2024 South Dakota Legislature

House Bill 1168

Introduced by: ***Representative*** *Jensen (Phil)*

An Act to require the dispensing of drugs prescribed for an off-label use during a public health emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. That § 13-33A-4 be AMENDED:

13-33A-4. Any school may acquire and maintain a stock of epinephrine auto-injectors pursuant to a prescription issued by an authorized health care provider for use in an emergency situation of a severe allergic reaction causing anaphylaxis. ~~The provisions of this section are not subject to the prescription requirements in subdivision 36-11-2(21).~~

Section 2. That § 36-11-2 be AMENDED:

36-11-2. Terms used in this chapter mean:

(1) "Association," the South Dakota Pharmacists Association;

(2) "Biological product," as defined in 42 U.S.C. § 262(i)~~, as of~~ (January 1, 2018);

(3) "Board~~" or "board of pharmacy~~," the State Board of Pharmacy~~ in South Dakota~~;

(4) "Brand name," the proprietary or registered trademark name given to a drug product by its manufacturer, labeler or distributor and placed on the drug or on its container, label or wrapping at the time of packaging;

(5) "Chemicals," the chemical materials or medicine;

(6) "Compounding," the preparation, mixing, assembling, packaging, or labeling of a drug or drug device, as the result of a practitioner's prescription drug order, or an initiative based on the pharmacist/patient/practitioner relationship in the course of professional practice, or for the purpose of or as an incident to research, teaching or chemical analysis, and not for sale or dispensing. The term also includes the preparation of drug or drug devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(7) "Delivery," the actual, constructive, or attempted transfer of a drug or drug device from one person to another, whether or not for a consideration;

(8) "Dispense~~" or "Dispensing~~," the preparation and delivery of a drug to a patient or a patient's agent, pursuant to a prescription drug order, in a suitable container, with appropriate labeling, for subsequent administration to or use by a patient. The term includes preparation of labels for drug devices if the labeling is related to the dosage and administration of drugs;

(9) "Distributing," the ~~delivery~~ delivering of a drug or drug device other than by administration or dispensing;

(10) "Drug administration," the direct application of a drug or drug device by injection, inhalation, ingestion, or any other means to the body of a patient or research subject;

(11) "Drug device," equipment, process, biotechnological entity, diagnostic agent, or other product used in combination with a drug, to provide effective management of medication regimens;

(12) "Drug utilization review program," any program operated solely or partially as a professional standards review organization, whose purpose is to educate pharmacists and practitioners on severe adverse reactions to drugs, therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse, as well as to identify and reduce the frequency of patterns of potential and actual fraud, abuse, gross overuse, inappropriate care or medically unnecessary care associated with specific drugs or groups of drugs among practitioners, pharmacists, and patients;

(13) "Equivalent drug product," a drug product, other than a biological product, that is considered to be therapeutically equivalent to other pharmaceutically equivalent products, as determined by the latest edition of Approved Drug Products with Therapeutic Equivalence Evaluations, as adopted by the board pursuant to chapter 1-26;

(14) "Interchangeable biological product," a biological product that the ~~U.S.~~ United States Food and Drug Administration either has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. § 262(k)(4), ~~as of~~ (January 1, 2018), or has determined is therapeutically equivalent as set forth in the latest edition of, or any supplement to, the Food and Drug Administration's Approved

Drug Products with Therapeutic Equivalence Evaluations publication, as adopted by the board pursuant to chapter 1-26;

(15) "Labeling," the process of preparing and affixing a label to any drug or drug device container exclusive of the labeling by the manufacturer, packer, or distributor of a nonprescription drug or commercially packaged legend drug or drug device;

(16) "Medical device," an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals, or is intended to affect the structure or any function of the body of man or other animals, that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals, and that is not dependent upon being metabolized for achievement of any of its principal intended purposes;

(17) "Medicines," drugs or chemicals, or their preparations, in suitable form for the prevention, relief, or cure of diseases, when used ~~either~~ internally or externally, by man or for animals;

(18) "Nonprescription drugs," drugs that are labeled for use by the general public in accordance with § 502 of the Federal Food, Drug and Cosmetic Act ~~as amended through~~ (January 1, 1997), and may be sold without a prescription drug order in accordance with § 503 of the Federal Food, Drug and Cosmetic Act ~~as amended through~~ (January 1, 1997). The term does not include drugs ~~which~~ that are required by federal law to bear the statement, "Caution: federal law prohibits dispensing without prescription," drugs intended for human use by hypodermic injection, or animal remedies regulated by chapter 39-18;

(19) "Off-label use," the use of a drug, biological product, or device, in a manner other than that for which the drug, product, or device was approved by the United States Food and Drug Administration;

(20) "Patient counseling," oral communication ~~by the pharmacist~~ of information, by the pharmacist to the patient or caregiver, as defined in rules promulgated pursuant to chapter 1-26, to improve therapy, by ensuring proper use of drugs and drug devices;

~~(20)~~(21) "Pharmaceutical care," the provision of 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;

~~(21)~~(22) "Pharmacist," a person licensed by the board to engage in the practice of pharmacy;

~~(22)~~(23) "Pharmacy," any place within or outside this state, licensed by the board, where drugs are dispensed and pharmaceutical care is provided to residents of this state;

~~(23)~~(24) "Practitioner," a person licensed, registered, or otherwise authorized by the jurisdiction in which the person is practicing, to prescribe drugs in the course of professional practice;

~~(24)~~(25) "Prescription drug order," a written or oral order of a practitioner for a drug or drug device for a specific patient;

~~(25)~~(26) "Proper name," the nonproprietary name for a biological product designated by the ~~U.S.~~ United States Food and Drug Administration license for use upon each package of the product;

~~(26)~~(27) "Registered pharmacy technician," a person who is registered by the board ~~who is~~ and employed by a pharmacy to assist licensed pharmacists, in the practice of pharmacy, by performing specific tasks delegated by and under the immediate personal supervision and control of a licensed pharmacist, as permitted by the board;

~~(27)~~(28) "Retail place of business," any place where merchandise is sold at retail and from which original packages of nonprescription drugs are sold or taken to be sold at retail; and

~~(28)~~(29) "Reverse distributor," any person or business that is registered with the United States Drug Enforcement Administration ~~that~~, accepts drug products from vendors, and returns the drug products to manufacturers for credit or destruction.

Section 3. That chapter 36-11 be amended with a NEW SECTION:

During a proclaimed public health emergency, a pharmacist shall dispense all prescription drug orders written by a practitioner for the off-label use of a prescription drug.

The pharmacist is immune from criminal prosecution and adverse board action or discipline if the pharmacist, in good faith, refuses to dispense a prescription because, in the pharmacist's professional judgement, the action would be:

(1) Contrary to law;

(2) Contrary to the health and safety of the patient, based on a documented clinical reason other than the prescription order being written for the off-label use of a prescription drug;

(3) Impossible because:

(a) The prescription drug is not available to the market at the time the prescription drug order is presented to the pharmacist;

(b) The pharmacist lacks sufficient equipment or inventory to dispense the prescription drug safely; or

(c) The pharmacy does not routinely stock the prescription drug as part of its usual and customary practice; or

(4) Inappropriate because the pharmacist lacks sufficient knowledge to dispense the prescription drug safely.