Chapter 69.45 RCW
DRUG SAMPLES

Sections

RCW 69.45.010 Definitions. The definitions in this section apply throughout this chapter.

(1) "Commission" means the pharmacy quality assurance commission.

(2) "Controlled substance" means a drug, substance, or immediate precursor of such drug or substance, so designated under or pursuant to chapter 69.50 RCW, the uniform controlled substances act.

(3) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a drug or device, whether or not there is an agency relationship.

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

(5) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(6) "Distribute" means to deliver, other than by administering or dispensing, a legend drug.

(7) "Drug samples" means any federal food and drug administration approved controlled substance, legend drug, or products requiring prescriptions in this state, which is distributed at no charge to a practitioner by a manufacturer or a manufacturer's representative, exclusive of drugs under clinical investigations approved by the federal food and drug administration.

(8) "Legend drug" means any drug that is required by state law or by regulations of the commission to be dispensed on prescription only or is restricted to use by practitioners only.

(9) "Manufacturer" means a person or other entity engaged in the manufacture or distribution of drugs or devices, but does not include a manufacturer's representative.

(10) "Manufacturer's representative" means an agent or employee of a drug manufacturer who is authorized by the drug manufacturer to

possess drug samples for the purpose of distribution in this state to appropriately authorized health care practitioners.

(11) "Person" means any individual, corporation, government or governmental subdivision or agency, business trust, estate, trust, partnership, association, or any other legal entity.

(12) "Practitioner" means a physician under chapter 18.71 RCW, an osteopathic physician or an osteopathic physician and surgeon under chapter 18.57 RCW, a dentist under chapter 18.32 RCW, a podiatric physician and surgeon under chapter 18.22 RCW, a veterinarian under chapter 18.92 RCW, a pharmacist under chapter 18.64 RCW, a commissioned medical or dental officer in the United States armed forces or the public health service in the discharge of his or her official duties, a duly licensed physician or dentist employed by the veterans administration in the discharge of his or her official duties, a registered nurse or *advanced registered nurse practitioner under chapter 18.79 RCW when authorized to prescribe by the **nursing care quality assurance commission, or a physician assistant under chapter 18.71A RCW when authorized by the Washington medical commission.

(13) "Reasonable cause" means a state of facts found to exist that would warrant a reasonably intelligent and prudent person to believe that a person has violated state or federal drug laws or regulations.

(14) "Secretary" means the secretary of health or the secretary's designee. [2020 c 80 s 42; 2019 c 55 s 10. Prior: 2013 c 19 s 81; 1994 sp.s. c 9 s 738; 1989 1st ex.s. c 9 s 444; 1987 c 411 s 1.]

Reviser's note: *(1) The term "advanced registered nurse practitioner" was changed to "advanced practice registered nurse" by 2024 c 239 s 1, effective June 30, 2027.

**(2) The reference to "nursing care quality assurance commission" was changed to "board of nursing" by 2023 c 123.

Effective date—2020 c 80 ss 12-59: See note following RCW 7.68.030.

Intent—2020 c 80: See note following RCW 18.71A.010.

Severability—Headings and captions not law—Effective date—1994 sp.s. c 9: See RCW 18.79.900 through 18.79.902.

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

RCW 69.45.020 Registration of manufacturers—Additional information required by the department. A manufacturer that intends to distribute drug samples in this state shall register annually with the department, providing the name and address of the manufacturer, and shall:

(1) Provide a twenty-four hour telephone number and the name of the individual(s) who shall respond to reasonable official inquiries from the department, as directed by the commission, based on reasonable cause, regarding required records, reports, or requests for information pursuant to a specific investigation of a possible violation. Each official request by the department and each response by a manufacturer shall be limited to the information specifically

relevant to the particular official investigation. Requests for the address of sites in this state at which drug samples are stored by the manufacturer's representative and the names and addresses of the individuals who are responsible for the storage or distribution of the drug samples shall be responded to as soon as possible but not later than the close of business on the next business day following the request; or

(2) If a twenty-four hour telephone number is not available, provide the addresses of sites in this state at which drug samples are stored by the manufacturer's representative, and the names and addresses of the individuals who are responsible for the storage or distribution of the drug samples. The manufacturer shall annually submit a complete updated list of the sites and individuals to the department. [2013 c 19 s 82; 1989 1st ex.s. c 9 s 445; 1987 c 411 s 2.]

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

RCW 69.45.030 Records maintained by manufacturer—Report of loss or theft of drug samples—Reports of practitioners receiving controlled substance drug samples. (1) The following records shall be maintained by the manufacturer distributing drug samples in this state and shall be available for inspection by authorized representatives of the department based on reasonable cause and pursuant to an official investigation:

(a) An inventory of drug samples held in this state for distribution, taken at least annually by a representative of the manufacturer other than the individual in direct control of the drug samples;

(b) Records or documents to account for all drug samples distributed, destroyed, or returned to the manufacturer. The records shall include records for sample drugs signed for by practitioners, dates and methods of destruction, and any dates of returns; and

(c) Copies of all reports of lost or stolen drug samples.

(2) All required records shall be maintained for two years and shall include transaction dates.

(3) Manufacturers shall report to the department the discovery of any loss or theft of drug samples as soon as possible but not later than the close of business on the next business day following the discovery.

(4) Manufacturers shall report to the department as frequently as, and at the same time as, their other reports to the federal drug enforcement administration, or its lawful successor, the name, address and federal registration number for each practitioner who has received controlled substance drug samples and the name, strength and quantity of the controlled substance drug samples distributed. [1989 1st ex.s. c 9 s 446; 1987 c 411 s 3.]

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

RCW 69.45.040 Storage and transportation of drug samples—Disposal of samples which have exceeded their expiration dates. (1)

Drug samples shall be stored in compliance with the requirements of federal and state laws, rules, and regulations.

(2) Drug samples shall be maintained in a locked area to which access is limited to persons authorized by the manufacturer.

(3) Drug samples shall be stored and transported in such a manner as to be free of contamination, deterioration, and adulteration.

(4) Drug samples shall be stored under conditions of temperature, light, moisture, and ventilation so as to meet the label instructions for each drug.

(5) Drug samples which have exceeded the expiration date shall be physically separated from other drug samples until disposed of or returned to the manufacturer. [1987 c 411 s 4.]

RCW 69.45.050 Distribution of drug samples—Written request—No fee or charge permitted—Possession of legend drugs or controlled substances by manufacturers' representatives. (1) Drug samples may be distributed by a manufacturer or a manufacturer's representative only to practitioners legally authorized to prescribe such drugs or, at the request of such practitioner, to pharmacies of hospitals or other health care entities. The recipient of the drug sample must execute a written receipt upon delivery that is returned to the manufacturer or the manufacturer's representative.

(2) Drug samples may be distributed by a manufacturer or a manufacturer's representative only to a practitioner legally authorized to prescribe such drugs pursuant to a written request for such samples. The request shall contain:

(a) The recipient's name, address, and professional designation;

(b) The name, strength, and quantity of the drug samples delivered;

(c) The name or identification of the manufacturer and of the individual distributing the drug sample; and

(d) The dated signature of the practitioner requesting the drug sample.

(3) No fee or charge may be imposed for sample drugs distributed in this state.

(4) A manufacturer's representative shall not possess legend drugs or controlled substances other than those distributed by the manufacturer they represent. Nothing in this section prevents a manufacturer's representative from possessing a legally prescribed and dispensed legend drug or controlled substance. [1989 c 164 s 2; 1987 c 411 s 5.]

Legislative finding—1989 c 164: "The legislature finds that chapter 69.45 RCW is more restrictive than the federal prescription drug marketing act of 1987, and the legislature further finds that a change in chapter 69.45 RCW accepting the position of the federal law is beneficial to the citizens of this state." [1989 c 164 s 1.]

RCW 69.45.060 Disposal of surplus, outdated, or damaged drug samples. Surplus, outdated, or damaged drug samples shall be disposed of as follows:

(1) Returned to the manufacturer; or

(2) Witnessed destruction by such means as to assure that the drug cannot be retrieved. However, controlled substances shall be

returned to the manufacturer or disposed of in accordance with rules adopted by the commission: PROVIDED, That the commission shall adopt by rule the regulations of the federal drug enforcement administration or its lawful successor unless, stating reasonable grounds, it adopts rules consistent with such regulations. [2013 c 19 s 83; 1987 c 411 s 6.]

RCW 69.45.070 Registration fees—Penalty. The department may charge reasonable fees for registration. The registration fee shall not exceed the fee charged by the department for a pharmacy location license. If the registration fee is not paid on or before the date due, a renewal or new registration may be issued only upon payment of the registration renewal fee and a penalty fee equal to the registration renewal fee. [1991 c 229 s 8; 1989 1st ex.s. c 9 s 447; 1987 c 411 s 7.]

Effective date—Severability—1989 1st ex.s. c 9: See RCW 43.70.910 and 43.70.920.

RCW 69.45.080 Violations of chapter—Manufacturer's liability—Enforcement—Seizure of drug samples. (1) The manufacturer is responsible for the actions and conduct of its representatives with regard to drug samples.

(2) Chapter 18.64 RCW governs the denial of licenses and the discipline of persons registered under this chapter.

(3) Specific drug samples which are distributed in this state in violation of this chapter, following notification by the commission, shall be subject to seizure following the procedures set out in RCW 69.41.060. [2024 c 121 s 41; 2013 c 19 s 84; 1987 c 411 s 8.]

RCW 69.45.085 Uniform disciplinary act. The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice of persons required to obtain a registration under this chapter. [2024 c 121 s 42.]

RCW 69.45.090 Confidentiality. All records, reports, and information obtained by the commission from or on behalf of a manufacturer or manufacturer's representative under this chapter are confidential and exempt from public inspection and copying under chapter 42.56 RCW. This section does not apply to public disclosure of the identity of persons found by the commission to have violated state or federal law, rules, or regulations. This section is not intended to restrict the investigations and proceedings of the commission so long as the commission maintains the confidentiality required by this section. [2013 c 19 s 85; 2005 c 274 s 330; 1987 c 411 s 9.]