Code.

23 (3) The following acts, or the failure to act, and the causing of any  
24 such act or failure are unlawful:

25 (a) The sale, delivery or administration of any prescription drug or  
26 legend drug unless:

27 (i) Such legend drug is dispensed or delivered by a pharmacist  
28 upon an original prescription, drug order or prescription drug or-  
29 der by a practitioner in good faith in the course of his practice.  
30 Any person violating the provisions of this subparagraph shall  
31 be guilty of a felony, and on conviction thereof shall be impris-  
32 oned in the state penitentiary for a term not to exceed three (3)  
33 years, or punished by a fine of not more than five thousand dollars  
34 (\$5,000) or by both such fine and imprisonment.

35 (ii) In the case of a legend drug dispensed by a pharmacist or pre-  
36 scriber, there is a label affixed to the immediate container in  
37 which such drug is dispensed. Any person violating this subpara-  
38 graph shall be guilty of a misdemeanor and upon conviction thereof  
39 shall be fined not more than five hundred dollars (\$500). Noth-  
40 ing in this subparagraph prohibits a practitioner from delivering  
41 professional samples of legend drugs in their original contain-  
42 ers in the course of his practice when oral directions for use are  
43 given at the time of such delivery.

44 (b) The refilling of any prescription or drug order for a legend drug  
45 except as designated on the prescription or drug order, or by the autho-  
46 rization of the practitioner. Any person guilty of violating this para-  
47 graph shall be guilty of a misdemeanor and upon conviction thereof shall  
48 be incarcerated in the county jail for a term not to exceed one (1) year,

1 or punished by a fine of not more than one thousand dollars (\$1,000) or  
2 by both such fine and incarceration.

3 (c) The possession or use of a legend drug or a precursor by any person  
4 unless such person obtains such drug on the prescription or drug order  
5 of a practitioner. Any person guilty of violating this paragraph shall  
6 be guilty of a misdemeanor and upon conviction thereof shall be incar-  
7 cerated in the county jail for a term not to exceed one (1) year, or pun-  
8 ished by a fine of not more than one thousand dollars (\$1,000) or by both  
9 such fine and incarceration.

10 (d) The wholesale distribution of drugs or devices by a pharmacy except  
11 for:

12 (i) The sale, transfer, merger or consolidation of all or part of  
13 the business of a pharmacy or pharmacies from or with another phar-  
14 macy or pharmacies, whether accomplished as a purchase and sale of  
15 stock or business assets.

16 (ii) The sale of minimal quantities of prescription drugs to prac-  
17 tioners for office use.

18 (iii) The sale of a prescription drug for emergency medical rea-  
19 sons, but never to a wholesale distributor.

20 (iv) Intracompany sales of prescription drugs, meaning any trans-  
21 action or transfer between any division, subsidiary, parent or af-  
22 iliated or related company under common ownership and control of  
23 a corporate entity, or any transaction or transfer between colli-  
24 censees or a colicensed product, but never to a wholesale distrib-  
25 utor.

26 (e) The failure to keep records as required by the board. Any person  
27 guilty of violating this paragraph shall be guilty of a misdemeanor and  
28 upon conviction thereof shall be incarcerated in the county jail for a  
29 term not to exceed one (1) year, or punished by a fine of not more than  
30 one thousand dollars (\$1,000) or by both such fine and incarceration.

31 (ef) The refusal to make available and to accord full opportunity to  
32 check any record, as required by the board. Any person guilty of violat-  
33 ing this paragraph shall be guilty of a misdemeanor and upon conviction  
34 thereof shall be incarcerated in the county jail for a term not to exceed  
35 one (1) year, or punished by a fine of not more than one thousand dollars  
36 (\$1,000) or by both such fine and incarceration.

37 (fg) It is unlawful to:

38 (i) Obtain or attempt to obtain a legend drug or procure or at-  
39 tempt to procure the administration of a legend drug by fraud, de-  
40 ceit, misrepresentation or subterfuge; by the forgery or alter-  
41 ation of a prescription, drug order, or of any written order; by  
42 the concealment of a material fact; or by the use of a false name or  
43 the giving of a false address.

44 (ii) Communicate information to a physician in an effort unlaw-  
45 fully to procure a legend drug, or unlawfully to procure the ad-  
46 ministration of any such drug. Any such communication shall not be  
47 deemed a privileged communication.

48 (iii) Intentionally make a false statement in any prescription,  
49 drug order, order, report or record required by this chapter.

1 (iv) For the purpose of obtaining a legend drug to falsely assume  
2 the title of, or represent himself to be, a manufacturer, whole-  
3 saler, pharmacist, physician, dentist, veterinarian or other per-  
4 son.

5 (v) Make or utter any false or forged prescription or false drug  
6 order or forged written order.

7 (vi) Affix any false or forged label to a package or receptacle  
8 containing legend drugs. This subparagraph does not apply to law  
9 enforcement agencies or their representatives while engaged in  
10 enforcing state and federal drug laws.

11 (vii) Wholesale or retail any prescription or legend drug to any  
12 person in this state not entitled by law to deliver such drug to  
13 another.

14 Every violation of ~~subsection (3)(f)~~ paragraph (g)(i) through (vi) of this  
15 subsection shall be a misdemeanor and any person convicted thereof shall  
16 be incarcerated in the county jail for a term not to exceed one (1) year, or  
17 fined not more than one thousand dollars (\$1,000), or punished by both such  
18 fine and imprisonment. Any person violating ~~subsection (3)(f)~~ paragraph  
19 (g)(vii) of this subsection is guilty of a felony and on conviction thereof  
20 shall be imprisoned in the state penitentiary for a term not to exceed three  
21 (3) years, or punished by a fine of not more than five thousand dollars  
22 (\$5,000), or by both such fine and imprisonment.

23 (4) Provided however, that a veterinarian may dispense or deliver a  
24 legend drug prescribed for an animal upon the prescription, drug order, or  
25 prescription drug order of another veterinarian. The label shall be affixed  
26 pursuant to subsection (3)(a)(ii) of this section, and penalties for vio-  
27 lations of the provisions of this subsection shall be as provided in this  
28 section for like violations by a pharmacist.

29 (5) The ultimate user of a legend drug who has lawfully obtained such  
30 legend drug may deliver, without being registered, the legend drug to an-  
31 other person for the purpose of disposal of the legend drug if the person re-  
32 ceiving the legend drug for purposes of disposal is authorized under a state  
33 or federal law or regulation to engage in such activity.

34 SECTION 3. That Section 54-1734, Idaho Code, be, and the same is hereby  
35 amended to read as follows:

36 54-1734. EXCEPTIONS POSSESSION OF LEGEND DRUGS. ~~The provisions of~~  
37 ~~this chapter pertaining to the sale of prescription drugs are not applica-~~  
38 ~~ble:~~

39 (1) ~~To the sale of legend drugs to persons included in any of the classes~~  
40 ~~named in paragraphs (a) through (g) in subsection (2) of this section, or~~  
41 ~~to the agents or employees of such persons, for use in the usual and lawful~~  
42 ~~course of their business or practice or in the performance of their lawful~~  
43 ~~official duties, as the case may be; or~~

44 (2) To the following persons or their agents or employees may pos-  
45 session of legend drugs by such persons or their agents or employees for such  
46 use in the usual and lawful course of their business or practice or in the  
47 performance of their lawful official duties, without a valid prescription  
48 drug order:

49 (a) Pharmacists;

1 (b) ~~Practitioners Prescribers;~~

2 (c) ~~Persons who procure legend drugs for handling by or under the su-~~  
 3 ~~per vision of pharmacists or practitioners employed by them, or for the~~  
 4 ~~purpose of lawful research, teaching, or testing, and not for resale~~  
 5 ~~Researchers who are prohibited from further distribution;~~

6 (d) ~~Hospitals and other institutions which procure legend drugs for~~  
 7 ~~lawful administration by practitioners institutional facilities;~~

8 (e) ~~Manufacturers and wholesalers;~~

9 (f) ~~Common carriers and warehousemen solely in the usual course of~~  
 10 ~~business of transporting prescription drugs; and~~

11 (g) ~~Schools possessing stock supplies of epinephrine auto-injectors~~  
 12 ~~pursuant to section 33-520A, Idaho Code.~~

13 (32) ~~To the sale by a business not licensed as a pharmacy of Veterinary~~  
 14 ~~drug outlets or their agents or employees may possess legend drugs,~~  
 15 ~~(excluding controlled substances), designated for veterinary use which re-~~  
 16 ~~quire in the usual and lawful course of their business or practice or in the~~  
 17 ~~performance of their lawful official duties, without a valid prescription,~~  
 18 ~~provided that: drug order.~~

19 ~~(a) The business is registered and licensed with the board of pharmacy.~~

20 ~~(b) The sale is authorized by a written or oral order from a veterinar-~~  
 21 ~~ian licensed in this or another state.~~

22 ~~1. Prior to dispensing an order from an out-of-state veterinar-~~  
 23 ~~ian, the seller must confirm and document that the veterinarian is~~  
 24 ~~properly licensed in his state.~~

25 ~~2. Oral orders must be confirmed by the veterinarian in writing no~~  
 26 ~~later than seven (7) days after the seller receives the order.~~

27 ~~(c) The written order or confirmation of an oral order must be retained~~  
 28 ~~on the premises of the business for at least two (2) years after the~~  
 29 ~~original date of the order.~~

30 SECTION 4. That Section 54-1735, Idaho Code, be, and the same is hereby  
 31 amended to read as follows:

32 54-1735. ~~MAINTENANCE OF PATIENT MEDICATION RECORDS. (1)~~  
 33 ~~Manufacturers and wholesalers. Manufacturers and wholesalers shall~~  
 34 ~~maintain records of the movement in commerce of legend drugs for two (2)~~  
 35 ~~years immediately following the date of the last entry on such record and~~  
 36 ~~shall make such records available, at reasonable times, to law enforcement~~  
 37 ~~agencies and their representatives in the enforcement of this act. Evidence~~  
 38 ~~obtained under this section may not be used in a criminal prosecution of the~~  
 39 ~~person from whom obtained.~~

40 ~~(2) Pharmacies. In order to effectively counsel patients, the pharma-~~  
 41 ~~cist shall make a reasonable effort to obtain, record and maintain signifi-~~  
 42 ~~cant patient information including, but not limited to:~~

43 ~~(a1) Name, address, telephone number;~~

44 ~~(b2) Date of birth (age), gender;~~

45 ~~(e3) Medical history:~~

46 ~~1. (a) Disease state(s);~~

47 ~~2. (b) Allergies/drug reactions; and~~

48 ~~3. (c) Current list of medications and devices;~~

49 ~~(d4) Pharmacist comments.~~

1 SECTION 5. That Section 54-1752, Idaho Code, be, and the same is hereby  
2 amended to read as follows:

3 54-1752. DEFINITIONS. As used in sections 54-1751 through 54-1759,  
4 Idaho Code:

5 (1) ~~"Authentication" means to affirmatively verify before any whole-~~  
6 ~~sale distribution of a prescription drug occurs that each transaction listed~~  
7 ~~on the pedigree has occurred.~~

8 ~~(2) "Authorized distributor of record" means a wholesale distributor~~  
9 ~~with whom a manufacturer has established an ongoing relationship to dis-~~  
10 ~~tribute the manufacturer's prescription drug. An ongoing relationship is~~  
11 ~~deemed to exist between such wholesale distributor and a manufacturer when~~  
12 ~~the wholesale distributor, including any affiliated group of the wholesale~~  
13 ~~distributor, as defined in section 1504 of the Internal Revenue Code, com-~~  
14 ~~plies with the following:~~

15 ~~(a) The wholesale distributor has a written agreement currently in ef-~~  
16 ~~fect with the manufacturer evidencing such ongoing relationship; and~~

17 ~~(b) The wholesale distributor is listed on the manufacturer's current~~  
18 ~~list of authorized distributors of record, which is updated by the manu-~~  
19 ~~facturer on no less than a monthly basis.~~

20 ~~(3) "Chain pharmacy warehouse" means a physical location for prescrip-~~  
21 ~~tion drugs that acts as a central warehouse and performs intracompany sales~~  
22 ~~or transfers of such drugs to a group of chain pharmacies that have the same~~  
23 ~~common ownership and control.~~

24 ~~(4) "Colicensed partner or product" means an instance where two (2) or~~  
25 ~~more parties have the right to engage in the manufacturing and/or marketing~~  
26 ~~of a prescription drug, consistent with the federal food and drug adminis-~~  
27 ~~tration's implementation of the prescription drug marketing act.~~

28 ~~(5) "Drop shipment" means the sale of a prescription drug to a whole-~~  
29 ~~sale distributor or chain pharmacy warehouse by the manufacturer of the~~  
30 ~~prescription drug, or that manufacturer's colicensed product partner, that~~  
31 ~~manufacturer's third party logistics provider or that manufacturer's ex-~~  
32 ~~clusive distributor, whereby the wholesale distributor or chain pharmacy~~  
33 ~~warehouse takes title but not physical possession of such prescription~~  
34 ~~drug and the wholesale distributor invoices the pharmacy or chain pharmacy~~  
35 ~~warehouse, or other person authorized by law to dispense or administer such~~  
36 ~~drug to a patient, and the pharmacy or chain pharmacy warehouse or other~~  
37 ~~authorized person receives delivery of the prescription drug directly from~~  
38 ~~the manufacturer, or that manufacturer's third party logistics provider, or~~  
39 ~~that manufacturer's exclusive distributor.~~

40 ~~(6) "Facility" means a facility of a wholesale distributor where pre-~~  
41 ~~scription drugs are stored, handled, repackaged or offered for sale.~~

42 ~~(7) "Manufacturer" means a person, including a colicensed partner or~~  
43 ~~affiliate of that person, who prepares, derives, manufactures, produces or~~  
44 ~~repackages a drug or is licensed or approved by the federal food and drug ad-~~  
45 ~~ministration to engage in the manufacture of drugs or devices, consistent~~  
46 ~~with the federal food and drug administration definition of "manufacturer"~~  
47 ~~under its regulations and guidance implementing the prescription drug mar-~~  
48 ~~keting act.~~

1       ~~(8) "Manufacturer's exclusive distributor" means anyone who contracts~~  
 2 ~~with a manufacturer to provide or coordinate warehousing, distribution or~~  
 3 ~~other services on behalf of a manufacturer and who takes title to that manu-~~  
 4 ~~facturer's prescription drug, but who does not have general responsibility~~  
 5 ~~to direct the sale or disposition of the manufacturer's prescription drug.~~  
 6 ~~Such manufacturer's exclusive distributor must be licensed as a wholesale~~  
 7 ~~distributor under section 54-1753, Idaho Code, and to be considered part of~~  
 8 ~~the normal distribution channel, must also be an authorized distributor of~~  
 9 ~~record.~~

10       ~~(9) "Normal distribution channel" means a chain of custody for a pre-~~  
 11 ~~scription drug that goes from a manufacturer of the prescription drug, from~~  
 12 ~~that manufacturer to that manufacturer's colicensed partner, from that~~  
 13 ~~manufacturer to that manufacturer's third party logistics provider, from~~  
 14 ~~that manufacturer to that manufacturer's exclusive distributor, or from~~  
 15 ~~that manufacturer directly or through its colicensed partner, third party~~  
 16 ~~logistics provider or manufacturer's exclusive distributor to a repackager~~  
 17 ~~who is an authorized distributor of record for the manufacturer, whose fa-~~  
 18 ~~cility is registered with the United States food and drug administration~~  
 19 ~~and who engages in the practice of repackaging the original dosage form of a~~  
 20 ~~prescription drug in accordance with applicable regulations and guidelines~~  
 21 ~~of the United States food and drug administration, either directly or by drop~~  
 22 ~~shipment, to:~~

23       ~~(a) A pharmacy to a patient;~~

24       ~~(b) Other designated persons authorized by law to dispense or adminis-~~  
 25 ~~ter such drug to a patient;~~

26       ~~(c) A wholesale distributor to a pharmacy to a patient or other desig-~~  
 27 ~~nated persons authorized by law to dispense or administer such drug to a~~  
 28 ~~patient;~~

29       ~~(d) A wholesale distributor to a chain pharmacy warehouse to that chain~~  
 30 ~~pharmacy warehouse's intracompany pharmacy to a patient or other desig-~~  
 31 ~~nated persons authorized by law to dispense or administer such drug to a~~  
 32 ~~patient; or~~

33       ~~(e) A chain pharmacy warehouse to the chain pharmacy warehouse's intra-~~  
 34 ~~company pharmacy to a patient or other designated persons authorized by~~  
 35 ~~law to dispense or administer such drug to a patient.~~

36       ~~(10) "Pedigree" means a document or electronic file containing infor-~~  
 37 ~~mation that records each wholesale distribution of any given prescription~~  
 38 ~~drug.~~

39       ~~(114) "Person" means an individual, corporation, business entity, gov-~~  
 40 ~~ernment, governmental subdivision or agency, partnership, business trust,~~  
 41 ~~association or any other legal entity.~~

42       ~~(125) "Prescription drug" means any drug, including any biological~~  
 43 ~~product, except for blood and blood components intended for transfusion or~~  
 44 ~~biological products that are also medical devices, required by federal law~~  
 45 ~~or federal regulation to be dispensed only by a prescription, including fin-~~  
 46 ~~ished dosage forms and bulk drug substances, subject to section 503(b) of the~~  
 47 ~~federal food, drug and cosmetic act.~~

48       ~~(136) "Repackage" means repackaging or otherwise changing the con-~~  
 49 ~~tainer, wrapper or labeling to further the distribution of a prescription~~

1 drug, excluding that completed by the pharmacist responsible for dispensing  
2 product to the patient.

3 (147) ~~"Repackager" means a person who repackages~~ "Reverse distributor"  
4 means a drug outlet that receives nonsaleable prescription drugs from per-  
5 sons or their agents, who may lawfully possess prescription drugs without  
6 being issued a valid prescription drug order, and processes for credit or  
7 disposes of such prescription drugs.

8 ~~(15) "Third party logistics provider" means anyone who contracts with a~~  
9 ~~prescription drug manufacturer to provide or coordinate warehousing, dis-~~  
10 ~~tribution or other services on behalf of a manufacturer, but does not take~~  
11 ~~title to the prescription drug or have general responsibility to direct~~  
12 ~~the prescription drug's sale or disposition. Such third party logistics~~  
13 ~~provider must be licensed as a wholesale distributor under section 54-1753,~~  
14 ~~Idaho Code, and to be considered part of the normal distribution channel,~~  
15 ~~must also be an authorized distributor of record.~~

16 ~~(16) "Veterinary pharmacy" means a business properly licensed as a~~  
17 ~~pharmacy engaging exclusively in the preparation and dispensing of pre-~~  
18 ~~scription drugs for veterinary prescribed use.~~

19 ~~(17) "Wholesale distributor" means anyone engaged in the wholesale dis-~~  
20 ~~tribution of prescription drugs including, but not limited to:~~

21 ~~(a) Manufacturers;~~

22 ~~(b) Repackagers;~~

23 ~~(c) Own label distributors;~~

24 ~~(d) Private label distributors;~~

25 ~~(e) Jobbers;~~

26 ~~(f) Brokers;~~

27 ~~(g) Warehouses, including manufacturers' and distributors' ware-~~  
28 ~~houses;~~

29 ~~(h) Manufacturers' exclusive distributors;~~

30 ~~(i) Authorized distributors of record;~~

31 ~~(j) Drug wholesalers or distributors;~~

32 ~~(k) Independent wholesale drug traders;~~

33 ~~(l) Specialty wholesale distributors;~~

34 ~~(m) Third party logistics providers;~~

35 ~~(n) Retail pharmacies that conduct wholesale distribution; and~~

36 ~~(o) Chain pharmacy warehouses that conduct wholesale distribution.~~

37 ~~To be considered part of the normal distribution channel, such wholesale~~  
38 ~~distributor, except for a chain pharmacy warehouse not engaged in wholesale~~  
39 ~~distribution, must also be an authorized distributor of record.~~

40 (18) "Wholesale distribution" means distribution of prescription drugs  
41 to persons other than a consumer or patient, but does not include:

42 (a) Intracompany sales of prescription drugs, meaning any transaction  
43 or transfer between any division, subsidiary, parent or affiliated  
44 or related company under common ownership and control of a corporate  
45 entity, or any transaction or transfer between colicensees of a coli-  
46 censed product.

47 (b) The sale, purchase, distribution, trade or transfer of a prescrip-  
48 tion drug or offer to sell, purchase, distribute, trade or transfer a  
49 prescription drug for emergency medical reasons.

1 ~~(c) The distribution of prescription drug samples by manufacturers'~~  
 2 ~~representatives.~~

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

5 ~~(e) Drug donations, when conducted in accordance with sections 54-1760~~  
 6 ~~through 54-1765, Idaho Code.~~

7 ~~(f) The sale of minimal quantities of prescription drugs by pharmacies~~  
 8 ~~to licensed practitioners for office use.~~

9 ~~(g) The sale, purchase or trade of a drug, an offer to sell, purchase or~~  
 10 ~~trade a drug, or the dispensing of a drug pursuant to a prescription.~~

11 ~~(h) The sale, transfer, merger or consolidation of all or part of the~~  
 12 ~~business of a pharmacy or pharmacies from or with another pharmacy or~~  
 13 ~~pharmacies, whether accomplished as a purchase and sale of stock or~~  
 14 ~~business assets.~~

15 ~~(i) The sale, purchase, distribution, trade or transfer of a pre-~~  
 16 ~~scription drug from one (1) authorized distributor of record to one (1)~~  
 17 ~~additional authorized distributor of record when the manufacturer has~~  
 18 ~~stated in writing to the receiving authorized distributor of record~~  
 19 ~~that the manufacturer is unable to supply such prescription drug and the~~  
 20 ~~supplying authorized distributor of record states in writing that the~~  
 21 ~~prescription drug being supplied had, until that time, been exclusively~~  
 22 ~~in the normal distribution channel.~~

23 ~~(j) The delivery of, or offer to deliver, a prescription drug by a~~  
 24 ~~common carrier solely in the common carrier's usual course of business~~  
 25 ~~of transporting prescription drugs, and such common carrier does not~~  
 26 ~~store, warehouse or take legal ownership of the prescription drug.~~

27 ~~(k) The sale or transfer from a retail pharmacy or chain pharmacy ware-~~  
 28 ~~house of expired, damaged, mis-picked, returned or recalled prescrip-~~  
 29 ~~tion drugs to the original manufacturer, original wholesaler, or third~~  
 30 ~~party returns processor, including a reverse distributor.~~

31 ~~(l) The sale of a prescription drug by a veterinary pharmacy to the pre-~~  
 32 ~~scribing veterinarian in which:~~

33 ~~(i) The prescribing veterinarian takes title but not physical~~  
 34 ~~possession of such prescription drug and invoices the owner or~~  
 35 ~~person having custody of the animal for whom the prescription drug~~  
 36 ~~is intended, and~~

37 ~~(ii) Pursuant to a valid prescription drug order the veterinary~~  
 38 ~~pharmacy labels and delivers the prescription drug directly to the~~  
 39 ~~owner or person having custody of the animal for whom the prescrip-~~  
 40 ~~tion drug is intended.~~

41 SECTION 6. That Section 54-1753, Idaho Code, be, and the same is hereby  
 42 amended to read as follows:

43 54-1753. WHOLESALE DRUG DISTRIBUTOR LICENSING REQUIREMENT -- MINIMUM  
 44 REQUIREMENTS FOR LICENSURE. (1) Every wholesale distributor who business  
 45 entity that engages in the wholesale distribution of prescription drugs in  
 46 or into Idaho must be licensed by the board, ~~and every nonresident wholesale~~  
 47 ~~distributor must be licensed by the board if it ships prescription drugs~~  
 48 ~~into this state in accordance with this act before engaging in wholesale~~

1 ~~distributions of wholesale prescription drugs. The board shall exempt as a~~  
2 ~~wholesale distributor except:~~

3 (a) Manufacturers distributing their own federal food and drug ad-  
4 ministration approved drugs and devices from any licensing and other  
5 requirements to the extent not required by federal law or regulation  
6 including distribution of prescription drug samples by manufacturer's  
7 representatives and intracompany sales, meaning any transaction or  
8 transfer between any division, subsidiary, parent or affiliated or re-  
9 lated company under common ownership and control of a corporate entity  
10 or any transfer between colicensees of a colicensed product, unless  
11 particular requirements are deemed necessary and appropriate following  
12 rulemaking.

13 (b) An entity that donates prescription drugs, when conducted in accor-  
14 dance with sections 54-1760 through 54-1765, Idaho Code.

15 (c) A pharmacy distributing in accordance with section 54-1732, Idaho  
16 Code.

17 (d) Persons selling, purchasing, distributing, trading or transfer-  
18 ring a prescription drug for emergency medical reasons.

19 (2) The board shall require the following minimum information from each  
20 wholesale distributor applying for a license under subsection (1) of this  
21 section:

22 (a) The name, full business address and telephone number of the li-  
23 censee;

24 (b) All trade or business names used by the licensee;

25 (c) Addresses, telephone numbers, and the names of contact persons for  
26 all facilities used by the licensee for the storage, handling, and dis-  
27 tribution of prescription drugs;

28 (d) The type of ownership or operation, i.e., partnership, corpora-  
29 tion, or sole proprietorship;

30 (e) The name of each person who is an owner or an operator of the li-  
31 censee;

32 (f) A list of all licenses and permits issued to the applicant by any  
33 other state that authorizes the applicant to purchase or possess pre-  
34 scription drugs;

35 (g) The name of the applicant's designated representative for the fa-  
36 cility, together with the personal information statement and finger-  
37 prints, required pursuant to paragraph (h) of this subsection ~~(2)~~ for  
38 such individual;

39 (h) Each individual required by paragraph (g) of this subsection ~~(2)~~  
40 to provide a personal information statement and fingerprints shall pro-  
41 vide the following information to the board:

42 (i) The individual's places of residence for the past seven (7)  
43 years;

44 (ii) The individual's date and place of birth;

45 (iii) The individual's occupations, positions of employment and  
46 offices held during the past seven (7) years;

47 (iv) The principal business and address of any business, corpo-  
48 ration or other organization in which each such office of the in-  
49 dividual was held or in which each such occupation or position of  
50 employment was carried on;

1 (v) Whether the individual has been, during the past seven (7)  
2 years, the subject of any proceeding for the revocation of any li-  
3 cense or any criminal violation and, if so, the nature of the pro-  
4 ceeding and the disposition of the proceeding;

5 (vi) Whether, during the past seven (7) years, the individual  
6 has been enjoined, either temporarily or permanently, by a court  
7 of competent jurisdiction from violating any federal or state law  
8 regulating the possession, control or distribution of prescrip-  
9 tion drugs or criminal violations, together with details concern-  
10 ing any such event;

11 (vii) A description of any involvement by the individual with any  
12 business, including any investments, other than the ownership of  
13 stock in a publicly traded company or mutual fund, during the past  
14 seven (7) years, which manufactured, administered, prescribed,  
15 distributed or stored pharmaceutical products, and any lawsuits  
16 in which such businesses were named as a party and in which the in-  
17 dividual was also a named party in the same lawsuit or, regardless  
18 of whether the individual was a named party, in which the individ-  
19 ual testified as a witness at trial or in a deposition;

20 (viii) A description of any felony criminal offense of which the  
21 individual, as an adult, was found guilty, regardless of whether  
22 adjudication of guilt was withheld or whether the individual pled  
23 guilty or nolo contendere. If the individual indicates that a  
24 criminal conviction is under appeal and submits a copy of the  
25 notice of appeal of that criminal offense, the applicant must,  
26 within fifteen (15) days after the disposition of the appeal, sub-  
27 mit to the board a copy of the final written order of disposition;  
28 and

29 (ix) A photograph of the individual taken in the previous year.

30 (3) The information required pursuant to subsection (2) of this section  
31 shall be provided under oath.

32 (4) The board shall not issue a wholesale distributor license to an ap-  
33 plicant, unless the board:

34 (a) Conducts a physical inspection of the facility at the address pro-  
35 vided by the applicant as required in subsection (2)(a) of this section  
36 or approves an inspection report that evidences equivalent standards to  
37 those in Idaho; and

38 (b) Determines that the designated representative meets the following  
39 qualifications:

40 (i) Is at least twenty-one (21) years of age;

41 (ii) Has been employed full time for at least three (3) years in  
42 a pharmacy or with a wholesale distributor in a capacity related  
43 to the dispensing and distribution of, and recordkeeping relating  
44 to, prescription drugs;

45 (iii) Is employed by the applicant full time in a managerial level  
46 position;

47 (iv) Is actively involved in and aware of the actual daily opera-  
48 tion of the wholesale distributor;

49 (v) Is physically present at the facility of the applicant during  
50 regular business hours, except when the absence of the designated

1 representative is authorized including, but not limited to, sick  
2 leave and vacation leave;

3 (vi) Is serving in the capacity of a designated representative  
4 for only one (1) applicant at a time, except where more than one  
5 (1) licensed wholesale distributor is colocated in the same facil-  
6 ity and such wholesale distributors are members of an affiliated  
7 group, as defined in section 1504 of the Internal Revenue Code;

8 (vii) Does not have any convictions under any federal, state or  
9 local law relating to wholesale or retail prescription drug dis-  
10 tribution or distribution of controlled substances; and

11 (viii) Does not have any felony convictions under federal, state  
12 or local law.

13 (5) ~~The board~~ All applicant-designated representatives shall submit  
14 the fingerprints provided by a person with a license application for a  
15 statewide to a fingerprint-based criminal records history check of the Idaho  
16 central criminal history database and for forwarding to the federal bureau  
17 of investigation for a national criminal records check of the individual  
18 history database. Each applicant shall submit a completed ten (10) finger  
19 fingerprint card or scan to the board of pharmacy at the time of application  
20 and shall pay the cost of the criminal history check.

21 (6) If a wholesale distributor distributes prescription drugs in or  
22 into Idaho from more than one (1) facility, the wholesale distributor shall  
23 obtain a license for each facility.

24 (7) ~~In accordance with each licensure renewal, the board shall send to~~  
25 ~~each wholesale distributor licensed under this section a form setting forth~~  
26 ~~the information that the wholesale distributor provided pursuant to subsec-~~  
27 ~~tion (2) of this section. Within thirty (30) days of receiving such form,~~  
28 ~~the wholesale distributor must identify and state under oath to the board all~~  
29 ~~changes or corrections to the information that was provided pursuant to sub-~~  
30 ~~section (2) of this section. Changes in, or corrections to, any information~~  
31 ~~in subsection (2) of this section shall be submitted to the board as required~~  
32 ~~by the board. The board may suspend or revoke the license of a wholesale~~  
33 ~~distributor if such authority determines that the wholesale distributor~~  
34 ~~no longer qualifies for the license issued under this section~~ A wholesale  
35 distributor shall have adequate processes in place for monitoring purchase  
36 activity of customers and identifying suspicious ordering patterns that  
37 identify potential diversion or criminal activity related to controlled  
38 substances such as orders of unusual size, orders deviating substantially  
39 from a normal pattern, orders for drugs that are outside of the prescriber's  
40 scope of practice, or orders of unusual frequency.

41 (8) The designated representative identified pursuant to subsection  
42 (2)(g) of this section must receive and complete continuing training in ap-  
43 plicable federal law and the law of this state governing wholesale distribu-  
44 tion of prescription drugs.

45 (9) The board may adopt rules to approve an accreditation body to eval-  
46 uate a wholesaler's operations to determine compliance with professional  
47 standards and any other applicable laws, and to perform inspections of each  
48 facility and location where wholesale distribution operations are conducted  
49 by the wholesaler.

1       ~~(10) Information provided under this section shall not be disclosed~~  
2 ~~to any person other than a state licensing authority, government board or~~  
3 ~~government agency, provided such licensing authority, government board or~~  
4 ~~agency needs such information for licensing or monitoring purposes.~~

5       SECTION 7. That Section 54-1754, Idaho Code, be, and the same is hereby  
6 amended to read as follows:

7       54-1754. RESTRICTIONS ON TRANSACTIONS. (1) A wholesale distributor  
8 shall receive prescription drug returns or exchanges from a pharmacy or  
9 chain pharmacy warehouse pursuant to the terms and conditions of the agree-  
10 ment between the wholesale distributor and the pharmacy or chain pharmacy  
11 warehouse. Returns of expired, damaged, recalled or otherwise nonsaleable  
12 pharmaceutical product shall be distributed by the receiving wholesale dis-  
13 tributor only to either the original manufacturer or third party returns  
14 processor, including a reverse distributor. ~~The returns or exchanges of~~  
15 ~~prescription drugs, saleable or otherwise, including any redistribution by~~  
16 ~~a receiving wholesaler, shall not be subject to the pedigree requirement of~~  
17 ~~section 54-1755, Idaho Code, so long as they are exempt from pedigree under~~  
18 ~~the federal food and drug administration's currently applicable prescrip-~~  
19 ~~tion drug marketing act guidance.~~ Wholesale distributors and pharmacies  
20 shall be held accountable for administering their returns process and ensur-  
21 ing that the aspects of this operation are secure and do not permit the entry  
22 of adulterated and counterfeit product.

23       (2) A wholesale distributor shall not engage in the wholesale distri-  
24 bution of prescription drugs that are purchased from pharmacies or practi-  
25 tioners or from wholesale distributors that purchase them from pharmacies or  
26 practitioners.

27       ~~(23)~~ A manufacturer or wholesale distributor shall furnish prescrip-  
28 tion drugs only to a person licensed by the appropriate state licensing  
29 agency to manufacture, distribute, dispense, conduct research or independ-  
30 ently administer such prescription drugs. A manufacturer or wholesale  
31 distributor shall furnish a scheduled controlled substance listed in sec-  
32 tion 37-2705, 37-2707, 37-2709, 37-2711 or 37-2713, Idaho Code, only to a  
33 person who has been issued a valid controlled substance registration by the  
34 United States drug enforcement administration and the Idaho board of phar-  
35 macy, unless exempted by state or federal law.

36       ~~(34)~~ Prescription drugs furnished by a manufacturer or wholesale dis-  
37 tributor shall be delivered only to the premises listed on the license; pro-  
38 vided that the manufacturer or wholesale distributor may furnish prescrip-  
39 tion drugs to an authorized person or agent of that person at the premises of  
40 the manufacturer or wholesale distributor if:

41       (a) The identity and authorization of the recipient is properly estab-  
42 lished; and

43       (b) This method of receipt is employed only to meet the immediate needs  
44 of a particular patient of the authorized person.

45       ~~(45)~~ Prescription drugs may be furnished to a hospital pharmacy receiv-  
46 ing area provided that a pharmacist or authorized receiving personnel signs,  
47 at the time of delivery, a receipt showing the type and quantity of the pre-  
48 scription drug so received. Any discrepancy between receipt and the type and  
49 quantity of the prescription drug actually received shall be reported to the

1 delivering manufacturer or wholesale distributor by the next business day  
2 after the delivery to the pharmacy receiving area.

3 (56) A manufacturer or wholesale distributor shall not accept payment  
4 for, or allow the use of, a person's credit to establish an account for the  
5 purchase of prescription drugs from any person other than the owner(s) of  
6 record, the chief executive officer or the chief financial officer listed  
7 on the license of a person legally authorized to receive prescription drugs.  
8 Any account established for the purchase of prescription drugs must bear the  
9 name of the licensee.

10 SECTION 8. That Section 54-1758, Idaho Code, be, and the same is hereby  
11 amended to read as follows:

12 54-1758. PROHIBITED ACTS. (1) It shall be unlawful for a person to  
13 knowingly perform, or cause the performance of, or aid and abet any of the  
14 following acts in this state:

15 (a) Failure to obtain a license when a license is required by this ~~act~~  
16 chapter;

17 (b) Operate as a wholesale distributor without a valid license when a  
18 license is required by this ~~act~~ chapter;

19 (c) Purchase from or otherwise receive, return or exchange a prescrip-  
20 tion drug from a pharmacy or chain pharmacy warehouse, other than in  
21 compliance with section 54-1754(1), Idaho Code;

22 (d) When a state license is required pursuant to section 54-1754(23),  
23 Idaho Code, sell, distribute, transfer or otherwise furnish a prescrip-  
24 tion drug to a person who is not authorized under the law of the jurisdic-  
25 tion in which the person received the prescription drug to receive  
26 the prescription drug;

27 (e) Failure to deliver prescription drugs to specified premises, as re-  
28 quired by section 54-1754(34), Idaho Code;

29 (f) Acceptance of payment or credit for the purchase of prescription  
30 drugs, other than in compliance with section 54-1754(56), Idaho Code;

31 ~~(g) Failure to maintain or provide pedigrees as required by this act;~~

32 ~~(h) Failure to obtain, pass or authenticate a pedigree, as required by  
33 this act;~~

34 ~~(i) Provide the board or any of its representatives or any federal offi-  
35 cial with false or fraudulent records or make false or fraudulent state-  
36 ments regarding any matter within the provisions of this ~~act~~ chapter;~~

37 ~~(j) Obtain, or attempt to obtain, a prescription drug by fraud, deceit  
38 or misrepresentation or engage in misrepresentation or fraud in the  
39 distribution of a prescription drug;~~

40 ~~(k) Manufacture, repackage, sell, transfer, deliver, hold or offer  
41 for sale any prescription drug that is adulterated, misbranded, coun-  
42 terfeit, suspected of being counterfeit or otherwise has been rendered  
43 unfit for distribution;~~

44 ~~(l) Adulterate, misbrand or counterfeit any prescription drug;~~

45 ~~(m) Receive any prescription drug that is adulterated, misbranded,  
46 stolen, obtained by fraud or deceit, counterfeit or suspected of being  
47 counterfeit;~~

1       (~~n~~) Deliver or proffer delivery of, for pay or otherwise, any pre-  
 2       scription drug that is adulterated, misbranded, stolen, obtained by  
 3       fraud or deceit, counterfeit or suspected of being counterfeit;

4       (~~o~~) Alter, mutilate, destroy, obliterate or remove the whole or any  
 5       part of the labeling of a prescription drug or commit any other act with  
 6       respect to a prescription drug that results in the prescription drug be-  
 7       ing misbranded; or

8       (~~p~~) Sell, deliver, transfer or offer to sell to a person not authorized  
 9       under law to receive the return or exchange of a prescription drug, a  
 10       prescription drug that has expired, been damaged or recalled by either  
 11       the original manufacturer, a third party returns processor or a reverse  
 12       distributor.

13       (2) The acts prohibited in subsection (1) of this section do not include  
 14       a prescription drug manufacturer, or agent of a prescription drug manufac-  
 15       turer, who obtains or attempts to obtain a prescription drug for the sole  
 16       purpose of testing the prescription drug for authenticity.

17       SECTION 9. That Section 54-1755, Idaho Code, be, and the same is hereby  
 18       repealed.

19       SECTION 10. That Section 54-1756, Idaho Code, be, and the same is hereby  
 20       repealed.

21       SECTION 11. That Section 37-3201, Idaho Code, be, and the same is hereby  
 22       amended to read as follows:

23       37-3201. DEFINITIONS. As used in this chapter:

24       (1) "Code imprint" means a series of letters or numbers assigned by the  
 25       manufacturer or distributor to a specific drug, or marks or monograms unique  
 26       to the manufacturer or distributor of the drug, or both;

27       (2) "Distributor" means a person who distributes for resale a drug in  
 28       solid dosage form under his own label even though he is not the actual manu-  
 29       facturer of the drug;

30       (3) "Solid dosage form" means capsules or tablets intended for oral  
 31       use;

32       (4) "Legend drug" means any drug defined by section 54-1705(367), Idaho  
 33       Code.

34       SECTION 12. That Section 54-1759, Idaho Code, be, and the same is hereby  
 35       amended to read as follows:

36       54-1759. PENALTIES. (1) Any person who commits any act prohibited by  
 37       section 54-1758(1)(a) through ~~(1)-(h)~~(f), Idaho Code, is guilty of a misde-  
 38       meanor, which is punishable by not more than one (1) year of imprisonment, or  
 39       by a fine not exceeding five thousand dollars (\$5,000), or both.

40       (2) Any person who commits any act prohibited by section 54-1758(1)(~~g~~)  
 41       through ~~(1)-(p)~~(n), Idaho Code, is guilty of a felony, which is punishable  
 42       by imprisonment for a term of not less than five (5) years and not more than  
 43       twenty (20) years, or by a fine not exceeding five hundred thousand dollars  
 44       (\$500,000), or both.

1 (3) Any person who, with the intent to commit any of the acts prohib-  
2 ited by section 54-1758(1)(~~ig~~) through ~~(1)(p)~~(n), Idaho Code, commits any  
3 act prohibited by section 54-1758(1)(a) through ~~(1)(h)~~(f), Idaho Code, is  
4 guilty of a felony, which is punishable by imprisonment for a term of not less  
5 than five (5) years and not more than twenty (20) years, or by a fine not ex-  
6 ceeding five hundred thousand dollars (\$500,000), or both.

7 (4) Any criminal penalty imposed on a person who commits any act prohib-  
8 ited by section 54-1758, Idaho Code, is in addition to, and not in lieu of,  
9 any other civil or administrative penalty or sanction authorized by law.

10 SECTION 13. That Section 54-1761, Idaho Code, be, and the same is hereby  
11 amended to read as follows:

12 54-1761. DEFINITIONS. As used in sections 54-1760 through 54-1765,  
13 Idaho Code:

14 (1) "Legend drug" has the same meaning as provided in section  
15 54-1705(367), Idaho Code.

16 (2) "Medically indigent" means any person who is in need of a legend  
17 drug and who is not eligible for medicaid or medicare, who cannot afford pri-  
18 vate prescription drug insurance or who does not have income and other re-  
19 sources available sufficient to pay for the legend drug.

20 (3) "Qualifying charitable clinic or center" means a community health  
21 center as defined in section 39-3203, Idaho Code, and means a free medical  
22 clinic as defined in section 39-7702, Idaho Code, acting in consultation  
23 with a pharmacist licensed in the state of Idaho.

24 SECTION 14. That Section 54-4702, Idaho Code, be, and the same is hereby  
25 amended to read as follows:

26 54-4702. DEFINITIONS. As used in this chapter:

27 (1) "Acupuncture" means that theory of health care developed from tra-  
28 ditional and modern Oriental medical philosophies that employs diagnosis  
29 and treatment of conditions of the human body based upon stimulation of spe-  
30 cific acupuncture points on meridians of the human body for the promotion,  
31 maintenance, and restoration of health and for the prevention of disease.  
32 Therapies within the scope of acupuncture include manual, mechanical, ther-  
33 mal, electrical and electromagnetic treatment of such specific indicated  
34 points. Adjunctive therapies included in, but not exclusive to, acupuncture  
35 include herbal and nutritional treatments, therapeutic exercise and other  
36 therapies based on traditional and modern Oriental medical theory.

37 (2) "Board" means the Idaho state board of acupuncture.

38 (3) "NCCAOM" means "National Certification Commission for Acupuncture  
39 and Oriental Medicine."

40 (4) "Practice of acupuncture" means the insertion of acupuncture nee-  
41 dles and use of similar devices and therapies, including application of mox-  
42 ibustion, to specific indicated points on the skin of the human body as indi-  
43 cated pursuant to traditional and modern theories of Oriental medicine. The  
44 "practice of acupuncture" does not include:

45 (a) Surgery; or

46 (b) Prescribing, dispensing or administering any prescription drug or  
47 legend drug as defined in section 54-1705(367), Idaho Code.

1 SECTION 15. That Section 54-5110, Idaho Code, be, and the same is hereby  
2 amended to read as follows:

3 54-5110. NATUROPATHIC MEDICAL FORMULARY COUNCIL ESTABLISHED. There  
4 is hereby established a naturopathic medical formulary council, which is  
5 separate and distinct from the board, to be composed of seven (7) members.  
6 Two (2) members shall be naturopathic physicians licensed under this chapter  
7 and appointed by the board of naturopathic medical examiners. Three (3) mem-  
8 bers shall be pharmacists licensed under chapter 17, title 54, Idaho Code,  
9 appointed by the board of naturopathic medical examiners from a list of nom-  
10 inees provided by the Idaho state board of pharmacy. Two (2) members shall  
11 be physicians licensed under chapter 18, title 54, Idaho Code, appointed by  
12 the board of naturopathic medical examiners from a list of nominees provided  
13 by the Idaho state board of medicine. The initial council shall be appointed  
14 as follows: One (1) naturopathic physician shall be appointed for a one (1)  
15 year term; one (1) physician licensed under chapter 18, title 54, Idaho Code,  
16 and one (1) pharmacist shall be appointed for a two (2) year term; and two (2)  
17 pharmacists, one (1) naturopathic physician and one (1) physician licensed  
18 under chapter 18, title 54, Idaho Code, shall be appointed for a three (3)  
19 year term. Thereafter, the term of office shall be three (3) years. A quorum  
20 shall consist of five (5) members and shall be required for any vote to be  
21 taken. It shall be the duty of the naturopathic medical formulary council to  
22 establish a formulary for use by naturopathic physicians, and immediately  
23 upon adoption or revision of the formulary, the council shall transmit the  
24 approved formulary to the board, which shall adopt the formulary by tempo-  
25 rary rule. The formulary will be reviewed annually by the council, or at  
26 any time at the request of the board. The formulary list may not go beyond  
27 the scope of prescription medicines and medical devices covered by approved  
28 naturopathic medical education and training and existing naturopathic medi-  
29 cal formularies, or board-approved continuing education. The naturopathic  
30 medical formulary shall not include medicines and devices that are inconsis-  
31 tent with the training provided by approved naturopathic medical colleges.  
32 Nothing herein shall allow a naturopathic physician to dispense, administer  
33 or prescribe any prescription drug as defined in section 54-1705(367), Idaho  
34 Code, or medical device unless such prescription drug or medical device is  
35 specifically included in the naturopathic medical formulary.

## STATEMENT OF PURPOSE

### RS 23223

Congress passed the Drug Quality and Security Act in November of 2013, which mandates that states regulate wholesale distribution consistently with this new federal law. This legislation will fulfill our federal responsibility by striking pertinent language and sections within the Idaho Wholesale Drug Distribution Act and the Idaho Pharmacy Act and inserting language consistent with this new federal requirement. Additionally, this bill establishes parameters that prohibit "grey wholesaling," requires wholesale distributors to identify suspicious controlled substances orders, strikes outdated and conflicting language, and streamlines and clarifies confusing language.

### FISCAL NOTE

The bill would require a wholesale distributor's designated representative applicant to pay for the cost of fingerprinting, just as all other applicable Board registrants and licensees are required to do. Current cost of fingerprinting to the Board is \$41.50 per applicant. The Board typically receives about fifty new designated representative applications a year, so this bill will reduce Board costs by approximately \$2,000 a year, for which the Board is not appropriated.

#### Contact

Mark Johnston  
Pharmacy, Board of  
334-2356

**Statement of Purpose/Fiscal Note**

**Bill No.**