LEGISLATURE OF THE STATE OF IDAHO

Sixty-first Legislature First Regular Session - 2011

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 4

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACISTS; AMENDING SECTION 37-3201, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE; AMENDING SECTION 54-1705, IDAHO CODE, TO REVISE DEFINITIONS AND TO DEFINE A TERM; AMENDING SECTION 54-1729, IDAHO CODE, TO REVISE PROVISIONS RELATING TO THE REGISTRATION OF DRUG OUTLETS DOING BUSINESS IN IDAHO AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1733, IDAHO CODE, TO PROVIDE CORRECT TERMINOLOGY; AMENDING SECTIONS 54-1761, 54-4702 AND 54-5110, IDAHO CODE, TO PROVIDE A CORRECT CODE REFERENCE.

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

SECTION 1. 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~~0~~1), Idaho Code.

SECTION 2. 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) "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 medications and devices. Specific areas of counseling shall include, but are not limited to:

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

(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 medication 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.

(3) "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.

(4) "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.

(5) "Dispense" or "dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful 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 drug.

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

(7) "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.

(8) "Drug order" means an ~~written~~ order~~, in a hospital or other health care institution, for an ultimate user of any drug or device issued and signed by a practitioner, or an order transmitted by other means of communication from a practitioner, which is immediately reduced to writing by a pharmacist, registered nurse or other licensed health care practitioner authorized by the hospital or institution. The order shall~~ for a patient of an institutional facility, or for other purposes when permitted by board rules that contains at least the name ~~and bed number~~ of the patient~~,~~; date of issuance; the drug name, ~~and~~ strength, ~~or size of the drug or device, unless specified by individual institution policy or guideline, the amount to be dispensed, either in quantity or days, adequate~~ and route of administration; directions for ~~the proper~~ use; ~~of the drug or device when it is administered~~

~~to the patient,~~ the name of the prescribing practitioner and~~,~~ ~~the name~~ if written, the prescribing practitioner's signature or the signature of the ~~prescriber~~ practitioner's agent.

(9) "Drug outlets" means all pharmacies~~, nursing homes, residential or assisted living facilities, convalescent homes, extended care facilities, drug abuse treatment centers, penal institutions, hospitals, family planning clinics, retail stores, wholesalers, manufacturers and mail order vendors with~~ and other facilities ~~located in this state which are~~ with employees or personnel engaged in the practice of pharmacy, in the provision of pharmaceutical care, or in the dispensing, ~~delivery~~ delivering, ~~or distribution of~~ distributing or manufacturing of drugs ~~and drug manufacturers and wholesalers with facilities located outside the state, but doing business within this state and institutions, as defined in the rules of the board, engaged in the practice of telepharmacy across state lines~~ or devices.

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

(11) "Externship" means a structured practical experience program in pharmacy, approved by the board and administered by a college of pharmacy.

(12) "~~Health care~~Institutional facility" means a ~~health care~~ facility ~~as defined in section 54-1601, Idaho Code~~ 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.

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

(14) "Internship" means a postgraduate practical experience program under the supervision of a preceptor at a preceptor site.

(15) "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.

(16) "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 or regulation.

(17) "Limited service outlet" means a facility that is subject to registration or licensure by the board, pursuant to section 54-1729(3), Idaho Code, in that it 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, telepharmacy across state lines or mail service pharmacy.

(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 or dispensing 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.

(1~~8~~9) "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.

(~~19~~20) "Nonprescription drugs" means medicines or drugs which may be sold without a prescription and which are prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of this state and the federal government.

(2~~0~~1) "Person" means an individual, corporation, partnership, association or any other legal entity.

(2~~1~~2) "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.

(2~~2~~3) "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy or a pharmacist licensed in another state who is registered by the board of pharmacy to engage in the practice of telepharmacy across state lines.

(2~~3~~4) "Pharmacy" means any facility, department or other place where prescriptions are filled or compounded and 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.

(2~~4~~5) "Practice of telepharmacy" means the provision of pharmaceutical care by registered or licensed pharmacies and pharmacists located within United States jurisdictions through the use of telecommunications or other technologies to patients at distances that are located within United States jurisdictions, as defined in the rules of the board.

(2~~5~~6) "Practice of telepharmacy across state lines" means the practice of telepharmacy when the patient is located within the state of Idaho and the pharmacist is located in a United States jurisdiction outside the state of Idaho, as defined in the rules of the board.

(2~~6~~7) "Practitioner" ~~shall~~ means a ~~physician, dentist, veterinarian, scientific investigator or other~~ 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.

(2~~7~~8) "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.

(2~~8~~9) "Preceptor" means a pharmacist licensed in the state and in good standing, who supervises the internship training of a registered intern. The preceptor shall be actively engaged in the practice of pharmacy on a full-time employment basis at a registered preceptor site.

(~~29~~30) "Preceptor site" means any training site for pharmacy interns and externs registered with the board pursuant to board rule.

(3~~0~~1) "Prescription drug or legend drug" means a drug which, 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 only or is restricted to use by practitioners only.

(3~~1~~2) "Prescription drug order" means a lawful written or verbal order of a practitioner for a drug or device for an ultimate user of the drug or device, issued and signed by a practitioner, or an order transmitted verbally from a practitioner or the practitioner's agent to a pharmacist in a pharmacy, or transmitted verbally from a practitioner and immediately reduced to writing by a licensed practical nurse or licensed professional nurse in ~~a health care~~ an institutional facility for a patient or resident of such facility.

(3~~2~~3) "Prospective drug review" includes, but is not limited to, the following activities:

(a) Evaluation of the prescription or medication 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 or medication order for duplication of therapy.

(c) Evaluation of the prescription or medication order for interactions:

(i) Drug-drug;

(ii) Drug-food; and

(iii) Drug-disease.

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

(i) Over or under utilization; and

(ii) Abuse/misuse.

(3~~3~~4) "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.

(3~~4~~5) "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.

(3~~5~~6) "Warehouseman" means a person who stores legend drugs for others and who has no control over the disposition of such drugs except for the purpose of such storage.

(3~~6~~7) "Wholesaler" means a person engaged in the business of distributing legend drugs that he himself has not produced or prepared, to persons included in any of the classes named in subsection (2)(a) through (f) of section 54-1734, Idaho Code.

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 annually register with or be licensed by, as applicable, the board of pharmacy.

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

(~~i~~a) Retail ~~drug outlet~~ pharmacy;

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

(~~iii~~c) ~~Manufacturing drug outlet~~ Manufacturer;

(~~iv~~d) ~~Wholesale drug outlet~~ Wholesaler;

(~~v~~e) ~~Business~~ Veterinary drug outlet ~~selling prescription drugs for veterinary use~~;

(~~vi~~f) Telepharmacy ~~drug outlet~~ across state lines;

(g) Mail service pharmacy;

(h) Limited service outlet.

~~(b) No individual who is employed by a corporation which is registered under paragraphs (a)(i) through (v) of this subsection need register under the provisions of this chapter. All employees or personnel of a drug outlet registered pursuant to paragraph (a)(vi) of this subsection who are engaged in the practice of telepharmacy across state lines must be registered by the board pursuant to section 54-1723A, Idaho Code.~~

(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 drug 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 limited service outlets ~~referred to~~ in ~~this~~ subsection (~~3~~2) where the board deems it necessary by reason of the type of drug outlet requesting a certificate.

(4) It shall be lawful for a drug outlet registered or licensed under this section to sell and distribute nonprescription drugs. Drug 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 licensed pharmacist or under the supervision of a licensed pharmacist or otherwise apply to or interfere with the sale and distribution of such medicines.

(5) Drug outlets registered under subsection (2)(~~a~~f)~~(vi)~~ of this section shall pay the same registration fee as those registering under subsection (2)(~~a~~b)~~(ii)~~ of this section, but shall also pay the actual costs of the out-of-state inspection of the drug outlet as may be required by the board, including the transportation, lodging and related expenses of the board's inspector. Nothing in this section shall preclude the board, in lieu of an inspection by the board, from relying on an inspection of the drug outlet conducted by the regulatory authority of the state within which the drug outlet is located.

SECTION 4. That Section 54-1733, Idaho Code, be, and the same is hereby amended to read as follows:

54-1733. VALIDITY OF PRESCRIPTION DRUG ORDERS. (1) A prescription drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose. A prescription drug order may be issued either:

(a) By a practitioner acting in the usual course of his profession; or

(b) By a physician, dentist, veterinarian, scientific investigator or other person, other than a pharmacist, who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to dispense, conduct research with respect to or administer the prescribed legend drugs in the course of his professional practice or research in such jurisdiction, so long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription drug order.

(c) The prescription drug order may be signed and sent electronically pursuant to chapter 50, title 28, Idaho Code.

(d) Transmission of prescription drug order. In addition to delivery of the original signed written prescription drug order to a licensed pharmacy:

(i) A prescription drug order that has been signed by the practitioner may be received by a licensed pharmacy for dispensing purposes through a facsimile transmission from the prescribing practitioner or the practitioner's agent, or from ~~a health care~~ an institutional facility for a patient or resident in such facility;

(ii) A prescription drug order may also be received by a licensed pharmacist verbally from the practitioner, the practitioner's agent or from a licensed practical nurse or licensed professional nurse in ~~a health care~~ an institutional facility for a patient or resident in such facility;

(iii) A prescription drug order received verbally from the practitioner by a licensed practical nurse or licensed professional nurse in a licensed ~~health care~~ institutional facility for a patient or resident in such facility may also be sent by facsimile transmission from the ~~health care~~ institutional facility to a licensed pharmacy for dispensing purposes provided the transmitted document includes the name of the prescriber issuing the prescription drug order, the name of the nurse who transcribed the order and the name of the person who sent the facsimile.

(e) In the event that there are no refills remaining on an existing prescription drug order, and the pharmacist requests a new prescription drug order from the practitioner, the practitioner's agent, after obtaining practitioner authorization, may sign and return the request via facsimile so long as:

(i) The request is generated from the pharmacy;

(ii) The request is for medication that the patient is currently taking;

(iii) There are no changes to the type of drug, its strength or directions for the continuation of therapy;

(iv) The practitioner's agent's transmission is received via facsimile from the practitioner's office; and

(v) The request, which is subsequently transmitted back to the requesting pharmacy by the practitioner's agent, contains all components of a valid prescription drug order.

(2) It is unlawful for a practitioner to knowingly issue an invalid prescription drug order for a legend drug.

(3) It is unlawful for a pharmacist or veterinarian to knowingly fill an invalid prescription drug order for a legend drug.

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~~0~~1), 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~~0~~1), Idaho Code.

SECTION 7. That Section 54-5110, Idaho Code, be, and the same is hereby amended to read as follows:

54-5110. NATUROPATHIC MEDICAL FORMULARY COUNCIL ESTABLISHED. There is hereby established a naturopathic medical formulary council, which is separate and distinct from the board, to be composed of seven (7) members. Two (2) members shall be naturopathic physicians licensed under this chapter, appointed by the board of naturopathic medical examiners. Three (3) members shall be pharmacists licensed under chapter 17, title 54, Idaho Code, appointed by the board of naturopathic medical examiners from a list of nominees provided by the Idaho state board of pharmacy. Two (2) members shall be physicians licensed under chapter 18, title 54, Idaho Code, appointed by the board of naturopathic medical examiners from a list of nominees provided by the Idaho state board of medicine. The initial council shall be appointed as follows: One (1) naturopathic physician shall be appointed for a one (1) year term; one (1) physician licensed under chapter 18, title 54, Idaho Code, and one (1) pharmacist shall be appointed for a two (2) year term; and two (2) pharmacists, one (1) naturopathic physician and one (1) physician licensed under chapter 18, title 54, Idaho Code, shall be appointed for a three (3) year term. Thereafter, the term of office shall be three (3) years. A quorum shall consist of five (5) members and shall be required for any vote to be taken. It shall be the duty of the naturopathic medical formulary council to establish a formulary for use by naturopathic physicians, and immediately upon adoption or revision of the formulary, the council shall transmit the approved formulary to the board, which shall adopt the formulary by temporary rule. The formulary will be reviewed annually by the council, or at any time at the request of the board. The formulary list may not go beyond the scope of prescription medicines and medical devices covered by approved naturopathic medical education and training and existing naturopathic medical formularies, or board-approved continuing education. The naturopathic medical formulary shall not include medicines

and devices that are inconsistent with the training provided by approved naturopathic medical colleges. Nothing herein shall allow a naturopathic physician to dispense, administer or prescribe any prescription drug as defined in section 54-1705(3~~0~~1), Idaho Code, or medical device unless such prescription drug or medical device is specifically included in the naturopathic medical formulary.