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First Regular Session - 2019

## IN THE HOUSE OF REPRESENTATIVES

## HOUSE BILL NO. 58

## BY HEALTH AND WELFARE COMMITTEE

| 1 | AN ACT  |
|---|---|
| 2 | RELATING TO PHARMACY; AMENDING SECTION 54-1732, IDAHO CODE, TO PROVIDE AN |
| 3 | EXCEPTION AND TO MAKE TECHNICAL CORRECTIONS; AMENDING SECTION 54-1761,    |
| 4 | IDAHO CODE, TO REVISE DEFINITIONS; REPEALING SECTION 54-1762, IDAHO       |
| 5 | CODE, RELATING TO THE IDAHO LEGEND DRUG DONATION ACT; AND AMENDING CHAP-  |
| 6 | TER 17, TITLE 54, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 54-1762,   |
| 7 | IDAHO CODE, TO ESTABLISH PROVISIONS REGARDING LEGEND DRUG DONATION.       |
| 8 | Be It Enacted by the Legislature of the State of Idaho:                   |
| 9 | SECTION 1. 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 reqistration 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(7), 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:
    - Such legend drug is dispensed or delivered by a pharmacist (i) 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 $_{T}$  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 quilty 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\_r 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 or to dispensing drug outlets for a specific patient need.
  - (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)  $year_{\tau}$  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  $(\$1,000)_{\tau}$  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  $(\$5,000)_{\tau}$  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 2. 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.
- $\underline{(2)}$  "Legend drug" has the same meaning as provided in section 54-1705(35), Idaho Code.
- (23) "Medically indigent <u>patient</u>" means any person who is  $\frac{\text{in need of a}}{\text{legend drug}}$  a resident of Idaho and who <u>meets one</u> (1) of the following conditions:
  - (a) The person is not eligible for medicaid or medicare, who;
  - (b) The person cannot afford private prescription drug insurance; or
  - (c) The person who does not have income and other resources available sufficient to pay for the a legend drug.
- (3) "Patient assistance program" means a program in which pharmaceutical manufacturers provide financial or medication assistance to low-income or medically indigent individuals.
- (4) "Qualifying charitable clinic or center" means a community health center as defined in section 39-3203, Idaho Code, and means a free medical clinic as defined in section 39-7702, Idaho Code, acting in consultation with a pharmacist licensed in the state of Idaho; or a designated regional behavioral health center as identified in chapter 31, title 39, Idaho Code; or a state charitable institution as defined in chapter 1, title 66, Idaho Code, acting in consultation with a pharmacist, physician, physician assistant or advanced practice professional nurse with prescriptive authority licensed in the state of Idaho
  - (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 3. That Section  $\underline{54-1762}$ , Idaho Code, be, and the same is hereby repealed.
- 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 54-1762, Idaho Code, and to read as follows:
- 54-1762. LEGEND DRUG DONATION. (1) Legend drugs may be transferred from a qualified donor to a donation repository for donation to medically indigent patients.
- (2) Qualified donors may distribute legend drugs in accordance with the following requirements:
  - (a) Drugs donated by an individual member of the public must be in the manufacturer's original sealed packaging, including those packaged in single unit doses when the outside packaging is open and the single unit dose packaging is intact; and
  - (b) Drugs donated by an entity that is a qualified donor must meet either of the following conditions:

- (i) The drugs are in the manufacturer's original sealed packaging, including those packaged in single unit doses when the outside packaging is open and the single unit dose packaging is intact; or
- (ii) The drugs are opened or unsealed but have remained under the control and storage of the qualified donor.
- (3) Donation repositories may accept drugs in accordance with the following specifications:
  - (a) Only drugs that bear a clear and verifiable lot number and expiration date may be accepted and dispensed. Drugs bearing an expiration date fewer than three (3) months from the date the drug is donated shall not be accepted and shall not be dispensed;
  - (b) Drugs and other substances provided in schedules II through V of article II, chapter 27, title 37, Idaho Code, shall not be accepted and shall not be dispensed; and
  - (c) A drug shall not be accepted or dispensed if the person accepting or dispensing the drug has reason to believe that the drug has been adulterated.
  - (4) Any donation repository dispensing legend drugs shall:
  - (a) Comply with all applicable federal and state laws related to the storage and distribution of drugs;
  - (b) Inspect all drugs prior to dispensing to determine that such drugs have not been adulterated;
  - (c) Dispense drugs pursuant only to a valid prescription; and
  - (d) Separate donated drugs from the donation repository's normal drug stock. Donated drugs may not be resold.
- (5) Nothing in this section shall require any person or entity to donate legend drugs, dispense donated legend drugs, transfer legend drugs for donation, or accept donated legend drugs.
- (6) Nothing in this section shall prohibit or restrict the return of unused prescription drugs to the Idaho medicaid program pursuant to rules promulgated by the Idaho department of health and welfare.