LEGISLATURE OF THE STATE OF IDAHO

Sixtieth Legislature First Regular Session - 2009

IN THE SENATE

SENATE BILL NO. 1109, As Amended

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACISTS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1760, IDAHO CODE, TO PROVIDE A SHORT TITLE; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1761, IDAHO CODE, TO DEFINE TERMS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1762, IDAHO CODE, TO PROVIDE FOR THE IDAHO LEGEND DRUG DONATION ACT; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1763, IDAHO CODE, TO PROVIDE FOR THE BOARD'S DUTIES AND POWERS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1764, IDAHO CODE, TO PROVIDE IMMUNITY FROM LIABILITY; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1765, IDAHO CODE, TO PROVIDE FOR AN EXEMPTION FROM THE IDAHO WHOLESALE DRUG DISTRIBUTION ACT; AMENDING SECTION 54-1752, IDAHO CODE, TO FURTHER DEFINE A TERM; AND PROVIDING SEVERABILITY.

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

SECTION 1. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1760, Idaho Code, and to read as follows:

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

SECTION 2. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1761, Idaho Code, and to read as follows:

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

(1) "Donating entity" means pharmacies, hospitals, nursing homes, drug manufacturers and wholesale distributors.

(2) "Legend drug" has the same meaning as provided in section 54-1705(28), Idaho Code.

(3) "Medically indigent" means any person who is in need of a legend drug and who is not eligible for medicaid or medicare, who cannot afford private prescription drug insurance or who does not have income and other resources available sufficient to pay for the legend drug.

(4) "Qualifying charitable clinic or center" means a community health center as defined in section 39-3203, Idaho Code, and means a free medical clinic as defined in section 39-7702, Idaho Code.

SECTION 3. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1762, Idaho Code, and to read as follows:

54-1762. IDAHO LEGEND DRUG DONATION ACT. (1) The board of pharmacy shall establish and implement a program through which legend drugs may be transferred from a donating entity that elects to participate in the program for the purpose of distribution to a charitable clinic's or center's pharmacy or to a qualifying charitable center or clinic acting in consultation with a pharmacist for donation to qualifying medically indigent patients.

(2) A qualifying charitable center or clinic in consultation with a pharmacist shall establish procedures consistent with the Idaho legend drug donation act and rules promulgated thereunder.

(3) The acceptance and distribution of legend drugs for use in the program shall be subject to the following requirements:

(a) Only drugs in the original, sealed and tamper evident packaging shall be accepted and dispensed, except that drugs packaged in single unit doses may be accepted and distributed when the outside packaging is open and the single unit dose packaging is intact.

(b) Only drugs that bear a clear and verifiable lot number and expiration date may be accepted and dispensed. However, drugs that bear an expiration date that is less than three (3) months from the date the drug is donated shall not be accepted and dispensed.

(c) Drugs and other substances provided in schedules II through V of article II, chapter 27, title 37, Idaho Code, shall not be accepted and shall not be dispensed.

(d) A drug shall not be accepted or dispensed if the person accepting or dispensing the drug has reason to believe that the drug has been adulterated.

(4) The following entities that are licensed or registered in the state of Idaho may donate legend drugs:

(a) Pharmacies;

(b) Hospitals and nursing homes;

(c) Drug manufacturers; and

(d) Wholesale distributors.

(5) The following entities may accept legend drugs:

(a) A qualifying charitable clinic's or center's pharmacy; or

(b) A qualifying charitable center or clinic in consultation with a pharmacist licensed in the state of Idaho.

(6) Any qualifying charitable clinic or center that participates in the program may dispense drugs donated under the Idaho legend drug donation act to persons who are medically indigent residents of the state of Idaho.

(7) Any qualifying charitable clinic or center dispensing legend drugs shall:

(a) Comply with the provisions of the Idaho legend drug donation act and all rules promulgated thereunder;

(b) Comply with all applicable federal and state laws related to the storage and distribution of drugs;

(c) Inspect all drugs prior to dispensing to determine that such drugs have not been adulterated; and

(d) Dispense drugs only pursuant to a valid prescription.

(8) Participation in the program is voluntary and nothing in the Idaho legend drug donation act shall require any person or entity to participate in the program.

(9) Nothing in the Idaho legend drug donation act shall prohibit or restrict the return of unused prescription drugs to the Idaho medicaid program pursuant to rules promulgated by the Idaho department of health and welfare.

SECTION 4. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1763, Idaho Code, and to read as follows:

54-1763. BOARD DUTIES AND POWERS. (1) The board of pharmacy shall adopt rules necessary for the implementation and enforcement of the program established under the Idaho legend drug donation act and for the enforcement of board rules promulgated thereunder, including:

(a) Standards and procedures for the transfer, acceptance and safe storage of donated drugs;

(b) Standards and procedures for inspecting donated drugs to ensure that the drugs are in compliance with the provisions of the Idaho legend drug donation act and all federal and state product integrity standards and regulations;

(c) Standards and procedures for the distribution of donated drugs to qualifying charitable centers or clinics;

(d) Standards and procedures for the dispensing of donated drugs to qualifying medically indigent patients; and

(e) Any other standards and procedures the board deems appropriate or necessary to implement or enforce the provisions of the Idaho legend drug donation act.

(2) The board shall provide technical assistance to entities that participate in the program.

SECTION 5. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1764, Idaho Code, and to read as follows:

54-1764. IMMUNITY FROM LIABILITY. Any entity that lawfully and voluntarily participates by donating, accepting, distributing or dispensing legend drugs under the Idaho legend drug donation act shall be immune from liability for any civil action arising out of the provision of such action. This section shall not extend immunity to the participating entity for any acts constituting intentional, willful or grossly negligent conduct or to acts by a participating entity that are outside the scope of practice authorized by the entity's licensure, certification or registration.

SECTION 6. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 54-1765, Idaho Code, and to read as follows:

54-1765. EXEMPT FROM THE IDAHO WHOLESALE DRUG DISTRIBUTION ACT. Any person or entity lawfully donating, accepting, distributing or dispensing legend drugs under the Idaho legend drug donation act shall be exempt from the provisions of the Idaho wholesale drug distribution act as provided in sections 54-1751 through 54-1759, Idaho Code.

SECTION 7. 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 or from that manufacturer to that manufacturer's exclusive distributor, 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) "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.

(12) "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.

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

(14) "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.

(15) "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 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.

(16) "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 retail pharmacies to licensed practitioners for office use.

(~~f~~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.

(~~g~~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.

(~~h~~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.

(~~i~~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.

(~~j~~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.

SECTION 8. The provisions of this act are hereby declared to be severable and if any provision of this act or the application of such provision to any person or circumstance is

declared invalid for any reason, such declaration shall not affect the validity of the remaining portions of this act.