LEGISLATURE OF THE STATE OF IDAHO

Sixty-sixth Legislature Second Regular Session - 2022

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 562

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACISTS; AMENDING SECTION 54-1705, IDAHO CODE, TO REMOVE DEFINITIONS, TO REVISE A DEFINITION, AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1729, IDAHO CODE, TO REVISE PROVISIONS REGARDING DRUG OUTLETS, TO PROVIDE FOR RESIDENT AND NONRESIDENT DRUG OUTLETS, AND TO MAKE A TECHNICAL CORRECTION; AMENDING SECTION 54-1761, IDAHO CODE, TO REMOVE A CODE REFERENCE; AMENDING SECTION 54-4702, IDAHO CODE, TO REMOVE A CODE REFERENCE; AND DECLARING AN EMERGENCY AND PROVIDING AN EFFECTIVE DATE.

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

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

54-1705. DEFINITIONS. In this chapter:

(1) "Board of pharmacy" or "board" means the Idaho state board of pharmacy.

(2) ~~"Central drug outlet" means a resident or nonresident pharmacy, drug outlet or business entity employing or contracting pharmacists to perform off-site pharmacy services.~~

~~(3)~~ "Certificate" means a license or registration issued by the board unless specifically stated.

(~~4~~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.

(~~5~~4) "Colicensed partner or product" means an instance where two (2) or more parties have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the federal food and drug administration's implementation of the prescription drug marketing act.

(~~6~~5) "Compounding" means the practice in which a pharmacist, a prescriber, or, in the case of an outsourcing facility, a person under the supervision of a pharmacist combines, mixes or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

(~~7~~6) "Counseling" or "counsel" means the effective communication by the pharmacist of information, as set out in this chapter, to the patient or caregiver in order to improve therapeutic outcomes by maximizing proper use of prescription drugs and devices.

(~~8~~7) "Deliver" or "delivery" means the actual, constructive or attempted transfer of a drug or device from one person to another, whether or not for a consideration.

(~~9~~8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article, including any component part or accessory that is:

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

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

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

(~~10~~9) "Dispense" or "dispensing" means the preparation and delivery of a drug pursuant to a lawful prescription drug order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription.

(1~~1~~0) "Distribute" means the delivery of a drug other than by administering or dispensing.

(1~~2~~1) "Drug" means:

(a) Articles recognized as drugs in the official United States Pharmacopoeia, official National Formulary, official Homeopathic Pharmacopoeia, other drug compendia or any supplement to any of them;

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

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

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

(1~~3~~2) "Drug outlet" means a resident or nonresident pharmacy, business entity or other facility subject to registration by the board, pursuant to section 54-1729, Idaho Code, where employees or personnel are engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, delivering, distributing or manufacturing of drugs or devices in or into Idaho.

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

(1~~5~~4) "Institutional facility" means a facility ~~for which its~~ whose primary purpose is to provide a physical environment for patients to obtain health care services and in which patients spend a majority of their time, as may be further defined by board rule.

(1~~6~~5) "Internship" means a practical experience program under the supervision of a preceptor.

(1~~7~~6) "Investigational or new drug" means any drug limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

(1~~8~~7) "Labeling" means the process of preparing and affixing a label to any drug container, exclusive however of the labeling by a manufacturer, packer or distributor of a nonprescription drug or commercially packaged

legend drug or device. Any such label shall include all information required by federal and state law.

~~(19) "Limited service outlet" means a resident or nonresident pharmacy, facility or business entity subject to registration by the board, pursuant to section 54-1729, Idaho Code, and has employees or personnel engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, delivering, distributing or manufacturing of drugs or devices as may be further defined by board rule but is not a community pharmacy, institutional facility, manufacturer, wholesaler, central drug outlet or mail service pharmacy.~~

~~(20) "Mail service pharmacy" means a nonresident pharmacy that ships, mails or delivers by any lawful means a dispensed legend drug to residents in this state pursuant to a legally issued prescription drug order and ensures the provision of corresponding related pharmaceutical care services required by law.~~

(~~21~~18) "Manufacture" means the production, preparation, propagation, compounding, conversion or processing of a device or a drug, either directly or indirectly by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of a drug by an individual for his own use or the preparation, compounding, packaging or labeling of a drug:

(a) By a pharmacist or practitioner as an incident to his administering, dispensing or, as authorized by board rule, distributing of a drug in the course of his professional practice; or

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

(~~22~~19) "Manufacturer" means a person who is licensed or approved by the federal food and drug administration to engage in the manufacture of drugs, including a colicensed partner or affiliate of that person, who compounds, cultivates, derives, harvests, mixes, or by other process produces or prepares legend drugs and includes persons who prepare such drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process, or who packages or repackages such drugs, but does not include pharmacists or practitioners in the practice of their profession.

(2~~3~~0) "Nonprescription drugs" means medicines or drugs that may be sold without a prescription drug order and that are prepackaged for use by the consumer and labeled in accordance with state and federal law.

(2~~4~~1) "Nonresident" means a person or business entity located in the District of Columbia or a state or territory other than Idaho that practices pharmacy including, but not limited to, pharmaceutical care services into Idaho.

(2~~5~~2) "Off-site pharmacy services" means services provided by a central drug outlet or an off-site pharmacist or technician. Services may include, but are not limited to: processing a request from another pharmacy to fill, refill or dispense a prescription drug order; performance of processing functions; or providing cognitive or pharmaceutical care services. Each

function may be performed by the same or different persons and at the same or different locations.

(2~~6~~3) "Outsourcing facility" means a pharmacy or facility that is registered by the United States food and drug administration pursuant to 21 U.S.C. 353b and either registered or endorsed by the board.

(2~~7~~4) "Person" means an individual, corporation, partnership, association or any other legal entity.

(2~~8~~5) "Person in charge" or "PIC" means a person whose qualifications, responsibilities, and reporting requirements are defined in rule.

(2~~9~~6) "Pharmaceutical care" means drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in the rules of the board.

(~~30~~27) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist registered by this state who is located in another state, territory or the District of Columbia and is engaged in the practice of pharmacy into Idaho, unless exempted.

(~~31~~28) "Pharmacist intern" means a person who is enrolled in or who has completed a course of study at an accredited school or college of pharmacy and is registered with the board as a pharmacist intern prior to commencement of an internship.

(~~32~~9) "Pharmacy" means any drug outlet, facility, department or other place where prescription drug orders are filled or compounded and prescriptions are sold, dispensed, offered or displayed for sale~~, which~~ and has, as its principal purpose, the dispensing of drug and health supplies intended for the general health, welfare and safety of the public.

(~~33~~0) "Practitioner" means a person licensed in this state and permitted by such license to dispense, conduct research with respect to or administer drugs in the course of professional practice or research in this state.

(3~~4~~1) "Preceptor" means a pharmacist or other health professional licensed and in good standing who supervises the internship training of a registered pharmacist intern.

(3~~5~~2) "Precursor" means a substance, other than a legend drug, that is an immediate chemical intermediate that can be processed or synthesized into a legend drug and is used or produced primarily for use in the manufacture of a legend drug.

(3~~6~~3) "Prescriber" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

(3~~7~~4) "Prescriber drug outlet" means a drug outlet in which prescription drugs or devices are dispensed directly to patients under the supervision of a prescriber, except where delivery is accomplished only through on-site administration or the provision of drug samples, patient assistance program drugs, or investigational drugs as permitted in chapter 94, title 39, Idaho Code.

(3~~8~~5) "Prescription drug or legend drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with one (1) of the following statements:

(a) "Caution: Federal law prohibits dispensing without a prescription"; or

(b) "Rx Only"; or

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

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

(3~~9~~6) "Prescription drug order" means a valid order of a prescriber for a drug or device for an ultimate user of the drug or device.

(~~40~~37) "Prospective drug review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription drug order for known allergies, rational therapy contraindications, reasonable dose and route of administration, and reasonable directions for use;

(b) Evaluation of the prescription drug order for duplication of therapy;

(c) Evaluation of the prescription drug order for drug, food, or disease interactions; and

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

(~~41~~38) "Record" means all papers, letters, memoranda, notes, prescriptions, drug orders, invoices, statements, patient medication charts or files, computerized records or other written indicia, documents or objects that are used in any way in connection with the purchase, sale or handling of any drug or device.

(~~42~~39) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug, excluding such actions when completed by the pharmacist responsible for dispensing product to the patient.

(~~43~~40) "Reverse distributor" means a drug outlet that receives nonsalable prescription drugs from persons or their agents, who may lawfully possess prescription drugs without being issued a valid prescription drug order, and that processes for credit or disposes of such prescription drugs.

(44~~1~~) "Sale" means every sale and includes:

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

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

(c) Holding, storing or any other possession;

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

(e) Applying, administering or any other usage.

(45~~2~~) "Ultimate user" means a person who lawfully possesses a drug for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household.

(46~~3~~) "Veterinary drug outlet" means a prescriber drug outlet that dispenses drugs or devices intended for animal patients.

(47~~4~~) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

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

(b) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(c) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs when such common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

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

(4~~8~~5) "Wholesaler" means a person~~,~~ who, in the usual course of business, lawfully distributes drugs or devices in or into Idaho to persons other than the ultimate user.

SECTION 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 and, if a pharmacy, have a PIC who is registered by the board;

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

(c) Pay the fee or fees specified by the board for the issuance of the certificate.

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

(a) ~~Community pharmacy~~ Resident drug outlet;

(b) ~~Institutional facility~~ Nonresident drug outlet;

(c) Manufacturer;

(d) Wholesaler; or

(e) Prescriber drug outlet.~~;~~

~~(f) 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 that each outlet with employees or personnel engaged in the practice of pharmacy must meet to qualify for registration or licensure in each classification designated in subsection (2) of this section. The board may issue various types of certificates with varying restrictions to such outlets designated in subsection (2) of this section where the board deems it necessary by reason of the type of outlet requesting a certificate.

(4) It shall be lawful for any outlet or facility to sell and distribute nonprescription drugs. Outlets engaging in the sale and distribution of such items shall not be deemed to be improperly engaged in the practice of pharmacy. No rule will be adopted by the board under this chapter that requires the sale of nonprescription drugs by a pharmacist or under the supervision of a pharmacist or otherwise applies to or interferes with the sale and distribution of such medicines.

(5) If the regulatory board or licensing authority of the state in which a nonresident outlet is located fails or refuses to conduct an inspection or fails to obtain records or reports required by the board, upon reasonable notice to the nonresident outlet, the board may conduct an inspection. Nonresident outlets shall also pay the actual costs of the out-of-state inspection of the outlet, including the transportation, lodging and related expenses of the board's inspector.

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

(7) A successful applicant for a certificate under the provisions of this section shall comply with the board's laws and the rules of this state unless compliance would violate the laws, regulations, or rules in the state in which the licensee or registrant is located.

(8) Renewal shall be required annually and submitted to the board no later than December 31. The board shall specify by rule the procedures to be followed and the fees to be paid for renewal of a certificate.

SECTION 3. That Section 54-1761, Idaho Code, be, and the same is hereby amended to read as follows:

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

(1) "Donation repository" means:

(a) A community health center as defined in section 39-3203, Idaho Code;

(b) A free medical clinic as defined in section 39-7702, Idaho Code;

(c) A designated regional behavioral health center as identified in chapter 31, title 39, Idaho Code;

(d) A state charitable institution as defined in chapter 1, title 66, Idaho Code; or

(e) A drug outlet as defined in section 54-1705, Idaho Code.

(2) "Legend drug" has the same meaning as provided in section 54-1705~~(38)~~, Idaho Code.

(3) "Medically indigent patient" means any person who is a resident of Idaho and who meets one (1) of the following conditions:

(a) The person is not eligible for medicaid or medicare;

(b) The person cannot afford private prescription drug insurance; or

(c) The person does not have income and other resources available sufficient to pay for a legend drug.

(4) "Qualified donor" means:

(a) Any entity that meets the definition of "donation repository" as provided in this section; or

(b) Any member of the public in accordance with section 54-1762, Idaho Code.

SECTION 4. That Section 54-4702, Idaho Code, be, and the same is hereby amended to read as follows:

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

(1) "Acupuncture" means that theory of health care developed from traditional and modern Oriental medical philosophies that employs diagnosis and treatment of conditions of the human body based upon stimulation of specific acupuncture points on meridians of the human body for the promotion, maintenance, and restoration of health and for the prevention of disease. Therapies within the scope of acupuncture include manual, mechanical, thermal, electrical and electromagnetic treatment of such specific indicated points. Adjunctive therapies included in, but not exclusive to, acupuncture include herbal and nutritional treatments, therapeutic exercise and other therapies based on traditional and modern Oriental medical theory.

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

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

(4) "Practice of acupuncture" means the insertion of acupuncture needles and use of similar devices and therapies, including application of moxibustion, to specific indicated points on the skin of the human body as indicated pursuant to traditional and modern theories of Oriental medicine. The "practice of acupuncture" does not include:

(a) Surgery; or

(b) Prescribing, dispensing or administering any prescription drug or legend drug as defined in section 54-1705~~(38)~~, Idaho Code.

SECTION 5. An emergency existing therefor, which emergency is hereby declared to exist, this act shall be in full force and effect on and after July 1, 2022.