

CHAPTER 328

FOOD, DRUGS, AND COSMETICS

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CHAPTER 328
FOOD, DRUGS, AND COSMETICS

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Part I. HAWAII FOOD, DRUG, AND COSMETIC ACT

§328-1 Definitions. For the purposes of this chapter:

"Agent" means a person who acts on behalf of or under the direction of another person.

"Brand" or "brand name" means any registered trade name commonly used to identify a drug.

"Certificate of medical necessity" means the United States Department of Health and Human Services, Health Care Financing Administration's FORM HCFA 484, which identifies the patient-recipient, the supplier, and the prescriber of medical services and establishes an estimated length of time of need for equipment or therapy, or both, to treat the ailment indicated by the diagnosis codes listed thereon.

"Color additive" means a material which:

- (1) Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

- (2) When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto, except that the term does not include any material which has been or hereafter is exempted under the Federal Act;

The term "color" includes black, white, and intermediate grays.

Nothing in this definition shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

"Computer" means a programmable electronic device, capable of multiple functions including but not limited to storage, retrieval, and processing of information.

"Consumer commodity" means any food, drug, cosmetic, or device as those terms are defined by this part or the Federal Act. The term shall not include:

- (1) Any meat or meat products or poultry or poultry products, except as these products are sold at retail in stores and restaurants in normal retail quantities; provided that any labeling requirements imposed under authority of this part shall comply with those established by the Secretary of Agriculture, United States Department of Agriculture;
- (2) Any tobacco or tobacco products;
- (3) Any commodity subject to packaging and labeling requirements imposed by the Secretary of Agriculture pursuant to the Federal Insecticide, Fungicide and Rodenticide Act or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Act of March 4, 1913 (37 Stat. 832-333; 21 U.S.C. §§151-158), commonly known as the Virus-Serum-Toxin Act;
- (4) Any drug subject to section 503(b)(1) or 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§353(b)(1) and 356);
- (5) Any beverage subject to or complying with packaging and labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C. §§201-219a); or
- (6) Any commodity subject to the Federal Seed Act (7 U.S.C. §§1551-1611).

"Cosmetic" means:

- (1) Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or
- (2) Articles intended for use as a component of any such articles, except that the term shall not include soap intended for cleansing purposes only.

"Department" means the department of health.

"Device", except when used (e.g., as an identification device in labeling) in sections 328-3(a), 328-6(10), 328-10(6), 328-15(3), and 328-19(3), means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended:

- (1) For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or
- (2) To affect the structure or any function of the body of humans or animals.

"Director" means the director of health.

"Downtime" means the period of time that a prescription information processing system is not operable.

"Drug" means:

- (1) Articles recognized in the official United States Pharmacopoeia, official United States Pharmacopoeia Dispensing Information, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;
- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;
- (3) Articles (other than food or clothing) intended to affect the structure or any function of the body of humans or animals; or
- (4) Articles intended for use as a component of any article specified in paragraph (1), (2), or (3); provided that the term "drug" shall not include devices or their components, parts or accessories, cosmetics, or liquor as defined in section 281-1.

"Drug sample" means a unit of a prescription drug that is not to be sold and is distributed to promote the sale of the drug under requirements of Public Law No. 100-293.

"Electronic prescription" means a prescription or certificate of medical necessity, which is electronically transmitted or conveyed, including a facsimile transmission.

"Established name" or "generic name" when applied to a drug has the meaning given in section 502(e) (3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §352(e) (3)).

"Federal Act" means the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040; 21 U.S.C. §§301-395).

"Food" means:

- (1) Articles used for food or drink by humans, dogs, or cats;
- (2) Chewing gum; or
- (3) Articles used for components of any such article.

"Food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, except that the term does not include:

- (1) A pesticide chemical in or on a raw agricultural commodity;
- (2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;
- (3) A color additive; or
- (4) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal Act, the Poultry Products Inspection Act (21 U.S.C. §§451-470), or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. §§601-695).

"Good manufacturing practices for drugs" means requirements for the manufacture, repackaging, production, storage, and dispensing of drug products as stated in 21 C.F.R. Parts 207, 210, and 211.

"Legible" means information that is capable of being read and understood.

"Medical oxygen" means the prescription drug oxygen.

"Medical oxygen distributor" means any person, including a licensed prescription drug wholesale distributor, who holds a permit under chapter 461 to distribute or dispense medical oxygen pursuant to a prescription.

"Nonprescription drug", "over-the-counter drug", or "nonlegend drug", means any packaged, bottled, or nonbulk chemical, drug, or medicine that may be lawfully sold without a practitioner's order.

"Official compendium" means the official United States Pharmacopoeia, official United States Pharmacopoeia Dispensing Information, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

"Out-of-state practitioner" means a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe drugs to patients under the applicable laws of any state of the United States except the State of Hawaii, or a physician, surgeon, osteopathic physician and surgeon, dentist, podiatrist, or veterinarian authorized to prescribe drugs under the applicable laws of Hawaii, but practicing in a state other than Hawaii.

"Pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is an "economic poison" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. §§135-135k) as amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

"Pharmacist" means a person who is licensed or holds a permit under chapter 461 to practice in a pharmacy, including a pharmacy intern under the immediate and direct supervision of a licensed pharmacist.

"Pharmacy" means a place of business operating as a pharmacy as permitted under chapter 461.

"Practitioner" means an individual licensed by the State or authorized by the laws of the State to prescribe prescription drugs within the scope of the person's practice.

"Prescriber's authorized agent" means a person, including but not limited to an institutional facility, who acts on behalf of, and under the direction of, the prescribing practitioner.

"Prescription" means an order or formula issued by a practitioner for the compounding or dispensing of drugs, or an order or formula issued by an out-of-state practitioner in compliance with section 328-17.6.

"Prescription drug" means:

- (1) Any drug required by federal or state statutes, regulations, or rules to be dispensed only upon a prescription, including finished dosage forms and active ingredients subject to section 328-16 or section 503(b) of the Federal Act; or
- (2) Any drug product compounded or prepared pursuant to a practitioner's order.

"Prescription information processing system" means a system for creating, generating, sending, receiving, storing, displaying, or processing prescription information, including but not limited to any electronic hardware, software, or files.

"Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

"Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium.

"Supply" means to sell, trade, distribute, exchange, barter, give, offer for sale, lease, rent, or provide.

§328-2 Same; label, etc. "Label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this part that any word, statement, or other information appears on the label shall not be considered to be complied with unless the word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of the article, or is easily legible through the outside container or wrapper.

"Immediate container" does not include package liners.

"Labeling" means all labels and other written, printed, or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying the article.

"Package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include (1) shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; (2) shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.

"Principal display panel" means that part, or those parts, of a package or label that is, or are, so designed as to most likely be displayed, presented, shown or examined under normal and customary conditions of display and purchase.

Whenever the principal display panel of the package is not coincident with the principal display panel of the label, the principal display panel of the package shall govern the declaration of quantity type size and the principal display panel of the label shall govern its location.

Whenever a difference of opinion exists as to which panel of a package constitutes the principal display panel, the larger panel most likely to be displayed shall be so construed.

Whenever a consumer package has more than one principal display panel, each such panel shall bear all mandatory information required by this part and by the Federal Act.

"Principal labeler" means the manufacturer, packer, or distributor whose name is on the package which contains the finished drug and is distributed to the dispenser. If more than one name is on the package, the principal labeler shall be the manufacturer, packer, or distributor whose name is on the package and who had possession of the package immediately before the dispenser of the drug.

§328-2.1 REPEALED.

§328-3 Same; misbranding or misleading advertisement. (a) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of the representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(b) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

§328-4 Same; antiseptic, germicide; new drug; contamination. (a) The representation of a drug, in its labeling, or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(b) "New drug" means (1) any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or (2) any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(c) "Contaminated with filth" applies to any food, drug, device, or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

§328-5 Same; "selling" includes what. The provisions of this part regarding the selling of food, drugs, devices, or cosmetics, include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; the sale, dispensing, and giving of any such article; and the supplying or applying of any such article in the conduct of any food, drug or cosmetic establishment.

§328-6 Prohibited acts. The following acts and the causing thereof within the State by any person are prohibited:

- (1) The manufacture, sale, delivery, holding, or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded;
- (2) The adulteration or misbranding of any food, drug, device, or cosmetic;

- (3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise;
- (4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of section 328-11, 328-12, or 328-17;
- (5) The dissemination of any false advertisement;
- (6) The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by sections 328-22 and 328-23 to 328-27, or to permit access to or copying of any record as authorized by section 328-23;
- (7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State from whom the person received in good faith the food, drug, device, or cosmetic;
- (8) The removal or disposal of a detained or embargoed article in violation of sections 328-25 to 328-27;
- (9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to a food, drug, device, or cosmetic, if the act is done while the article is held for sale and results in the article being adulterated or misbranded;
- (10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part or regulations adopted under the Federal Act;
- (11) The use, on the labeling of any drug or in any advertisement relating to the drug, of any representation or suggestion that an application with respect to the drug is effective under section 328-17, or that the drug complies with that section;
- (12) The use by any person to the person's own advantage, or revealing other than to the department of health or to the courts when relevant in any judicial proceeding under this part, any information acquired under authority of section 328-11, 328-12, 328-17, or 328-23, concerning any method or process which as a trade secret is entitled to protection;
- (13) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner who makes written request for information as to the drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the Federal Act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this part;
- (14)
 - (A) Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or
 - (B) Selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container

- thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subparagraph (A); or
- (C) Making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof;
- (15) Except as provided in part VI and section 461-1, dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without express permission in each case of the person ordering or prescribing;
- (16) The distribution in commerce of a consumer commodity as defined in this part, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to this part and of rules adopted under authority of this part; provided that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:
- (A) Are engaged in the packaging or labeling of such commodities; or
- (B) Prescribe or specify by any means the manner in which such commodities are packaged or labeled;
- (17) The selling or dispensing in restaurants, soda fountains, drive-ins, lunch wagons, or similar public eating establishments of imitation milk and imitation milk products in place of fresh milk and fresh milk products respectively; of liquid or dry products which simulate cream but do not comply with content requirements for cream in place of cream; of non-dairy frozen desserts which do not comply with content requirements for dairy frozen desserts in place of dairy frozen desserts; and of any other imitation food or one made in semblance of a genuine food in place of such genuine food, unless the consumer is notified by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements informing of such substitution, to include but not limited to the substitution of imitation milk in milk shake and malted milk drinks;
- (18) Wilfully and falsely representing or using any devices, substances, methods, or treatment as effective in the diagnosis, cure, mitigation, treatment, or alleviation of cancer. This paragraph shall not apply to any person who depends exclusively upon prayer for healing in accordance with teachings of a bona fide religious sect, denomination, or organization, nor to a person who practices such teachings;
- (19) The selling or offering for sale at any food facility which serves or sells over the counter directly to the consumer an unlabeled or unpackaged food that is a confectionery which contains alcohol in excess of one-half of one per cent by weight unless the consumer is notified of that fact by either proper labeling or conspicuous posted signs or conspicuous notices on menu cards and advertisements;

- (20) The sale to a person below the age of twenty-one years of any food which is a confectionery which contains alcohol in excess of one-half of one per cent by weight.

§328-7 Remedies for violation of law. In addition to the remedies hereinafter provided the department of health may apply to a circuit judge for and the judge shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating section 328-6, irrespective of whether or not there exists any other remedy.

§328-13 Adding of poisonous or deleterious substance, regulation of. (a) Any added poisonous or deleterious substance, and food additive, any pesticide chemical in or on a raw agricultural commodity, or any color additive, shall, with respect to any particular use or intended use, be deemed unsafe for the purpose of application of clause (B)(i) of section 328-9(1) with respect to any food, section 328-14(1) with respect to any drug or device, or section 328-18(1) with respect to any cosmetic, unless there is in effect a regulation pursuant to section 328-19.1, or subsection (b) of this section limiting the quantity of the substance, and the use or intended use of the substance conform to the terms prescribed by the regulation. While the regulation relating to such substance is in effect, a food, drug, or cosmetic shall not, by reason of bearing or containing the substance in accordance with the regulation, be considered adulterated within the meaning of section 328-9(1)(A), section 328-14(1), or section 328-18(1).

(b) The director of health, whenever public health or other considerations in the State so require, may adopt, amend, or repeal regulations whether or not in accordance with regulations promulgated under the Federal Act prescribing therein tolerances for any added poisonous or deleterious substances, for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including, but not limited to, zero tolerances, and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions where the food additive or color additive is to be used solely for investigational or experimental purposes, upon the director's own motion or upon the petition of any interested party requesting that such a regulation be established. It shall be incumbent upon the petitioner to establish by data submitted to the director that a necessity exists for the regulation, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the director to determine whether such regulation should be promulgated, the director may require additional data to be submitted and failure to comply with the request shall be sufficient grounds to deny the request. In adopting, amending, or repealing regulations relating to such substances the director shall consider among other relevant factors, the following which the petitioner, if any, shall furnish:

- (1) The name and all pertinent information concerning the substance including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations, and suggestions and including specimens of proposed labeling, all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect;

- (2) The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance;
- (3) The probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet;
- (4) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;
- (5) The availability of any needed practicable methods of analysis for determining the identity and quantity of (A) such substance in or on an article, (B) any substance formed in or on such article because of the use of such substance, and (C) the pure substance and all intermediates and impurities; and
- (6) Facts supporting a contention that the proposed use of such substance will serve a useful purpose.

§328-14 Drugs or devices deemed adulterated when. A drug or device shall be deemed to be adulterated:

- (1) (A) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or
 - (B) (i) If it has been produced, prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or
 - (ii) If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess; or
- (C) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- (D) If:
 - (i) It bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act; or
 - (ii) It is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the Federal Act;
- (2) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the Federal Act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor

set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the United States Pharmacopoeia;

- (3) If it is not subject to paragraph (2) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;
- (4) If it is a drug and any substance has been (A) mixed or packed therewith so as to reduce its quality or strength; or (B) substituted wholly or in part therefor.

§328-15 Drugs or devices deemed misbranded when; prescriptions excepted, when. A drug or device shall be deemed to be misbranded:

- (1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of section 328-19.1.
- (2) If in package form, unless it bears a label containing
 - (A) The name and place of business of the manufacturer, packer, or distributor; and
 - (B) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label, provided that under this subparagraph reasonable variations shall be permitted, and exemptions as to small packages shall be allowed, in accordance with rules adopted by the director. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count shall not be required for any commodity subject to packaging and labeling requirements imposed by the Secretary of Agriculture pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the Act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. §§151-158), commonly known as the Virus-Serum-Toxin Act.
- (3) If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (4) If it is for use by a person and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, cabromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphomethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as habit forming, by rules adopted by the director under this part, or by regulations issued pursuant to

section 502(d) of the Federal Act, unless its label bears the name and quantity or proportion of the substance or derivative and in juxtaposition therewith the statement "Warning-May be habit forming."

- (5) (A) If it is a drug unless:
- (i) Its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), the established name, as defined in subparagraph (B), of the drug, if such there be; and in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the established name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein; provided that the requirement for stating the quantity of the active ingredients, other than the quantity of these specifically named in this paragraph, shall apply only to prescription drugs; and
 - (ii) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; provided further that to the extent that compliance with the requirements of this subparagraph is impracticable, exemptions shall be allowed under rules adopted by the director.
- (B) As used in this paragraph, the term "established name", with respect to a drug or ingredient thereof, means:
- (i) The applicable official name designated pursuant to section 508 of the Federal Act;
 - (ii) If there is no such name and the drug, or the ingredient, is an article recognized in an official compendium, then the official title thereof in the compendium; or
 - (iii) If neither clause (i) nor clause (ii) of this subparagraph applies, then the common or usual name, if any, of such drug or of the ingredient; provided further that where clause (ii) of this subparagraph applies to an article recognized in the United States Pharmacopoeia, in the United States Pharmacopoeia Dispensing Information, and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

- (6) Unless its labeling bears:
 - (A) Adequate directions for use; and
 - (B) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; provided that where any requirement of subparagraph (A), as applied to any drug or device, is not necessary for the protection of the public health, the director shall adopt rules exempting the drug or device from such requirements; provided further that articles exempted under regulations issued under section 502(f) of the Federal Act may also be exempt.
- (7) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein; provided that the method of packaging may be modified with the consent of the director, or if consent is obtained under the Federal Act. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to the packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia; provided that in the event of inconsistency between the requirements of this paragraph and those of paragraph (5) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (5) shall prevail.
- (8) If it has been found by the director to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the rules adopted by the director or regulations issued under the Federal Act require as necessary for the protection of public health. No such rule shall be established for any drug recognized in an official compendium until the director shall have informed the appropriate body charged with the revision of the compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.
- (9)
 - (A) If it is a drug and its container is so made, formed, or filled as to be misleading;
 - (B) If it is an imitation of another drug; or
 - (C) If it is offered for sale under the name of another drug.
- (10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- (11) If it is, purports to be, or is represented as a drug composed wholly or partly of insulin, unless:
 - (A) It is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the Federal Act; and
 - (B) The certificate or release is in effect with respect to the drug.

- (12) If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless:
- (A) It is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the Federal Act; and
 - (B) The certificate or release is in effect with respect to the drug; provided that this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the Federal Act.
- For the purpose of this paragraph, the term "antibiotic drug" means any drug intended for use by a person containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).
- (13) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with the packaging and labeling requirements applicable to such color additive prescribed under section 328-13(b).
- (14) In the case on any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of:
- (A) The established name, as defined in paragraph (5)(B), printed prominently and in type at least half as large as that used for any trade or brand name thereof;
 - (B) The formula showing quantitatively each ingredient of the drug to the extent required for labels under section 502(e) of the Federal Act; and
 - (C) Such other information in brief summary relating to side effects, contra-indications, and effectiveness as shall be required in rules adopted by the director.
- (15) If a trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.
- (16) Drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed shall be exempt from any labeling or packaging requirements of this part; provided that such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with rules adopted by the director.
- (17) If it has met or exceeded the expiration date established by the manufacturer or principal labeler.

§328-16 Drugs limited to dispensing on prescription. (a) A prescription drug shall be dispensed only if its label bears the following:

- (1) The name, business address, and telephone number of the seller. The business address shall be the physical location of the pharmacy or the dispensing practitioner's office;
- (2) The name of the person for whom the drug was prescribed or the name of the owner of the animal for which the drug was prescribed;
- (3) The serial number of the prescription;
- (4) The date the prescription was prepared;
- (5) The name of the practitioner if the seller is not the practitioner;
- (6) The name, strength, and quantity of the drug;
- (7) The "use by" date for the drug, which shall be:
 - (A) The expiration date on the manufacturer's container; or
 - (B) One year from the date the drug is dispensed, whichever is earlier;
- (8) The number of refills available, if any;
- (9) In the case of the dispensing of an equivalent generic drug product, the statement "same as (brand name of the drug product prescribed or the referenced listed drug name)", or words of similar meaning; and
- (10) Specific directions for the drug's use; provided that if the specific directions for use are too lengthy for inclusion on the label, the notation "take according to written instructions" may be used if separate written instructions for use are actually issued with the drug by the practitioner or the pharmacist, but in no event shall the notation "take as directed", referring to oral instructions, be considered acceptable.

If any prescription for a drug does not indicate the number of times it may be refilled, if any, the pharmacist shall not refill that prescription unless subsequently authorized to do so by the practitioner. The act of dispensing a prescription drug other than a professional sample or medical oxygen contrary to this subsection shall be deemed to be an act that results in a drug being misbranded while held for sale.

(b) In addition to the requirements enumerated in subsection (a), a prescription drug shall be dispensed only:

- (1) By a pharmacist pursuant to a valid prescription or section 461-1;
- (2) By a medical oxygen distributor pursuant to a prescription or certificate of medical necessity; provided that the drug to be dispensed is medical oxygen; or
- (3) By a practitioner to an ultimate user; provided that:
 - (A) The practitioner shall inform the patient, prior to dispensing any drug other than a professional sample, that the patient may have a written, orally ordered, or electronically transmitted or conveyed prescription directed to a pharmacy or a medical oxygen distributor of the patient's own choice;
 - (B) The practitioner shall promptly record in the practitioner's records:
 - (i) The prescription in full;
 - (ii) The name, strength, and quantity of the drug, and specific directions for the drug's use;
 - (iii) The date the drug was dispensed; and

- (iv) The name and address of the person for whom the drug was prescribed or the name of the owner of the animal for which the drug was prescribed;
 - (C) The records described in subparagraph (B) shall be subject to the inspection of the department or its agents at all times; and
 - (D) No undisclosed rebate, refund, commission, preference, discount, or other consideration, whether in the form of money or otherwise, has been offered to the practitioner as compensation or inducement to dispense or prescribe any specific drug in preference to other drugs that might be used for the identical therapeutic indication.
- (c) A prescription may be communicated in writing, orally, or by electronic transmission, and shall include the following information:
- (1) The authorization of the practitioner noted as follows:
 - (A) Written prescriptions shall include the original signature of the practitioner;
 - (B) Oral prescriptions shall be promptly recorded by the pharmacist or medical oxygen distributor and shall include the practitioner's oral code designation; and
 - (C) Electronic prescriptions shall be irrefutably traceable to the prescribing practitioner by a recognizable and unique practitioner identifier such as:
 - (i) A bitmap or graphic image of the prescriber's handwritten signature and the prescriber's oral code designation (or license number or other identifier if the prescriber is an out-of-state practitioner);
 - (ii) An electronic signature;
 - (iii) A digital signature; or
 - (iv) By other means as approved by the director;
 - (2) The date of issuance;
 - (3) The practitioner's name, business telephone number, and business address, unless the practitioner is otherwise uniquely identified and the pharmacy or medical oxygen distributor dispensing the prescription has the prescriber's contact information on file accessible within the dispensing area;
 - (4) The name, strength, and quantity of the drug to be dispensed, and specific directions for the drug's use;
 - (5) The name and address of the person for whom the prescription was written or the name of the owner of the animal for which the drug was prescribed, unless the pharmacy or medical oxygen distributor dispensing the prescription has the address on file accessible within the dispensing area;
 - (6) The room number and route of administration, if the patient is in an institutional facility; and
 - (7) The number of allowable refills, if the prescription is refillable. If the number of refills authorized by the practitioner is indicated using the terms "as needed" or "prn", the prescription may be refilled up to twelve months from the date the original prescription was written. After the twelve-month period, the "as needed" or

"prn" prescription may be refilled for a subsequent three-month period; provided:

- (A) The prescription is refilled only once during the three-month period;
- (B) The refill does not exceed a thirty-day supply of the drug;
- (C) The refill does not provide any amount of the drug fifteen months beyond the date the original prescription was written;
- (D) In the case of medical oxygen, the duration of therapy indicated on a certificate of medical necessity shall supersede any limitations or restrictions on refilling; and
- (E) Subparagraphs (A) to (D) shall apply only to pharmacies and medical oxygen distributors practicing in the State.

(d) Any prescription may be refilled by the pharmacy and a prescription for medical oxygen may be refilled by the medical oxygen distributor if that refilling is authorized by the practitioner either:

- (1) In the original prescription; or
- (2) By oral or electronic order, which shall be promptly recorded and filed by the receiving pharmacist or medical oxygen distributor.

(e) Prescription information may be transferred between pharmacies, between a pharmacy and a medical oxygen distributor, and between medical oxygen distributors for dispensing purposes; provided that:

- (1) Medical oxygen distributors may communicate or receive prescription information related only to the dispensing of medical oxygen;
- (2) The prescription information includes all elements of subsection (c) (2) to (7) and the following:
 - (A) Authentication of the transmitting pharmacy or medical oxygen distributor who is providing the prescription information including the following:
 - (i) The name of the pharmacist or medical oxygen distributor providing the information;
 - (ii) The name, telephone number, and address or location of the pharmacy or medical oxygen distributor firm providing the information; and
 - (iii) The serial number, prescription number, control number, or other unique identifier of the prescription record from which the information was transferred;
 - (B) The date the original prescription was issued;
 - (C) The date of the last refill; and
 - (D) The number of refills remaining.

(f) For the purposes of this section, a "prescription drug" is a drug intended for use by a person that:

- (1) Is a habit forming drug to which section 328-15(4) applies;
- (2) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner; or
- (3) Is limited by an approved application under section 505 of the Federal Act, or section 328-17, to use under the professional supervision of a practitioner.

(g) Any drug other than medical oxygen dispensed pursuant to a prescription shall be exempt from the requirements of section 328-15 (except paragraphs (1), (9), (11), and (12), and the packaging requirements of paragraphs (7) and (8)), if the drug bears a label containing:

- (1) The name and address of the pharmacy;
- (2) The serial number and the date of the prescription or of its filling;
- (3) The name of the practitioner;
- (4) The name of the patient;
- (5) The directions for use; and
- (6) Any cautionary statements contained in the prescription.

This exemption shall not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a), (b), (c), or (d).

(h) The director of health, by rule, may remove drugs subject to sections 328-15(4) and 328-17 from the requirements of subsection (a), (b), (c), or (d) when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the Federal Act by regulations issued thereunder may also, by rules issued by the director, be removed from the requirements of subsection (a), (b), (c), or (d).

(i) A drug that is subject to subsections (a), (b), (c), and (d) shall be deemed to be misbranded if, at any time prior to dispensing, its label fails to bear the statement "Caution: Federal law prohibits dispensing without prescription", "Caution: State law prohibits dispensing without prescription", or "Rx only". A drug to which subsections (a), (b), (c), and (d) do not apply shall be deemed to be misbranded if, at any time prior to dispensing, its label bears a caution statement quoted in the preceding sentence.

(j) Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classifications of controlled substances as defined in the applicable federal and state laws relating to controlled substances.

(k) Oral code numbers or designations shall be issued by the department of public safety, pursuant to applicable laws and rules.

(l) Any person who transmits, maintains, or receives any prescription or prescription refill orally, in writing, or electronically shall ensure the security, integrity, and confidentiality of the prescription and any information contained therein.

[§328-16.5] Prescription labeling. (a) A practitioner or the practitioner's authorized representative shall:

- (1) Offer to the consumer the option of having the symptom or condition for which a drug is being prescribed listed on the consumer's prescription drug label; and
- (2) Inform the consumer of the consumer's right to not have the symptom or condition listed on the prescription drug label.

(b) The symptom or condition shall not appear on the prescription drug label if the consumer refuses.

(c) Instructions for including the symptom or condition on the consumer's prescription drug label shall be written by the practitioner on the prescription.

(d) The symptom or condition shall be printed on the prescription drug label only if it is written on the prescription as part of the directions for use. Any symptom or condition written on a prescription that is not part of the directions for use shall not be printed on the prescription drug label.

§328-17 New drugs, regulation of sale, etc.; exceptions. (a) No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug unless (1) an application with respect thereto has been approved and the approval has not been withdrawn under section 505 of the Federal Act, or (2) when not subject to the Federal Act, unless the drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale the drug, there has been filed with the director of health an application setting forth (A) full reports of investigations which have been made to show whether or not the drug is safe for use and whether the drug is effective in use; (B) a full list of the articles used as components of the drug; (C) a full statement of the composition of the drug; (D) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of the drugs; (E) such samples of the drug and of the articles used as components thereof as the director may require; and (F) specimens of the labeling proposed to be used for the drug.

(b) An application provided for in subsection (a)(2) shall become effective on the one hundred eightieth day after the filing thereof, except that if the director finds, after due notice to the applicant and giving him an opportunity for a hearing, (1) that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; or (2) the methods used in, and the facilities and controls used for the manufacture, processing, and packing of such drugs are inadequate to preserve its identity, strength, quality, and purity; or (3) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the director.

(d) The director shall promulgate regulations for exempting from the operation of the foregoing subsections of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the director, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon: (1) the submission to the director before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing; (2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and (3) the establishment and maintenance of such records, and the making of such reports to the director by the manufacturer or the sponsor of the investigation of

such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drugs, as the director finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b). Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any person to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such person or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such person.

(e) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the application shall establish and maintain such records, and make such reports to the director, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drugs, as the director may by regulation, or by order with respect to such application, prescribe; provided that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the director deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the director.

Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the director permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(f) The director may, after affording an opportunity for hearing, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health.

§328-17.5 Principal labeler responsibility under recall of drug. Whenever the manufacturer of a drug voluntarily recalls the drug or the Federal Food and Drug Administration or a court orders the recall of a drug, the principal labeler of the drug shall remove the drug from all pharmacies, prescriber offices, medical oxygen distributors, distributors of nonprescription drugs, and health care facilities.

§328-17.6 Out-of-state prescriptions. (a) An out-of-state practitioner may issue a written, oral, or electronic prescription within the confines of the practitioner's license and in accordance with Hawaii laws and rules. An oral or electronic prescription shall be issued by the out-of-state practitioner or the prescriber's authorized agent and received only by a pharmacist; provided that a medical oxygen order may be received by a medical oxygen distributor.

(b) An out-of-state pharmacy may transfer prescription information for refilling purposes and an out-of-state medical oxygen distributor may transfer prescription information for the purpose of refilling a medical oxygen order.

(c) Any pharmacist or medical oxygen distributor who fills or refills a prescription from an out-of-state practitioner shall:

- (1) Note the following on the prescription record: the out-of-state practitioner's full name, address, and telephone number;
- (2) Be responsible for validating and verifying the practitioner's prescriptive authority by virtue of a valid out-of-state license, a Drug Enforcement Administration registration number, or other measures as appropriate; and
- (3) Demand proper identification from the person whose name appears on the prescription prior to filling the prescription, in addition to complying with any identification procedures established by the department for filling and refilling an out-of-state prescription.

(d) Before refilling a transferred out-of-state prescription, a pharmacist or medical oxygen distributor shall:

- (1) Advise the person whose name appears on the prescription that the prescription on file at the originating out-of-state pharmacy or medical oxygen distributor may be canceled; and
- (2) Record all information required to be on a prescription, including:
 - (A) The date of issuance of the original prescription;
 - (B) The number of refills authorized on the original prescription;
 - (C) The date the original prescription was dispensed;
 - (D) The number of valid refills remaining and the date of the last refill;
 - (E) The out-of-state pharmacy's or out-of-state medical oxygen distributor's name, telephone number, and address, and the original prescription number or control number from which the prescription information was transferred; and
 - (F) The name of the transferor pharmacist or the medical oxygen distributor's agent.

(e) A pharmacist or medical oxygen distributor who fills or refills an out-of-state prescription shall be responsible if the prescription is not written in the form prescribed by Hawaii laws and rules.

(f) An out-of-state prescription record shall state the date of filling or refilling and the local address of the person whose name appears on the prescription.

(g) All transferred prescriptions shall be maintained for a period of five years from the date of filling or refilling. Filled out-of-state prescriptions shall be kept on file for five years. The department may establish additional recordkeeping and reporting procedures for filled and refilled out-of-state prescriptions.

(h) Nothing in this section shall be construed to relieve any person from any requirement, prescribed by or under authority of law with respect to drugs now included or that may hereafter be included within the classifications of controlled substances as defined in the applicable federal and state laws relating to controlled substances including but not limited to chapter 329.

§328-17.7 Record of prescriptions. (a) Every practitioner, pharmacist, or medical oxygen distributor who compounds, sells, or delivers any prescribed drug to a patient or a patient's agent shall maintain records that identify:

- (1) The specific drug product dispensed, including:
 - (A) The product's national drug code (NDC) number; or
 - (B) The brand name or the established name and the name or commonly accepted abbreviation of the principal labeler of the drug product dispensed, the product strength, and the dosage form;
- (2) The quantity of the drug;
- (3) Directions for use;
- (4) The number of allowable refills;
- (5) The date of initial dispensing and the dates of all refilling;
- (6) The date of any transfer of the prescription;
- (7) The name, business address, and telephone number of the recipient pharmacist or medical oxygen distributor for any transfer of prescription;
- (8) The prescribing practitioner, including name, business address, and telephone number;
- (9) The format (oral, written, or electronic) in which the prescription was received;
- (10) The patient, including name, address, and telephone number;
- (11) The date of prescribing; and
- (12) The name of the practitioner, pharmacist, or medical oxygen distributor dispensing the drug.

Every prescription dispensed shall have the name of the pharmacist, dispensing practitioner, or medical oxygen distributor responsible for the dispensing appended to the prescription record, and every prescription record shall be preserved and legible for a period of not less than five years. The prescription records shall be subject at all times to the inspection of the director of health or the director's agent.

(b) Prescription records may be electronically maintained using an appropriate prescription information processing system; provided that:

- (1) There are procedures to maintain the records, including but not limited to auxiliary procedures for backing up files, computer downtime, and the protection of patient confidentiality; and
- (2) Upon request the prescription records, or a subset thereof, shall be provided to the director or the director's agent, in a form specified by the director, within forty-eight hours.

(c) Prescription records shall be maintained electronically or manually such that the information is readily retrievable during the pharmacy's normal operating hours.

[§328-17.8] Electronic prescription information. (a) Prescription information may be transmitted electronically; provided that:

- (1) The information shall be communicated only between the prescribing practitioner or the prescriber's authorized agent and pharmacies or medical oxygen distributors of the patient's choice;

- (2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient;
 - (3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval, on a per prescription or per order basis. Transmitted prescription information shall not be altered by any system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy or medical oxygen distributor recipient;
 - (4) The prescription information processing system shall provide for adequate confidentiality safeguards provided by any applicable federal or state law; and
 - (5) Practitioners, pharmacists, and medical oxygen distributors shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any prescription information communicated, received, or transferred.
- (b) Nothing in this section shall be construed or interpreted to prevent the transmission of health care information, including prescription information, between health plans and their authorized agents and prescribing practitioners, pharmacists, and medical oxygen distributors for the purpose of the adjudication or payment of claims.

[§328-17.9] Supply of electronic equipment. No person shall supply prescription information processing system equipment, including computer hardware, software, facsimile machines, and related equipment, to practitioners, pharmacists, pharmacies, or medical oxygen distributors, on the condition, agreement, or understanding that the recipient of the equipment shall not deal in the commodity of a competitor, shall not deal with a competitor, or shall deal only with persons identified by the supplier of the equipment.

§328-20 False advertising; exceptions. (a) An advertisement of a food, drug, device, or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this part the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, or venereal disease shall also be deemed to be false, except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, osteopathic, podiatric, dental, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices; provided that whenever the department determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the department shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interest of public health; provided that this subsection shall not be

construed as indicating that self-medication for diseases other than those named herein is safe of efficacious.

§328-21 Rules and regulations, hearings. (a) Subject to chapter 91 the director of health may adopt and enforce such rules or regulations as the director may deem necessary for the efficient enforcement of this part. The director may make the rules or regulations prescribed under this part conform in so far as practicable with those promulgated under the Federal Act.

(b) Hearings authorized or required by this part shall be conducted by the director or any officer, agent, or employee designated by the director for that purpose and shall be subject to chapter 91.

§328-22 Duties of department. The department of health shall inquire carefully into the quality of any food, drug, device, or cosmetic manufactured, sold, or kept or exhibited or offered for sale by any person; and it may in a lawful manner procure samples thereof, submit the same to careful examination and report the result of such analysis of all or any such food, drugs, devices, or cosmetics as are adulterated, impure, or unwholesome, in contravention of the laws of the State, to the director; and the director shall make complaint with the necessary evidence through the proper authorities, against such person; provided that nothing in this part shall require the department to report for the institution of proceedings under this part, minor violations of this part, whenever it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning; provided further that whenever the department believes that the public interest will be adequately served by the issuance of a warning to the general public by virtue of the degree of adulteration, impurity, or unwholesomeness in contravention of the laws of the State present in any food, drugs, devices, or cosmetics which constitute a hazardous condition, it shall issue a warning through all available news media including television, radio, newspaper, and other available methods of communication. When the hazardous condition has been corrected, the department shall issue a statement to be made through all available news media that conditions as corrected have returned to a safe and normal level.

The department shall investigate complaints on the information of any person who lays before it satisfactory evidence of the same.

§328-23 Inspection powers of director. The director of health or any of the director's agents are authorized upon presenting appropriate credentials to the owner, operator or agent in charge, (1) to enter at all reasonable hours any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in commerce; (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers and labeling therein to determine if this part is being violated; (3) to have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the

holding thereof during or after such movement, and the quantity, shipper and consignee thereof; provided that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further that carriers shall not be subject to the other provisions of this part by reason of the receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers; and (4) To secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for the sample. The director shall make or cause to be made examinations of samples secured under this section to determine whether or not this part is being violated.

§328-24 Furnishing of samples to director. (a) If any person manufacturing, keeping for sale, exhibiting for sale, or offering for sale any food, drug, device, or cosmetic included in this part refuses to furnish the duly appointed director of health or any of the director's agents, upon demand, either personal or in writing, a sample sufficient for the analysis of the food, drug, device, or cosmetic, which is in the person's possession, such refusal shall be prima facie evidence that the food, drug, device, or cosmetic so manufactured, kept for sale, exhibited for sale, or offered for sale is adulterated within the meaning of this part.

(b) A sample of any product covered under this section that is known to be or suspected of being contaminated shall be furnished upon request to the director or any of the director's agents at no cost to the department.

The director or agent securing a sample under this section from any retailer or wholesaler or any person other than the manufacturer shall, prior to leaving the premises, provide the establishment with a receipt describing the sample obtained. The receipt may be used for reimbursement from the appropriate supplier or manufacturer.

§328-25 Director's right to inspect, require recordkeeping, demand records, seize, and conduct hearings. (a) The director of health or any of the director's agents may in the performance of their duties:

- (1) Enter at all reasonable hours into any creamery, factory, restaurant, store, salesroom, storage room, drug store, or laboratory, or any place where they have probable cause to believe that food, drugs, devices, cosmetics, or consumer commodity as defined by this part are made, prepared, sold, or kept, exhibited or offered for sale, and open any cask, tub, bottle, case, or package containing or supposed to contain any such food, drug, device, cosmetic, or consumer commodity, and examine or cause to be examined the contents thereof;
- (2) Adopt rules pursuant to chapter 91 requiring a person to keep records relating to the manufacture, distribution, or sale of food, drugs, devices, cosmetics, or consumer commodity; and
- (3) Demand a person to provide records or copies of records relating to the manufacture, distribution, or sale of food, drugs, devices, cosmetics, or consumer commodity which the director has probable cause to believe is adulterated or misbranded; provided that no confidential information concerning secret processes or methods of manufacture secured pursuant to this section by any person who is an official or employee of the department of health within the scope and course of the

person's employment shall be disclosed by the person except as it relates directly to the adulteration or misbranding of a commodity, and then, only in connection with the person's official duties and within the scope and course of the person's employment. Any officer, employee or agent of the department acquiring confidential information concerning secret processes or methods of manufacture who divulges information except as authorized in this section or as ordered by a court or at an administrative hearing regarding an alleged adulteration or misbranding or of any rule or regulation or standard adopted pursuant to this part shall be guilty of a misdemeanor.

(b) If any food, drug, device, cosmetic, or consumer commodity is found to be adulterated or misbranded within the meaning of this part and the owner or person in charge thereof refuses to comply with the instructions of the director or any of the director's agents for the proper disposal thereof, the food, drug, device, cosmetic, or consumer commodity shall be liable to seizure. The director or any of the director's agents shall affix to the article or articles a tag or other appropriate marking, giving notice that the article is, or is suspected of, being adulterated or misbranded, and has been detained or embargoed, and warning all persons not to remove or dispose of the article by sale or otherwise until permission for removal or disposal is given by the director or any of the director's agents or by the court or judge having jurisdiction over such matters. Upon the request of the director or any of the director's agents, made to such court, the court shall order and direct that the food, drug, device, cosmetic, or consumer commodity be seized and delivered into the custody of the court, and the same shall be held in such custody until a hearing has been held to determine whether or not it is adulterated or misbranded.

§328-26 Disposal of questioned articles; court orders; expenses; bond. If the court finds that a detained or embargoed article is adulterated or misbranded, the article shall, after entry of the decree be destroyed at the expense of the claimant thereof, under the supervision of the director of health or any of the director's deputies; and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of the article or the claimant's agent; provided that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that the article shall be so labeled or processed, has been executed, may by order direct that the article be delivered to the claimant thereof for such labeling or processing under the supervision of the director or any of the director's agents. The expense of supervision shall be paid by the claimant. The bond shall be returned to the claimant of the article on representation to the court by the director or any of the director's agents that the article is no longer in violation of this part, and that the expenses of supervision have been paid.

§328-28 Duties of county attorneys, prosecuting attorney. Each county attorney, or prosecuting attorney to whom the department of health reports any violation of this part, shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law. Before any violation of this part is reported to any such attorney for

the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views before the department either orally or in writing, in person or by attorney, with regard to such contemplated proceeding.

§328-29 Penalty; exceptions. (a) Any person who violates section 328-6 shall be fined not more than \$500, or imprisoned not more than one year, or both.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated section 328-6(1) or (3) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the State from whom he received in good faith the article, to the effect that the article is not adulterated or misbranded within the meaning of this part, designating this part.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused on the request of the department of health to furnish the department the name and post office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the State who caused him to disseminate such advertisement.

§328-30 Administrative penalties. (a) Any person who violates this part or any rule adopted by the department pursuant to this part shall be fined not more than \$10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and that the penalty remains unpaid.

[§328-31] Injunctive relief. The director may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this part or any rule adopted to implement this part. The court shall have powers to grant relief in accordance with the Hawaii rules of civil procedure.

[Part VI.] DRUG PRODUCT SELECTION

§328-91 Definitions. As used in this part:

"Agent" means a person under the direct supervision of a pharmacist, acting in the pharmacist's presence.

"Bioequivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability, as defined by the Federal Food and Drug Administration.

"Board" means the drug product selection board.

"Compendia of therapeutically equivalent generic drugs" means the Orange Book and any United States Food and Drug Administration documentation of any United States Food and Drug Administration-approved therapeutic equivalency, including but not limited to:

- (1) Letters of approval of Abbreviated New Drug Applications with therapeutic equivalency evaluations;
- (2) Published listings of approved New Drug Applications or approved Abbreviated New Drug Applications with therapeutic equivalency evaluations; and
- (3) Listings of first time generics with therapeutic equivalency evaluations, adopted by the board.

"Equivalent drug product" means a drug product with the same established name, active ingredient strength, quantity, and dosage form as the drug product identified in the prescription, and listed as therapeutically equivalent in the current state drug formulary.

"Hawaii additions and deletions list" means:

- (1) A list of drug products that the board has determined to be safe, effective, and therapeutically equivalent generic drug products but are not in the compendia of therapeutically equivalent generic drugs; and
- (2) A list of drug products that are included in the compendia of therapeutically equivalent generic drugs, but that the board has determined not to be safe, effective, therapeutically equivalent, or bioequivalent generic drug products.

"Multiple source drug" means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different brand names, or both, under a brand name and without such a name.

"Orange Book" means the United States Food and Drug Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication and its cumulative supplements, which include a list of approved prescription drug products with therapeutic equivalence evaluations.

"Savings" means the financial benefit derived from utilizing the substituted equivalent generic drug product from the perspective of the consumer or the ultimate payer, including third party payers.

§328-92 Drug product selection. (a) When filling a prescription order for a drug prescribed by its brand name, a pharmacist or the pharmacist's authorized agent shall:

- (1) Offer to the consumer an equivalent generic drug product from the formulary adopted pursuant to section 328-96; and
- (2) Upon the request of the consumer, inform the consumer of the savings; and
- (3) Inform the consumer of the consumer's right to refuse substitution.

The pharmacist shall substitute an equivalent generic drug product if the practitioner does not prohibit substitution under subsection (b), and the substitute equivalent generic drug product results in a savings. The pharmacist shall not substitute if the consumer refuses.

(b) The pharmacist shall not substitute an equivalent generic drug product if the practitioner indicates "brand medically necessary" or words of similar meaning on the prescription. The designation "brand medically necessary" or other similar words or phrases must be handwritten by the practitioner and shall not be preprinted or stamped on the written prescription. The pharmacist shall not substitute an equivalent generic drug product if a prescription is orally or electronically ordered and the practitioner or authorized employee of the practitioner indicates "brand medically necessary" or other similar words or phrases.

The pharmacist shall note the practitioner's instructions on the prescription record required to be maintained under section 328-17.7.

This subsection shall not apply when it does not comply with any federal requirement for services reimbursable by medicaid or medicare.

(c) The pharmacist shall not substitute an equivalent generic drug product for any prescription for an anti-epileptic drug, except upon the consent of the practitioner and the patient or the patient's parent or guardian. This narrow exception for epileptic patients shall not be construed as a policy decision to make exceptions for any other conditions.

(d) The county prosecutors and the attorney general may bring action upon complaint by an aggrieved person or upon their own motion in the name of the State against any person to enjoin any violation of this part.

§328-93 REPEALED.

§328-94 Prescription record. Each pharmacist or practitioner shall maintain a record of any substitution of an equivalent generic drug product for a prescribed brand name drug product as provided in this part.

[§328-95] Establishment of drug product selection board. (a) There is established a drug product selection board composed of one representative from the department of health, one representative from either the University of Hawaii school of medicine or the University of Hawaii school of public health, two physicians, and two pharmacists; to be appointed by the governor with the advice and consent of the senate, pursuant to section 26-34. The board shall designate the chairman from its duly appointed membership. A seventh member shall be the director of health or the director's designated representative.

(b) The drug product selection board shall be placed, for administrative purposes only, within the department of health.

(c) The members of the drug product selection board shall serve without compensation, but shall be reimbursed for expenses, including travel expenses, incurred in the performance of their duties.

§328-96 Drug formulary. (a) The board may adopt rules, pursuant to chapter 91, to effectuate the purpose of this part. Without regard to chapter 91, the board may adopt as rules the compendia of therapeutically equivalent generic drugs as the state drug formulary of equivalent multiple source drug products. The board may adopt rules pursuant to chapter 91 to establish a Hawaii additions and deletions list; provided that section 328-92(c) shall apply, and no pharmacist shall substitute an equivalent generic drug product for any prescription for an anti-epileptic drug to treat epilepsy, except upon the consent of the practitioner and the patient or the patient's parent or guardian. Upon the adoption of the compendia of therapeutically equivalent generic drugs by the board, the board shall notify all pharmacies in the State and other interested individuals, within thirty working days, that the formulary has been updated. The Hawaii additions and deletions list may list additional substitutable drug products that are determined by the board to be safe, effective, and therapeutically equivalent. The Hawaii additions and deletions list may delete drug products listed in the compendia of therapeutically equivalent generic drugs upon the board's finding that product quality or therapeutic equivalency or bioequivalency, as appropriate, is not adequately assured.

(b) Pursuant to chapter 91, the Hawaii additions and deletions list may be changed, added to, or deleted from as the board deems appropriate. Any person who requests that any change be made or that a drug product be included or added to or deleted from the Hawaii additions and deletions list shall have the burden of proof to show cause why the change, inclusion, addition, or deletion should be made.

(c) The board shall revise or supplement the Hawaii additions and deletions list as necessary.

(d) The department shall provide for distribution of the Hawaii additions and deletions list and its revisions and supplements, and the dissemination of notices of changes to the compendia of therapeutically equivalent generic drugs, to all pharmacies in the State and to any other interested individuals. The department may establish fees to be charged to persons who receive the Hawaii additions and deletions list and its revisions and supplements, and notices of changes to the compendia of therapeutically equivalent generic drugs. The amounts of the fees charged shall be approximately the same as the costs of producing and distributing the Hawaii additions and deletions list and its revisions and supplements, and the notices of changes to the compendia of therapeutically equivalent generic drugs.

(e) Each pharmacy in the State shall:

- (1) Maintain, and update the compendia of therapeutically equivalent generic drugs as it is approved by the board; and
- (2) Obtain the Hawaii additions and deletions list.

(f) The department shall provide for public education regarding the provisions of this part and shall monitor the effects of this part.

[§328-97] Posting requirements. Every pharmacy shall prominently display, in clear and unobstructed public view, a sign in block letters which shall read: "HAWAII LAW REQUIRES THAT LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG PRODUCTS BE OFFERED TO THE CONSUMER. CONSULT YOUR PHYSICIAN AND PHARMACIST CONCERNING THE AVAILABILITY OF THE LEAST EXPENSIVE DRUG PRODUCT FOR YOUR USE." The letters must be at least one inch in height.

§328-98 Pharmacist liability. A pharmacist who selects an equivalent drug product pursuant to this part assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

§328-99 Exceptions. Out-of-state prescriptions filled pursuant to section 328-17.6 shall be exempt from this part.

§328-100 REPEALED.

§328-101 REPEALED.

[§328-102] Criminal penalty. Any person who wilfully violates this part or rules adopted under this part shall be guilty of a misdemeanor.

[§328-103] Administrative penalties. (a) Any person who violates this part or any rule adopted by the department of health pursuant to this part shall be fined not more than \$10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director of health may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violations, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director of health need only show that notice was given, a hearing was held or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and the penalty remains unpaid.

[§328-104] Injunctive relief. The director of health may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this part or of any rule adopted under this part. The court shall have the power to grant relief in accordance with the Hawaii rules of civil procedure.

[§328-105] Powers and duties. The department of health shall enforce this part and shall have, in connection therewith, all the powers and duties conferred and imposed upon it pursuant to part I.

**[PART VII.] WHOLESALE PRESCRIPTION DRUGS: STORAGE, HANDLING,
AND RECORDKEEPING**

[§328-111] Objective. The purpose of this part is to establish the minimum requirements for the storage and handling of wholesale prescription drugs and for the establishment and maintenance of prescription drug distribution records by wholesale distributors, as required by the federal Prescription Drug Marketing Act of 1987.

[§328-112] Definitions. As used in this part:

"Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

"Blood component" means that part of blood separated by physical or mechanical means.

"Common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

"Department" means the department of health except when otherwise provided.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling a prescription drug.

"Prescription drug" means any human drug required by federal or state statutes, regulations, or rules to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 328-16 or to section 503(b) of the federal Food, Drug, and Cosmetic Act.

"Wholesale distribution" means the distribution of prescription drugs to persons other than a consumer or patient, but does not include:

- (1) Intracompany sales, defined as any transaction or transfer between an entity and any division, subsidiary, parent, or affiliated or related company under common ownership and control;
- (2) The purchase or other acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug for the entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the group purchasing organization;
- (3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1986, as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;
- (5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this definition the term "emergency medical reasons" includes, but is not limited to, transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five per cent of the total

prescription drug sales revenue of either the transferor or transferee pharmacy during any period of twelve consecutive months;

- (6) The sale, purchase, or trade of a drug, or an offer to sell, purchase, or trade a drug, or the dispensing of a drug, pursuant to a prescription;
- (7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or
- (8) The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means any person or entity engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; jobbers; private label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; prescription drug repackagers; physicians; dentists; veterinarians; birth control and other clinics; individuals; hospitals; nursing homes and their providers; health maintenance organizations and other health care providers; and retail and hospital pharmacies that conduct wholesale distributions. The term "wholesale distributor" shall not include any carrier for hire or person or entity hired solely to transport prescription drugs.

[§328-113] Rules. (a) The department may adopt such rules as may be necessary to carry out the purposes and enforce the provisions of this part and to implement the requirements of 21 Code of Federal Regulations part 205, including minimum requirements for the storage and handling of wholesale prescription drugs; the keeping of records regarding their receipt and distribution; written policies and procedures for wholesale prescription drug distributors; and the salvaging and reprocessing of prescription drugs. All rules adopted under this part shall meet or exceed the requirements of the wholesale prescription drug distributor guidelines contained in 21 Code of Federal Regulations part 205, and in case of conflict between any rule adopted under this part and the provisions of 21 Code of Federal Regulations part 205, the more stringent provision shall prevail.

(b) The director may, without regard to chapter 91, adopt standards regarding conditions and temperatures for the storage of prescription drugs by reference to the provisions of an official compendium such as the United States Pharmacopeia/National Formulary (USP/NF), as updated from time to time.

[§328-114] Notice. Before any violation of this part is reported for the institution of a criminal proceeding, the person against whom the proceeding is contemplated shall be given appropriate notice and an opportunity to present the person's views before the department either orally or in writing, in person or by an attorney, with regard to the contemplated proceeding.

[§328-115] Inspection. Wholesale distributors shall permit agents of the department, agents of the department of commerce and consumer affairs, and authorized federal, state, or local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit

their records, written operating procedures, and lists of responsible persons, at reasonable times and in a reasonable manner, to the extent authorized by law.

[§328-116] Penalty; exceptions. (a) Any person who violates this part or rules adopted under this part shall be fined not more than \$500, or imprisoned not more than one year, or both.

(b) No person shall be subject to the penalties of subsection (a) of this section for having violated this part or rules adopted under this part if the person establishes a guaranty or undertaking signed by, and containing the name and address of, the individual from whom the person received the article in good faith, to the effect that the article is not adulterated or misbranded within the meaning of part I of this chapter.

[§328-117] Administrative penalties. (a) Any person who violates this part or any rule adopted by the department pursuant to this part shall be fined not more than \$10,000 for each separate offense. Any action taken to collect the penalty provided for in this subsection shall be considered a civil action.

(b) In addition to any other administrative or judicial remedy provided by this part, or by rules adopted pursuant to this part, the director may impose by order the administrative penalty specified in this section. Factors to be considered in imposing the administrative penalty include the nature and history of the violation and of any prior violation, and the opportunity, difficulty, and history of corrective action. For any judicial proceeding to recover the administrative penalty imposed, the director need only show that notice was given, a hearing was held, or the time granted for requesting a hearing has expired without such a request, the administrative penalty was imposed, and the penalty remains unpaid.

[§328-118] Injunctive relief. The director may institute a civil action in any court of competent jurisdiction for injunctive relief to prevent any violation of this part of any rule adopted under this part. The court shall have powers to grant relief in accordance with the Hawaii rules of civil procedure.

[§328-119] Minimum requirements for the storage and handling of prescription drugs. Wholesale distributors of prescription drugs and their officers, agents, representatives, and employees shall ensure that the following requirements are met:

- (1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered for sale or distribution, marketed, or displayed shall:
 - (A) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (B) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (C) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate

- containers or sealed secondary containers that have been opened;
 - (D) Be maintained in a clean and orderly condition; and
 - (E) Be free from infestation by insects, rodents, birds, and vermin of any kind.
- (2) Security.
- (A) All facilities used for wholesale distribution, storage, or warehousing of prescription drugs shall be secure from unauthorized entry.
 - (i) Access from outside the premises shall be kept to a minimum and shall be well controlled.
 - (ii) The outside perimeter of the premises shall be well lighted.
 - (iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
 - (B) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (C) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (3) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements, if any, in the labeling of the drugs, or in accordance with the standards regarding conditions and temperatures for the storage of prescription drugs adopted under this part.
- (A) If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.
 - (B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be used to document the proper storage of prescription drugs.
- (4) Examination of materials.
- (A) Upon receipt, each outside shipping container of prescription drugs shall be examined visually to confirm the identity of the drugs and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (B) Each outgoing shipment of prescription drugs shall be inspected carefully to confirm the identity of the drugs and to ensure that no prescription drugs are delivered that have been damaged in storage or held under improper conditions.
 - (C) The recordkeeping requirements in section 328-120 shall be followed for all incoming and outgoing prescription drugs.
- (5) Returned, damaged, outdated, deteriorated, misbranded, and adulterated prescription drugs.

- (A) Prescription drugs that are damaged, outdated, deteriorated, misbranded, or adulterated shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
- (B) Any prescription drugs whose immediate or sealed outer or sealed secondary containers are found upon arrival to have been opened or used shall be identified as such, and shall be physically separated from other prescription drugs and stored, in such a way that no cross-contamination or confusion are possible, until they are destroyed or returned to the supplier.
- (C) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be either destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
- (D) The recordkeeping requirements in section 328-120 shall be followed for all outdated, damaged, deteriorated, misbranded, adulterated or returned prescription drugs.

[§328-120] Recordkeeping. (a) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

- (1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
 - (2) The identity and quantity of the drugs received and distributed or disposed of; and
 - (3) The dates of receipt and distribution or other disposition of the drugs.
- (b) Inventories and records shall be made available for inspection and photocopying by the department or any authorized federal, state, or local law enforcement officials for a period of five years following disposition of the drugs.
- (c) Records described in this section that are kept at the inspection site or that can be retrieved immediately by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by the department or any authorized official of a federal, state, or local law enforcement agency.

[§328-121] Written policies and procedures. Wholesale distributors shall establish, maintain, and follow written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale distributors shall include in their written policies and procedures the following:

- (1) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary and appropriate.
- (2) A procedure for handling recalls and withdrawals of prescription drugs. The procedure shall be adequate to deal with recalls and withdrawals caused by:
 - (A) Any action initiated at the request of the department, the Food and Drug Administration, or any other federal, state, or local law enforcement or other government agency;
 - (B) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
 - (C) Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.
- (3) A procedure to ensure that the distributor prepares for, protects against, and handles properly any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or in other emergencies.
- (4) A procedure to ensure that all outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall require written documentation of the disposition of outdated prescription drugs, which documentation shall be maintained for five years after disposition of the outdated drugs.

[§328-122] Responsible persons. Wholesale distributors shall establish and maintain current lists of officers, directors, managers, and other persons in charge of the wholesale distribution, storage, and handling of prescription drugs, including a description of each person's duties and a summary of each person's qualifications.

[§328-123] Salvaging and reprocessing. Wholesale distributors shall be subject to the provisions of 21 Code of Federal Regulations parts 207, 210, and 211, regarding salvaging and reprocessing of prescription drugs.