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Second Regular Session - 2016

IN THE SENATE

SENATE BILL NO. 1322

BY HEALTH AND WELFARE COMMITTEE

AN ACT RELATING TO EPINEPHRINE AUTO-INJECTORS; AMENDING SECTION 54-1704, IDAHO 2 CODE, TO PROVIDE THAT THE PRACTICE OF PHARMACY INCLUDES PRESCRIBING 3 EPINEPHRINE AUTO-INJECTORS; AMENDING SECTION 54-1732, IDAHO CODE, 4 5 TO REVISE PROVISIONS REGARDING VIOLATIONS AND PENALTIES AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1733, IDAHO CODE, TO RE-6 VISE PROVISIONS REGARDING VALIDITY OF PRESCRIPTION DRUG ORDERS AND 7 TO MAKE A TECHNICAL CORRECTION; AMENDING CHAPTER 17, TITLE 54, IDAHO 8 CODE, BY THE ADDITION OF A NEW SECTION 54-1733C, IDAHO CODE, TO PROVIDE 9 10 THAT EPINEPHRINE AUTO-INJECTORS MAY BE PRESCRIBED AND DISPENSED TO CERTAIN ENTITIES, TO PROVIDE THAT CERTAIN ENTITIES MAY STOCK EPINEPH-11 RINE AUTO-INJECTORS, TO PROVIDE THAT EPINEPHRINE AUTO-INJECTORS MAY 12 BE PROVIDED OR ADMINISTERED TO CERTAIN PERSONS, TO REQUIRE TRAINING, 13 TO PROVIDE THAT CERTAIN PERSONS ARE EXEMPT FROM TRAINING, TO PROVIDE 14 15 IMMUNITY, TO REQUIRE DISPOSAL OF OUTDATED PRODUCT AND TO DEFINE TERMS; AMENDING CHAPTER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SEC-16 TION 54-1733D, IDAHO CODE, TO PROVIDE THAT PHARMACISTS OR PRESCRIBERS 17 MAY PRESCRIBE EPINEPHRINE AUTO-INJECTORS TO CERTAIN PERSONS; AND 18 19 AMENDING SECTION 54-1734, IDAHO CODE, TO REVISE PROVISIONS REGARDING POSSESSION OF LEGEND DRUGS. 20

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

22 SECTION 1. That Section 54-1704, Idaho Code, be, and the same is hereby amended to read as follows: 23

54-1704. PRACTICE OF PHARMACY. "Practice of pharmacy" means:

- (1) The interpretation, evaluation and dispensing of prescription drug
- (2) Participation in drug and device selection, drug administration, prospective and retrospective drug reviews and drug or drug-related re-
- (3) The provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care;
 - (4) The responsibility for:
 - (a) Compounding and labeling of drugs and devices, except labeling by a manufacturer, repackager or distributor of nonprescription drugs and commercially packaged legend drugs and devices;
 - (b) Proper and safe storage of drugs and devices, and maintenance of proper records for them; and
 - (c) The offering or performing of those acts, services, operations or transactions necessary to the conduct, operation, management and control of pharmacy;
 - (5) The prescribing of:

- (a) Dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
- (b) Agents for active immunization when prescribed for susceptible persons twelve (12) years of age or older for the protection from communicable disease; and
- (c) Opioid antagonists pursuant to section 54-1733B, Idaho Code; and
- (d) Epinephrine auto-injectors pursuant to sections 54-1733C and 54-1733D, Idaho Code.
- SECTION 2. That Section 54-1732, Idaho Code, be, and the same is hereby amended to read as follows:
- 54-1732. VIOLATIONS AND PENALTIES. (1) No drug outlet designated in section 54-1729, Idaho Code, shall be operated until a certificate of registration has been issued to said facility by the board. Upon the finding of a violation of this subsection, the board may impose one (1) or more of the penalties enumerated in section 54-1728, Idaho Code.
- (2) Reinstatement of a certificate that has been suspended, revoked or restricted by the board may be granted in accordance with the procedures specified in section 54-1728(6), Idaho Code.
- (3) The following acts, or the failure to act, and the causing of any such act or failure are unlawful:
 - (a) The sale, delivery or administration of any prescription drug or legend drug, except an opioid antagonist pursuant to section 54-1733B, Idaho Code, or an epinephrine auto-injector pursuant to sections 54-1733C and 54-1733D, Idaho Code, unless:
 - (i) Such legend drug is dispensed or delivered by a pharmacist upon an original prescription, drug order or prescription drug order by a practitioner in good faith in the course of his practice. Any person violating the provisions of this subparagraph shall be guilty of a felony, and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years, or punished by a fine of not more than five thousand dollars (\$5,000) or by both such fine and imprisonment.
 - (ii) In the case of a legend drug dispensed by a pharmacist or prescriber, there is a label affixed to the immediate container in which such drug is dispensed. Any person violating this subparagraph shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than five hundred dollars (\$500). Nothing in this subparagraph prohibits a practitioner from delivering professional samples of legend drugs in their original containers in the course of his practice when oral directions for use are given at the time of such delivery.
 - (b) The refilling of any prescription or drug order for a legend drug except as designated on the prescription or drug order, or by the authorization of the practitioner. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not

to exceed one (1) year, or punished by a fine of not more than one thousand dollars (\$1,000) or by both such fine and incarceration.

- (c) The possession or use of a legend drug or a precursor, except an opioid antagonist pursuant to section 54-1733B, Idaho Code, or an epinephrine auto-injector pursuant to sections 54-1733C and 54-1733D, Idaho Code, by any person unless such person obtains such drug on the prescription or drug order of a practitioner. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars (\$1,000) or by both such fine and incarceration.
- (d) The wholesale distribution of drugs or devices by a pharmacy except for:
 - (i) 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.
 - (ii) The sale of minimal quantities of prescription drugs to practitioners for office use.
 - (iii) The sale of a prescription drug for emergency medical reasons, but never to a wholesale distributor.
 - (iv) 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 or a colicensed product, but never to a wholesale distributor.
- (e) The failure to keep records as required by the board. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars (\$1,000) or by both such fine and incarceration.
- (f) The refusal to make available and to accord full opportunity to check any record, as required by the board. Any person guilty of violating the provisions of this paragraph shall be guilty of a misdemeanor and upon conviction thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or punished by a fine of not more than one thousand dollars (\$1,000) or by both such fine and incarceration.
- (q) It is unlawful to:

- (i) Obtain or attempt to obtain a legend drug or procure or attempt to procure the administration of a legend drug by fraud, deceit, misrepresentation or subterfuge; by the forgery or alteration of a prescription, drug order, or of any written order; by the concealment of a material fact; or by the use of a false name or the giving of a false address.
- (ii) Communicate information to a physician in an effort unlawfully to procure a legend drug, or unlawfully to procure the administration of any such drug. Any such communication shall not be deemed a privileged communication.

- (iii) Intentionally make a false statement in any prescription, drug order, order, report or record required by this chapter.
- (iv) For the purpose of obtaining a legend drug to falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian or other person.
- (v) Make or utter any false or forged prescription or false drug order or forged written order.
- (vi) Affix any false or forged label to a package or receptacle containing legend drugs. This subparagraph does not apply to law enforcement agencies or their representatives while engaged in enforcing state and federal drug laws.
- (vii) Wholesale or retail any prescription or legend drug to any person in this state not entitled by law to deliver such drug to another.

Every violation of paragraph (g) (i) through (vi) of this subsection shall be a misdemeanor, and any person convicted thereof shall be incarcerated in the county jail for a term not to exceed one (1) year, or fined not more than one thousand dollars (\$1,000), or punished by both such fine and imprisonment. Any person violating paragraph (g) (vii) of this subsection is guilty of a felony and on conviction thereof shall be imprisoned in the state penitentiary for a term not to exceed three (3) years, or punished by a fine of not more than five thousand dollars (\$5,000), or by both such fine and imprisonment.

- (4) Provided however, that a veterinarian may dispense or deliver a legend drug prescribed for an animal upon the prescription, drug order, or prescription drug order of another veterinarian. The label shall be affixed pursuant to subsection (3)(a)(ii) of this section, and penalties for violations of the provisions of this subsection shall be as provided in this section for like violations by a pharmacist.
- (5) The ultimate user of a legend drug who has lawfully obtained such legend drug may deliver, without being registered, the legend drug to another person for the purpose of disposal of the legend drug if the person receiving the legend drug for purposes of disposal is authorized under a state or federal law or regulation to engage in such activity.

SECTION 3. 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 valid only if it is issued by a prescriber 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.
- (2) A prescriber who is otherwise authorized to perform any of the activities listed herein in this section may prescribe or perform any of the following activities for a patient with whom the prescriber does not have a prescriber-patient relationship under the following circumstances:
 - (a) Writing initial admission orders for a newly hospitalized patient;

- (b) Writing a prescription drug order for a patient of another prescriber for whom the prescriber is taking call;
- (c) Writing a prescription drug order for a patient examined by a physician assistant, advanced practice registered nurse or other licensed practitioner with whom the prescriber has a supervisory or collaborative relationship;
- (d) Writing a prescription drug order for a medication on a short-term basis for a new patient prior to the patient's first appointment;
- (e) Writing a prescription for an opioid antagonist pursuant to section 54-1733B, Idaho Code;
- (f) In emergency situations where the life or health of the patient is in imminent danger;
- (g) In emergencies that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;
- (h) Epinephrine auto-injectors in the name of a school pursuant to section 33-520A, Idaho Code, or an authorized entity pursuant to section 54-1733C, Idaho Code; and
- (i) If a prescriber makes a diagnosis of a sexually transmitted disease in a patient, the prescriber may prescribe or dispense antibiotics to the infected patient's named sexual partner or partners for treatment of the sexually transmitted disease as recommended by the most current centers for disease control and prevention (CDC) guidelines.
- (3) 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.
- (4) A prescription drug order shall only be issued by a prescriber including a prescriber who is licensed in a jurisdiction other than the state of Idaho and is permitted by such license to prescribe legend drugs in the course of his professional practice so long as the individual is acting within the jurisdiction, scope and authority of his license when issuing the prescription drug order.
 - (5) The following acts shall be unlawful:
 - (a) To knowingly issue an invalid prescription drug order for a legend drug;
 - (b) To knowingly dispense a legend drug pursuant to an invalid prescription drug order; or
 - (c) To prescribe drugs to individuals without a prescriber-patient relationship, unless excepted in this section.

Such acts shall constitute unprofessional conduct and the prescriber or dispenser shall be subject to discipline according to the provisions of the Idaho Code chapter pursuant to which the prescriber or dispenser is licensed, certified or registered.

SECTION 4. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1733C, Idaho Code, and to read as follows:

54-1733C. EPINEPHRINE AUTO-INJECTORS -- EMERGENCY ADMINISTRATION. Notwithstanding any provision of law to the contrary:

- (1) A health care practitioner, including a pharmacist, may prescribe epinephrine auto-injectors in the name of an authorized entity for use in accordance with this section, and pharmacists and other health care practitioners may dispense epinephrine auto-injectors pursuant to a prescription issued in the name of an authorized entity.
- (2) An authorized entity may acquire and stock a supply of epinephrine auto-injectors pursuant to a prescription issued in accordance with this section. Such epinephrine auto-injectors shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injector's instructions for use and any additional requirements that may be established by the department of health and welfare.
- (3) An employee or agent of an authorized entity or other individual who has completed the training required by subsection (4) of this section may use an epinephrine auto-injector prescribed pursuant to subsection (1) of this section to:
 - (a) Provide an epinephrine auto-injector to any individual whom the employee, agent or other individual believes in good faith to be experiencing anaphylaxis, or the parent, guardian or caregiver of such an individual, for immediate administration, regardless of whether the person has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy; or
 - (b) Administer an epinephrine auto-injector to any individual whom the employee, agent or other individual believes in good faith to be experiencing anaphylaxis, regardless of whether the individual has a prescription for an epinephrine auto-injector or has previously been diagnosed with an allergy.
- (4) An employee, agent or other individual described in subsection (2) or (3) of this section must complete an anaphylaxis training program. Such training shall be conducted by a nationally recognized organization experienced in training laypersons in emergency health treatment or an entity or individual approved by the department of health and welfare. Training may be conducted online or in person, and at a minimum shall cover:
 - (a) How to recognize signs and symptoms of severe allergic reactions, including anaphylaxis;
 - (b) Standards and procedures for the storage, administration and disposal of an epinephrine auto-injector; and
 - (c) Emergency follow-up procedures.

The entity that conducts training shall issue a document of completion to each person who successfully completes the anaphylaxis training program.

- (5) Nurses, pharmacists or other health care practitioners may act pursuant to subsection (3) of this section without completing the training required by subsection (4) of this section.
- (6) The following shall not be liable for any injuries or related damages that result from any act or omission taken pursuant to this section:
 - (a) An authorized entity that possesses and makes available epinephrine auto-injectors, and the employees, agents or other individuals associated with such entity;
 - (b) A pharmacist or other health care practitioner who prescribes or dispenses epinephrine auto-injectors to an authorized entity; and

- (c) An individual or entity that conducts the training required by subsection (4) of this section.
- This provision of immunity does not apply to acts or omissions constituting gross negligence. The administration of an epinephrine auto-injector in accordance with this section is not the practice of medicine or any other profession that otherwise requires licensure. This section does not eliminate, limit or reduce any other immunity or defense that may be available under state law, including that provided under section 5-330, Idaho Code.
- (7) An entity located in this state shall not be liable for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector outside of this state if the entity:
 - (a) Would not have been liable for such injuries or related damages had the provision or administration occurred within this state; or
 - (b) Is not liable for such injuries or related damages under the law of the state in which such provision or administration occurred.
- (8) An authorized entity that possesses and makes available epinephrine auto-injectors shall take effort to remove outdated product and dispose of it properly.
 - (9) As used in this section:

- (a) "Administer" means the direct application of an epinephrine autoinjector to the body of an individual.
- (b) "Authorized entity" means any entity or organization, other than a school pursuant to section 33-520A, Idaho Code, in connection with or at which allergens capable of causing anaphylaxis may be present including, but not limited to, recreation camps, colleges and universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment and sports arenas.
- (c) "Epinephrine auto-injector" means a single-use device used for the automatic injection of a premeasured dose of epinephrine into the human body.
- (d) "Health care practitioner" means an individual currently licensed, registered or otherwise authorized to prescribe and administer drugs in the course of professional practice.
- (e) "Provide" means to supply one (1) or more epinephrine auto-injectors to an individual.
- SECTION 5. That Chapter 17, Title 54, Idaho Code, be, and the same is hereby amended by the addition thereto of a $\underline{\text{NEW SECTION}}$, to be known and designated as Section 54-1733D, Idaho Code, and to read as follows:
- 54-1733D. EPINEPHRINE AUTO-INJECTORS -- PRESCRIPTION AND ADMINISTRATION. Notwithstanding any other provision of law, any prescriber or pharmacist acting in good faith and exercising reasonable care may prescribe an epinephrine auto-injector to:
 - (1) A person at risk of experiencing anaphylaxis;
 - (2) A person in a position to assist a person at risk of experiencing anaphylaxis;
 - (3) A person who, in the course of the person's official duties or business, may encounter a person experiencing anaphylaxis; and
 - (4) A person who, in the opinion of the prescriber or pharmacist, has a valid reason to be in possession of an epinephrine auto-injector.

SECTION 6. That Section 54-1734, Idaho Code, be, and the same is hereby amended to read as follows:

- 54-1734. POSSESSION OF LEGEND DRUGS. (1) The following persons or their agents or employees may possess legend drugs for use in the usual and lawful course of their business or practice or in the performance of their lawful official duties, without a valid prescription drug order:
 - (a) Pharmacists;

- (b) Prescribers;
- (c) Researchers who are prohibited from further distribution;
- (d) Hospitals and other institutional facilities;
- (e) Manufacturers and wholesalers;
- (f) Common carriers solely in the usual course of business of transporting prescription drugs;
- (g) Schools <u>or other authorized entities</u> possessing stock supplies of epinephrine auto-injectors pursuant to section 33-520A <u>or 54-1733C</u>, Idaho Code; and
- (h) Persons, agencies and organizations possessing opioid antagonists pursuant to section 54-1733B, Idaho Code.
- (2) Veterinary drug outlets or their agents or employees may possess legend drugs, excluding controlled substances, for use in the usual and lawful course of their business or practice or in the performance of their lawful official duties, without a valid prescription drug order.