RCW 69.48.020 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

(1) "Administer" means the direct application of a legend drug whether by injection, inhalation, ingestion, or any other means, to the body of the patient or research subject by:

(a) A practitioner; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Authorized collector" means any of the following persons or entities that have entered into an agreement with a program operator to collect covered drugs:

(a) A person or entity that is registered with the United States drug enforcement administration and that qualifies under federal law to modify its registration to collect controlled substances for the purpose of destruction;

(b) A law enforcement agency; or

(c) An entity authorized by the department to provide an alternative collection mechanism for certain covered drugs that are not controlled substances, as defined in RCW 69.50.101.

(3) "Collection site" means the location where an authorized collector operates a secure collection receptacle for collecting covered drugs.

(4)(a) "Covered drug" means a drug from a covered entity that the covered entity no longer wants and that the covered entity has abandoned or discarded or intends to abandon or discard. "Covered drug" includes legend drugs and nonlegend drugs, brand name and generic drugs, drugs for veterinary use for household pets, and drugs in medical devices and combination products.

(b) "Covered drug" does not include:

(i) Vitamins, minerals, or supplements;

(ii) Herbal-based remedies and homeopathic drugs, products, or remedies;

(iii) Controlled substances contained in schedule I of the uniform controlled substances act, chapter 69.50 RCW;

(iv) Cosmetics, shampoos, sunscreens, lip balm, toothpaste, antiperspirants, or other personal care products that are regulated as both cosmetics and nonprescription drugs under the federal food, drug, and cosmetic act, 21 U.S.C. Sec. 301 et seq.;

(v) Drugs for which manufacturers provide a pharmaceutical product stewardship or drug take-back program as part of a federal food and drug administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1;

(vi) Biological drug products, as defined by 21 C.F.R. 600.3 (h) as it exists on June 7, 2018, for which manufacturers provide a pharmaceutical product stewardship or drug take-back program and who provide the department with a report describing the program, including how the drug product is collected and safely disposed and how patients are made aware of the drug take-back program, and who updates the department on changes that substantially alter their drug take-back program;

(vii) Drugs that are administered in a clinical setting;

(viii) Emptied injector products or emptied medical devices and their component parts or accessories;

(ix) Exposed needles or sharps, or used drug products that are medical wastes; or

(x) Pet pesticide products contained in pet collars, powders, shampoos, topical applications, or other forms.

(5) "Covered entity" means a state resident or other nonbusiness entity and includes an ultimate user, as defined by regulations adopted by the United States drug enforcement administration. "Covered entity" does not include a business generator of pharmaceutical waste, such as a hospital, clinic, health care provider's office, veterinary clinic, pharmacy, or law enforcement agency.

(6) "Covered manufacturer" means a person, corporation, or other entity engaged in the manufacture of covered drugs sold in or into Washington state. "Covered manufacturer" does not include:

(a) A private label distributor or retail pharmacy that sells a drug under the retail pharmacy's store label if the manufacturer of the drug is identified under RCW 69.48.040;

(b) A repackager if the manufacturer of the drug is identified under RCW 69.48.040; or

(c) A nonprofit, 501(c)(3) health care corporation that repackages drugs solely for the purpose of supplying a drug to facilities or retail pharmacies operated by the corporation or an affiliate of the corporation if the manufacturer of the drug is identified under RCW 69.48.040.

(7) "Department" means the department of health.

(8)(a) "Drug" means:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

(b) Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in human beings or animals;

(c) Substances other than food, minerals, or vitamins that are intended to affect the structure or any function of the body of human beings or animals; and

(d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection.

(9) "Drug take-back organization" means an organization designated by a manufacturer or group of manufacturers to act as an agent on behalf of each manufacturer to develop and implement a drug take-back program.

(10) "Drug take-back program" or "program" means a program implemented by a program operator for the collection, transportation, and disposal of covered drugs.

(11) "Drug wholesaler" means an entity licensed as a wholesaler under chapter 18.64 RCW.

(12) "Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. The inactive ingredients in a generic drug need not be identical to the inactive ingredients in the chemically identical or bioequivalent brand name drug.

(13) "Legend drug" means a drug, including a controlled substance under chapter 69.50 RCW, that is required by any applicable federal or state law or regulation to be dispensed by prescription only or that is restricted to use by practitioners only.

(14) "Mail-back distribution location" means a facility, such as a town hall or library, that offers prepaid, preaddressed mailing envelopes to covered entities.

(15) "Mail-back program" means a method of collecting covered drugs from covered entities by using prepaid, preaddressed mailing envelopes.

(16) "Manufacture" has the same meaning as in RCW 18.64.011.

(17) "Nonlegend drug" means a drug that may be lawfully sold without a prescription.

(18) "Pharmacy" means a place licensed as a pharmacy under chapter 18.64 RCW.

(19) "Private label distributor" means a company that has a valid labeler code under 21 C.F.R. Sec. 207.17 and markets a drug product under its own name, but does not perform any manufacturing.

(20) "Program operator" means a drug take-back organization, covered manufacturer, or group of covered manufacturers that implements or intends to implement a drug take-back program approved by the department.

(21) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package containing a covered drug for further sale, or for distribution without further transaction.

(22) "Retail pharmacy" means a place licensed as a pharmacy under chapter 18.64 RCW for the retail sale and dispensing of drugs.

(23) "Secretary" means the secretary of health. [2018 c 196 s 2.]

Sunset Act application: See note following chapter digest.