LEGISLATURE OF THE STATE OF IDAHO

Sixty-third Legislature Second Regular Session - 2016

IN THE SENATE

SENATE BILL NO. 1387

BY STATE AFFAIRS COMMITTEE

AN ACT

RELATING TO THE IDAHO PHARMACY ACT; AMENDING SECTION 54-1705, IDAHO CODE, TO ADD A DEFINITION AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1719, IDAHO CODE, TO CLARIFY THE PHARMACY BOARD'S AUTHORITY OVER DURABLE MEDICAL SUPPLIES; AMENDING SECTION 54-1729, IDAHO CODE, TO CLARIFY THAT THE PHARMACY BOARD MAY ISSUE ENHANCED CERTIFICATES TO ANY OUTLET AND TO ESTABLISH ADDITIONAL REGISTRATION REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT SUPPLIERS OF CERTAIN TYPES OF EQUIPMENT; AMENDING SECTION 37-3201, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE; AMENDING SECTION 54-1761, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE; AND AMENDING SECTION 54-4702, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE.

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 centralized pharmacy services.

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

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

(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.

(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. Specific areas of counseling shall include, but are not limited to:

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

(b) Route of administration, dosage, dosage form, continuity of therapy and refill information;

(c) Special directions and precautions for preparation, administration, storage and use by the patient as deemed necessary by the pharmacist;

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

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

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

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

(8) "Device" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar related article including any component part or accessory which 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.

(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.

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

(11) "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 animals; and

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

(12) "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 rules. Unless specifically differentiated, state law applicable to a prescription drug order is also applicable to a drug order.

(13) "Drug outlets" means all resident or nonresident pharmacies, business entities and other facilities 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.

(14) (a) "Durable medical equipment supplier" means a person or entity that:

(i) Currently bills or plans to bill the medicare program for services or products listed in the centers for medicare and medicaid durable medical equipment, prosthetics, orthotics and supplies competitive bid product categories in this state in the current calendar year; or

(ii) Intends to bid for services or products listed in the centers for medicare and medicaid durable medical equipment, prosthetics, orthotics and supplies competitive bid product categories in this state in the current calendar year.

(b) "Durable medical equipment supplier" does not include:

(i) A person or entity that supplies or provides insulin infusion pumps and related supplies or services;

(ii) A person or entity that supplies or provides products that are part of medicare's national mail order program;

(iii) A pharmacy located in Idaho that has a current pharmacy accreditation exemption that is accepted and recognized by the national supplier clearinghouse that enables the pharmacy to be enrolled in medicare to supply durable medical equipment without having the accreditation;

(iv) A practitioner identified in 42 U.S.C. 1395u(b)(18)(C) or a physician, if the practitioner or physician is supplying or providing durable medical equipment to his or her own patients as part of the practitioner's or physician's own services; or

(v) A person or entity that supplies or provides devices, directly to a practitioner identified in 42 U.S.C. 1395u(b)(18)(C) or to a physician, that require a prescription for dispensing to the patient as part of his or her own services, whether mailed to the practitioner or physician for fitting or mailed directly to the patient.

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

(15~~6~~) "Externship" means a structured practical experience program in pharmacy administered by a school or college of pharmacy.

(16~~7~~) "Institutional facility" means a facility for which its 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 rules.

(17~~8~~) "Intern" means any person who has completed a course of study at an approved school or college of pharmacy, received the first professional degree in pharmacy and is registered with the board as a pharmacist intern. Interns must register with the board prior to commencement of an internship program.

(18~~9~~) "Internship" means a postgraduate practical experience program under the supervision of a preceptor.

(~~19~~20) "Investigational or new drug" means any drug which is limited by state or federal law to use under professional supervision of a practitioner authorized by law to prescribe or administer such drug.

(2~~0~~1) "Labeling" means the process of preparing and affixing of 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.

(2~~1~~2) "Limited service outlet" means a resident or nonresident facility or business entity that is 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 but is not a retail pharmacy, institutional facility, manufacturer, wholesaler, veterinary drug outlet, nonresident central drug outlet or mail service pharmacy.

(2~~2~~3) "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.

(2~~3~~4) "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.

(2~~4~~5) "Manufacturer" means a person who by compounding, cultivating, harvesting, mixing or 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~~5~~6) "Nonprescription drugs" means medicines or drugs which may be sold without a prescription drug order and which are prepackaged for use by the consumer and labeled in accordance with state and federal law.

(2~~6~~7) "Nonresident" means a person or business entity located in the District of Columbia or a state other than Idaho that practices pharmacy including, but not limited to, pharmaceutical care services into Idaho.

(2~~7~~8) "Outsourcing facility" means a facility that is registered by the United States food and drug administration pursuant to 21 U.S.C. section 353b and either registered or endorsed by the board.

(2~~8~~9) "Person" means an individual, corporation, partnership, association or any other legal entity.

(~~29~~30) "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.

(3~~0~~1) "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 or the District of Columbia and is engaged in the practice of pharmacy into Idaho, unless exempted.

(3~~1~~2) "Pharmacist-in-charge" (PIC) means a pharmacist whose qualifications, responsibilities and reporting requirements are defined in rule.

(3~~2~~3) "Pharmacy" means any facility, department or other place where prescription drug orders are filled or compounded and prescriptions are sold, dispensed, offered or displayed for sale, which has, as its principal purpose, the dispensing of drug and health supplies intended for the general health, welfare and safety of the public.

(3~~3~~4) "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.

~~(34) "Precursor" means a substance, other than a legend drug, which 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 by persons other than persons licensed to manufacture such legend drugs by the Idaho board of pharmacy, registered by the state board of health and welfare, or licensed to practice pharmacy by the Idaho board of pharmacy.~~

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

(36) "Precursor" means a substance, other than a legend drug, which 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 by persons other than persons licensed to manufacture such legend drugs by the Idaho board of pharmacy, registered by the state board of health and welfare, or licensed to practice pharmacy by the Idaho board of pharmacy.

(3~~6~~7) "Prescriber" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.

(3~~7~~8) "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 which is required by any applicable federal or state law or regulation to be dispensed on prescription drug order only or is restricted to use by practitioners only.

(3~~8~~9) "Prescription drug order" means a valid order of a practitioner for a drug or device for an ultimate user of the drug or device.

(~~39~~40) "Prospective drug review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription drug order for:

(i) Known allergies;

(ii) Rational therapy contraindications;

(iii) Reasonable dose and route of administration; and

(iv) Reasonable directions for use.

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

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

(i) Drug-drug;

(ii) Drug-food; and

(iii) Drug-disease.

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

(i) Over or under utilization; and

(ii) Abuse/misuse.

(4~~0~~1) "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 which are used in any way in connection with the purchase, sale or handling of any drug or device.

(4~~1~~2) "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.

(4~~2~~3) "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.

(4~~3~~4) "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 54-1719, Idaho Code, be, and the same is hereby amended to read as follows:

54-1719. MEDICATIONS -- DRUGS -- DEVICES -- OTHER MATERIALS. The board of pharmacy shall also have the following responsibilities in regard to medications, drugs, devices <u>including durable medical equipment,</u> and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness and disease:

(1) The regulation of the sale at retail and the dispensing of medications, drugs, devices <u>including durable medical equipment,</u> and other materials, including the method of dispensing in institutional facilities, and

including the right to seize such drugs, devices, durable medical equipment and other materials found to be detrimental to the public health and welfare by the board after appropriate hearing as required under the administrative procedure act;

(2) The specifications of minimum professional and technical equipment, environment, supplies and procedures for the compounding, dispensing and distribution of such medications, drugs, devices, durable medical equipment and other materials within the practice of pharmacy;

(3) The control of the purity and quality of such medications, drugs, devices, durable medical equipment and other materials within the practice of pharmacy;

(4) The issuance and renewal of certificates of registration of drug and device outlets , including durable medical equipment suppliers, for purposes of ascertaining those persons engaged in the manufacture and distribution of drugs and medical devices, including durable medical equipment.

SECTION 3. 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) 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 or enhancements to ~~such~~ any 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 un-

der 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~~ rules and ~~rules~~ the laws 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~~ Idaho laws and rules;

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

(d) A pharmacy shall not exceed the pharmacy staffing ratio as defined in Idaho rules.

(8) Renewal shall be required annually and submitted to the board no later than 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.

(9) A durable medical equipment supplier, upon initial application for registration under subsection (2) of this section and upon each annual renewal, shall certify that it meets the requirements of paragraph (c) of this subsection if it supplies or intends to supply any of the services or products set forth in paragraph (b) of this subsection.

(a) All durable medical equipment suppliers shall comply with the requirements for a limited service outlet in this section.

(b) Any durable medical equipment supplier who supplies or intends to supply any of the following services or products must meet the requirements of paragraph (c) of this subsection: medical oxygen equipment, continuous positive airway pressure devices, respiratory assist devices, ventilators, invasive or noninvasive mechanical ventilation devices, mechanical insufflation-exsufflation devices, high frequency chest wall oscillation devices and supplies, negative pressure wound therapy pumps, continuous passive motion devices, hospital beds and accessories, support services (e.g., group II mattress replacement systems), custom orthoses and prosthetics, patient lifts, manual and power wheelchairs, rehabilitative seating and related accessories, gastric suction pumps or enteral pumps.

(c) Any durable medical equipment supplier selling one (1) or more products in paragraph (b) of this subsection shall have at least one

(1) accredited physical facility that meets federal supplier standards under 42 CFR 424.57 and is either located in Idaho or is within one hundred fifty (150) miles of any customer located in Idaho served by the supplier, and shall maintain sufficient inventory and staff to service or repair such products.

SECTION 4. That Section 37-3201, Idaho Code, be, and the same is hereby amended to read as follows:

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

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

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

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

(4) "Legend drug" means any drug defined by section 54-1705(3~~7~~8), Idaho Code.

SECTION 5. 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) "Legend drug" has the same meaning as provided in section 54-1705(3~~7~~8), Idaho Code.

(2) "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.

(3) "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, acting in consultation with a pharmacist licensed in the state of Idaho.

SECTION 6. 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(3~~7~~8), Idaho Code.