LEGISLATURE OF THE STATE OF IDAHO

Sixty-second Legislature Second Regular Session - 2014

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 350

BY HEALTH AND WELFARE COMMITTEE

AN ACT

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

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

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

54-1723A. REGISTRATION TO ENGAGE IN THE PRACTICE OF PHARMACY INTO IDAHO. (1) To obtain a registration 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;

(c) Pay the fee(s) specified by the board for the issuance of the registration; and

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

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

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

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

(a) A technician shall not exceed the practice limitations for technicians in Idaho;

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

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

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

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

procedures to be followed and the fees to be paid for renewal of registration.

SECTION 2. 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;

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

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

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

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

(2) Each drug or device outlet shall apply for a certificate of registration or a license in one (1) of the following classifications:

(a) Retail pharmacy;

(b) Institutional facility;

(c) Manufacturer;

(d) Wholesaler;

(e) Veterinary drug outlet;

(f) Nonresident central drug outlet;

(g) Mail service pharmacy;

(h) Limited service 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 which each outlet, that has 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) It shall be lawful for an outlet registered or licensed under this section 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 which shall require the sale of nonprescription drugs by a pharmacist or under the supervision of a pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

(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 registration under the provisions of this section shall be subject to the disciplinary provisions of section 54-1726, Idaho Code, the penalty provisions of section 54-1728, Idaho Code, and the rules of the board.

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

(a) A technician shall not exceed the practice limitations for technicians in Idaho;

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

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

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

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

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

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

(1) "Authentication" means to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in section 1504 of the Internal Revenue Code, complies with the following:

(a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and

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

(3) "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.

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

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

prescription drug, or that manufacturer's colicensed product partner, that manufacturer's third party logistics provider or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

(6) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged or offered for sale.

(7) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices, consistent with the federal food and drug administration definition of "manufacturer" under its regulations and guidance implementing the prescription drug marketing act.

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

(9) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, from that manufacturer to that manufacturer's colicensed partner, from that manufacturer to that manufacturer's third party logistics provider, from that manufacturer to that manufacturer's exclusive distributor, or from that manufacturer directly or through its colicensed partner, third party logistics provider or manufacturer's exclusive distributor to a repackager who is an authorized distributor of record for the manufacturer, whose facility is registered with the United States food and drug administration and who engages in the practice of repackaging the original dosage form of a prescription drug in accordance with applicable regulations and guidelines of the United States food and drug administration, either directly or by drop shipment, to:

(a) A pharmacy to a patient;

(b) Other designated persons authorized by law to dispense or administer such drug to a patient;

(c) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(d) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(e) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

(10) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of any given prescription drug.

(11) "Person" means an individual, corporation, government, governmental subdivision or agency, partnership, business trust, association or any other legal entity.

(12) "Prescription drug" means any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law or federal regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances, subject to section 503(b) of the federal food, drug and cosmetic act.

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

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

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

(156) "Veterinary pharmacy" means a business properly licensed as a pharmacy engaging exclusively in the preparation and dispensing of prescription drugs for veterinary prescribed use.

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

(a) Manufacturers;

(b) Repackagers;

(c) Own-label distributors;

(d) Private-label distributors;

(e) Jobbers;

(f) Brokers;

(g) Warehouses, including manufacturers' and distributors' warehouses;

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

(i) Authorized distributors of record;

(j) Drug wholesalers or distributors;

(k) Independent wholesale drug traders;

(l) Specialty wholesale distributors;

(m) Third party logistics providers;

(n) Retail pharmacies that conduct wholesale distribution; and

(o) Chain pharmacy warehouses that conduct wholesale distribution.

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

(1~~7~~8) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) 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 of a colicensed product.

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

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

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

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

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

(g) 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.

(h) 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.

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

(j) 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, and such common carrier does not store, warehouse or take legal ownership of the prescription drug.

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

(l) The sale of a prescription drug by a veterinary pharmacy to the prescribing veterinarian in which:

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

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

SECTION 4. That Section 54-1754, Idaho Code, be, and the same is hereby amended to read as follows:

54-1754. RESTRICTIONS ON TRANSACTIONS. (1) A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled or otherwise nonsaleable pharmaceutical product shall be distributed by the receiving wholesale distributor only to either the original manufacturer or third party returns processor, including a reverse distributor. The returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirement of section 54-1755, Idaho Code, so long as they are exempt from pedigree under the federal food and drug administration's currently applicable prescription drug marketing act guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the ~~board or other~~ appropriate state licensing ~~authorities. Before furnishing prescription drugs to a person not known~~ agency to ~~the manufacturer~~ manufacture, distribute, dispense, conduct research or ~~wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the~~ independently administer such prescription drugs ~~by contacting the appropriate state licensing authorities~~. A manufacturer or wholesale distributor shall furnish a scheduled controlled substance listed in section 37-2705, 37-2707, 37-2709, 37-2711 or 37-2713, Idaho Code, only to a person who has been issued a valid controlled substance registration by the United States drug enforcement administration and the Idaho board of pharmacy, unless exempted by state or federal law.

(3) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided that the manufacturer or wholesale distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

(a) The identity and authorization of the recipient is properly established; and

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

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the

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

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