

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 350

BY HEALTH AND WELFARE COMMITTEE

AN ACT

1 RELATING TO THE BOARD OF PHARMACY; AMENDING SECTION 54-1723A, IDAHO CODE,
2 TO REVISE A PROVISION RELATING TO REGISTRATION TO PRACTICE AS A PHAR-
3 MACIST; AMENDING SECTION 54-1729, IDAHO CODE, TO REVISE A PROVISION
4 RELATING TO REQUIREMENTS FOR A DRUG OR DEVICE OUTLET DOING BUSINESS IN
5 THIS STATE AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1752,
6 IDAHO CODE, TO ADD A DEFINITION AND TO MAKE A TECHNICAL CORRECTION; AND
7 AMENDING SECTION 54-1754, IDAHO CODE, TO REVISE A PROVISION RELATING TO
8 WHOM A MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY FURNISH PRESCRIPTION
9 DRUGS OR SCHEDULED CONTROLLED SUBSTANCES.
10

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

12 SECTION 1. That Section 54-1723A, Idaho Code, be, and the same is hereby
13 amended to read as follows:

14 54-1723A. REGISTRATION TO ENGAGE IN THE PRACTICE OF PHARMACY INTO
15 IDAHO. (1) To obtain a registration to practice as a pharmacist into the
16 state of Idaho, the applicant shall:

17 (a) Be licensed and in good standing in the state from which the appli-
18 cant practices pharmacy;

19 (b) Submit a written application in the form prescribed by the board;

20 (c) Pay the fee(s) specified by the board for the issuance of the regis-
21 tration; and

22 (d) ~~Be located in one (1) of the fifty (50) states or the District of~~
23 ~~Columbia; and~~

24 ~~(e) Comply with all other requirements of the board.~~

25 (2) A successful applicant for registration under this section shall
26 be subject to the disciplinary provisions of section 54-1726, Idaho Code,
27 the penalty provisions of section 54-1728, Idaho Code, and the rules of the
28 board.

29 (3) A successful applicant for registration under this section shall
30 comply with the board's laws and rules of this state unless compliance would
31 violate the laws or rules in the state in which the registrant is located,
32 except as follows:

33 (a) A technician shall not exceed the practice limitations for techni-
34 cians in Idaho;

35 (b) A pharmacist shall only substitute drug products in accordance with
36 Idaho law;

37 (c) A pharmacist shall only select drug products in accordance with
38 Idaho law; and

39 (d) A pharmacist shall not exceed the pharmacy staffing ratio, as de-
40 fined in rule.

41 (4) Renewal shall be required annually and submitted to the board no
42 later than the thirtieth day of June. The board shall specify by rule the

1 procedures to be followed and the fees to be paid for renewal of registra-
2 tion.

3 SECTION 2. That Section 54-1729, Idaho Code, be, and the same is hereby
4 amended to read as follows:

5 54-1729. REGISTRATION AND LICENSURE OF FACILITIES. (1) All drug or de-
6 vice outlets doing business in or into Idaho shall:

7 (a) If a nonresident, be licensed or registered and in good standing in
8 the applicant's state of residence;

9 (b) Submit a written application in the form prescribed by the board;

10 (c) Pay the fee or fees specified by the board for the issuance of the
11 registration or license; and

12 ~~(d) Be located in one (1) of the fifty (50) states or the District of~~
13 ~~Columbia; and~~

14 ~~(e) Have a PIC or director who is licensed or registered by the board,~~
15 ~~except manufacturers, wholesalers, veterinary drug outlets and limited~~
16 ~~service outlets without a pharmacy.~~

17 (2) Each drug or device outlet shall apply for a certificate of regis-
18 tration or a license in one (1) of the following classifications:

19 (a) Retail pharmacy;

20 (b) Institutional facility;

21 (c) Manufacturer;

22 (d) Wholesaler;

23 (e) Veterinary drug outlet;

24 (f) Nonresident central drug outlet;

25 (g) Mail service pharmacy;

26 (h) Limited service outlet.

27 (3) The board shall establish by rule under the powers granted to it un-
28 der sections 54-1718 and 54-1719, Idaho Code, the criteria which each out-
29 let, that has employees or personnel engaged in the practice of pharmacy,
30 must meet to qualify for registration or licensure in each classification
31 designated in subsection (2) of this section. The board may issue various
32 types of certificates with varying restrictions to such outlets designated
33 in subsection (2) of this section where the board deems it necessary by rea-
34 son of the type of outlet requesting a certificate.

35 (4) It shall be lawful for an outlet registered or licensed under this
36 section to sell and distribute nonprescription drugs. Outlets engaging in
37 the sale and distribution of such items shall not be deemed to be improperly
38 engaged in the practice of pharmacy. No rule will be adopted by the board un-
39 der this chapter which shall require the sale of nonprescription drugs by a
40 pharmacist or under the supervision of a pharmacist or otherwise apply to or
41 interfere with the sale and distribution of such medicines.

42 (5) If the regulatory board or licensing authority of the state in which
43 a nonresident outlet is located fails or refuses to conduct an inspection or
44 fails to obtain records or reports required by the board, upon reasonable no-
45 tice to the nonresident outlet, the board may conduct an inspection. Nonres-
46 ident outlets shall also pay the actual costs of the out-of-state inspection
47 of the outlet, including the transportation, lodging and related expenses of
48 the board's inspector.

1 (6) A successful applicant for registration under the provisions of
 2 this section shall be subject to the disciplinary provisions of section
 3 54-1726, Idaho Code, the penalty provisions of section 54-1728, Idaho Code,
 4 and the rules of the board.

5 (7) A successful applicant for registration under the provisions of
 6 this section shall comply with the board's laws and rules of this state un-
 7 less compliance would violate the laws or rules in the state in which the
 8 registrant is located, except as follows:

9 (a) A technician shall not exceed the practice limitations for techni-
 10 cians in Idaho;

11 (b) A pharmacist shall only substitute drug products in accordance with
 12 the board's laws and rules;

13 (c) A pharmacist shall only select drug products in accordance with the
 14 board's laws and rules; and

15 (d) A pharmacy shall not exceed the pharmacy staffing ratio, as defined
 16 in rule.

17 (8) Renewal shall be required annually and submitted to the board no
 18 later than ~~the thirtieth day of June 30~~. The board shall specify by rule the
 19 procedures to be followed and the fees to be paid for renewal of registration
 20 or licensure.

21 SECTION 3. That Section 54-1752, Idaho Code, be, and the same is hereby
 22 amended to read as follows:

23 54-1752. DEFINITIONS. As used in sections 54-1751 through 54-1759,
 24 Idaho Code:

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

28 (2) "Authorized distributor of record" means a wholesale distributor
 29 with whom a manufacturer has established an ongoing relationship to dis-
 30 tribute the manufacturer's prescription drug. An ongoing relationship is
 31 deemed to exist between such wholesale distributor and a manufacturer when
 32 the wholesale distributor, including any affiliated group of the wholesale
 33 distributor, as defined in section 1504 of the Internal Revenue Code, com-
 34 plies with the following:

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

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

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

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

48 (5) "Drop shipment" means the sale of a prescription drug to a whole-
 49 sale distributor or chain pharmacy warehouse by the manufacturer of the

1 prescription drug, or that manufacturer's colicensed product partner, that
2 manufacturer's third party logistics provider or that manufacturer's ex-
3 clusive distributor, whereby the wholesale distributor or chain pharmacy
4 warehouse takes title but not physical possession of such prescription
5 drug and the wholesale distributor invoices the pharmacy or chain pharmacy
6 warehouse, or other person authorized by law to dispense or administer such
7 drug to a patient, and the pharmacy or chain pharmacy warehouse or other
8 authorized person receives delivery of the prescription drug directly from
9 the manufacturer, or that manufacturer's third party logistics provider, or
10 that manufacturer's exclusive distributor.

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

13 (7) "Manufacturer" means a person licensed or approved by the federal
14 food and drug administration to engage in the manufacture of drugs or de-
15 vices, consistent with the federal food and drug administration definition
16 of "manufacturer" under its regulations and guidance implementing the pre-
17 scription drug marketing act.

18 (8) "Manufacturer's exclusive distributor" means anyone who contracts
19 with a manufacturer to provide or coordinate warehousing, distribution or
20 other services on behalf of a manufacturer and who takes title to that manu-
21 facturer's prescription drug, but who does not have general responsibility
22 to direct the sale or disposition of the manufacturer's prescription drug.
23 Such manufacturer's exclusive distributor must be licensed as a wholesale
24 distributor under section 54-1753, Idaho Code, and to be considered part of
25 the normal distribution channel, must also be an authorized distributor of
26 record.

27 (9) "Normal distribution channel" means a chain of custody for a pre-
28 scription drug that goes from a manufacturer of the prescription drug, from
29 that manufacturer to that manufacturer's colicensed partner, from that
30 manufacturer to that manufacturer's third party logistics provider, from
31 that manufacturer to that manufacturer's exclusive distributor, or from
32 that manufacturer directly or through its colicensed partner, third party
33 logistics provider or manufacturer's exclusive distributor to a repackager
34 who is an authorized distributor of record for the manufacturer, whose fa-
35 cility is registered with the United States food and drug administration
36 and who engages in the practice of repackaging the original dosage form of a
37 prescription drug in accordance with applicable regulations and guidelines
38 of the United States food and drug administration, either directly or by drop
39 shipment, to:

40 (a) A pharmacy to a patient;

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

43 (c) A wholesale distributor to a pharmacy to a patient or other desig-
44 nated persons authorized by law to dispense or administer such drug to a
45 patient;

46 (d) A wholesale distributor to a chain pharmacy warehouse to that chain
47 pharmacy warehouse's intracompany pharmacy to a patient or other desig-
48 nated persons authorized by law to dispense or administer such drug to a
49 patient; or

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

4 (10) "Pedigree" means a document or electronic file containing infor-
5 mation that records each wholesale distribution of any given prescription
6 drug.

7 (11) "Person" means an individual, corporation, government, governmen-
8 tal subdivision or agency, partnership, business trust, association or any
9 other legal entity.

10 (12) "Prescription drug" means any drug, including any biological prod-
11 uct, except for blood and blood components intended for transfusion or bi-
12 ological products that are also medical devices, required by federal law or
13 federal regulation to be dispensed only by a prescription, including fin-
14 ished dosage forms and bulk drug substances, subject to section 503(b) of the
15 federal food, drug and cosmetic act.

16 (123) "Repackage" means repackaging or otherwise changing the con-
17 tainer, wrapper or labeling to further the distribution of a prescription
18 drug, excluding that completed by the pharmacist responsible for dispensing
19 product to the patient.

20 (134) "Repackager" means a person who repackages.

21 (145) "Third party logistics provider" means anyone who contracts with
22 a prescription drug manufacturer to provide or coordinate warehousing, dis-
23 tribution or other services on behalf of a manufacturer, but does not take
24 title to the prescription drug or have general responsibility to direct
25 the prescription drug's sale or disposition. Such third party logistics
26 provider must be licensed as a wholesale distributor under section 54-1753,
27 Idaho Code, and to be considered part of the normal distribution channel,
28 must also be an authorized distributor of record.

29 (156) "Veterinary pharmacy" means a business properly licensed as a
30 pharmacy engaging exclusively in the preparation and dispensing of pre-
31 scription drugs for veterinary prescribed use.

32 (167) "Wholesale distributor" means anyone engaged in the wholesale
33 distribution of prescription drugs including, but not limited to:

34 (a) Manufacturers;

35 (b) Repackagers;

36 (c) Own-label distributors;

37 (d) Private-label distributors;

38 (e) Jobbers;

39 (f) Brokers;

40 (g) Warehouses, including manufacturers' and distributors' ware-
41 houses;

42 (h) ~~Manufacturer's~~ Manufacturers' exclusive distributors;

43 (i) Authorized distributors of record;

44 (j) Drug wholesalers or distributors;

45 (k) Independent wholesale drug traders;

46 (l) Specialty wholesale distributors;

47 (m) Third party logistics providers;

48 (n) Retail pharmacies that conduct wholesale distribution; and

49 (o) Chain pharmacy warehouses that conduct wholesale distribution.

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

4 (178) "Wholesale distribution" means distribution of prescription
5 drugs to persons other than a consumer or patient, but does not include:

6 (a) Intracompany sales of prescription drugs, meaning any transaction
7 or transfer between any division, subsidiary, parent or affiliated
8 or related company under common ownership and control of a corporate
9 entity, or any transaction or transfer between colicensees of a colic-
10 censed product.

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

14 (c) The distribution of prescription drug samples by manufacturers'
15 representatives.

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

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

20 (f) The sale of minimal quantities of prescription drugs by pharmacies
21 to licensed practitioners for office use.

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

24 (h) The sale, transfer, merger or consolidation of all or part of the
25 business of a pharmacy or pharmacies from or with another pharmacy or
26 pharmacies, whether accomplished as a purchase and sale of stock or
27 business assets.

28 (i) The sale, purchase, distribution, trade or transfer of a pre-
29 scription drug from one (1) authorized distributor of record to one (1)
30 additional authorized distributor of record when the manufacturer has
31 stated in writing to the receiving authorized distributor of record
32 that the manufacturer is unable to supply such prescription drug and the
33 supplying authorized distributor of record states in writing that the
34 prescription drug being supplied had, until that time, been exclusively
35 in the normal distribution channel.

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

40 (k) The sale or transfer from a retail pharmacy or chain pharmacy ware-
41 house of expired, damaged, returned or recalled prescription drugs to
42 the original manufacturer or third party returns processor, including a
43 reverse distributor.

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

46 (i) The prescribing veterinarian takes title but not physical
47 possession of such prescription drug and invoices the owner or
48 person having custody of the animal for whom the prescription drug
49 is intended; and

1 (ii) Pursuant to a valid prescription drug order the veterinary
2 pharmacy labels and delivers the prescription drug directly to the
3 owner or person having custody of the animal for whom the prescrip-
4 tion drug is intended.

5 SECTION 4. 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 manufacturer or wholesale distributor shall furnish prescription
24 drugs only to a person licensed by the ~~board or other~~ appropriate state li-
25 censing ~~authorities. Before furnishing prescription drugs to a person not~~
26 ~~known agency to the manufacturer manufacture, distribute, dispense, con-~~
27 ~~duct research or wholesale distributor, the manufacturer or wholesale dis-~~
28 ~~tributor shall affirmatively verify that the person is legally authorized~~
29 ~~to receive the independently administer such prescription drugs by contact-~~
30 ~~ing the appropriate state licensing authorities. A manufacturer or whole-~~
31 sale distributor shall furnish a scheduled controlled substance listed in
32 section 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 (3) 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 (4) 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 (5) 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.