

ensure compliance with this chapter and the treatment standard authorized by this chapter. A methadone treatment center shall not have a caseload in excess of three hundred fifty persons. The caseload limit shall not be enforced so as to terminate involuntarily any person participating in a methadone program as of the effective date of this act. Any methadone program exceeding the caseload limit on the effective date of this act shall be allowed to continue to serve existing clients but not take on new clients until the program caseload has been decreased, through attrition, to three hundred fifty persons.

(2) The department, in consultation with treatment service providers, shall establish state-wide operating standards for methadone treatment centers no later than August 1, 1987, and shall submit such operating standards to the legislature in a report for review and consideration prior to the regular session of the legislature in 1988. The department and counties that authorize methadone treatment programs shall enforce these operating standards. The operating standards shall include, but not be limited to reasonable provisions necessary to enable the department and authorizing counties to monitor certified and licensed methadone treatment programs for compliance with this chapter and the treatment standards authorized by this chapter and to minimize the impact of the treatment programs upon the business and residential neighborhoods in which the program is located.

NEW SECTION. Sec. 5. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. Sec. 6. This act is necessary for the immediate preservation of the public peace, health, and safety, the support of the state government and its existing public institutions, and shall take effect immediately.

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CHAPTER 411

[Engrossed Substitute House Bill No. 931]

DRUG SAMPLES

AN ACT Relating to regulating the possession and distribution of legend drug samples; reenacting and amending RCW 42.17.310; adding a new chapter to Title 69 RCW; and prescribing penalties.

Be it enacted by the Legislature of the State of Washington:

NEW SECTION. Sec. 1. The definitions in this section apply throughout this chapter.

(1) "Board" means the board of pharmacy.

(2) "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.

(3) "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.

(4) "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.

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

(8) "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.

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

(10) "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 podiatrist 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 under chapter 18.88 RCW when authorized to prescribe by the board of nursing, an osteopathic physician's assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, or a physician's assistant under chapter 18.71A RCW when authorized by the board of medical examiners.

(11) "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.

(12) "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.

NEW SECTION. Sec. 2. A manufacturer that intends to distribute drug samples in this state shall register annually with the board, providing the name and address of the manufacturer, and shall:

(1) Provide the board with a twenty-four hour telephone number and the name of the individual(s) who shall respond to reasonable official inquiries from the board, 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 board 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 board's 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 board with 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 board.

NEW SECTION. Sec. 3. (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 board 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 board the discovery of any loss or theft of drug samples as soon as possible but not later than the board's close of business on the next business day following the discovery.

(4) Manufacturers shall report to the board 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.

NEW SECTION. Sec. 4. (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.

NEW SECTION. Sec. 5. (1) Drug samples may be distributed by a manufacturer or a manufacturer's representative only to practitioners legally authorized to prescribe such drugs.

(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.

NEW SECTION. Sec. 6. 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 board:

PROVIDED, That the board 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.

NEW SECTION. Sec. 7. The board may charge reasonable fees for registration. The registration fee shall not exceed the fee charged by the board for a pharmacy location license.

NEW SECTION. Sec. 8. (1) The manufacturer is responsible for the actions and conduct of its representatives with regard to drug samples.

(2) The board may hold a public hearing to examine a possible violation and may require a designated representative of the manufacturer to attend.

(3) If a manufacturer fails to comply with this chapter following notification by the board, the board may impose a civil penalty of up to five thousand dollars. The board shall take no action to impose any civil penalty except pursuant to a hearing held in accordance with chapter 34.04 RCW.

(4) Specific drug samples which are distributed in this state in violation of this chapter, following notification by the board, shall be subject to seizure following the procedures set out in RCW 69.41.060.

NEW SECTION. Sec. 9. All records, reports, and information obtained by the board 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 42.17 RCW. This section does not apply to public disclosure of the identity of persons found by the board to have violated state or federal law, rules, or regulations. This section is not intended to restrict the investigations and proceedings of the board so long as the board maintains the confidentiality required by this section.

Sec. 10. Section 31, chapter 1, Laws of 1973 as last amended by section 7, chapter 276, Laws of 1986 and by section 25, chapter 299, Laws of 1986 and RCW 42.17.310 are each reenacted and amended to read as follows:

(1) The following are exempt from public inspection and copying:

(a) Personal information in any files maintained for students in public schools, patients or clients of public institutions or public health agencies, welfare recipients, prisoners, probationers, or parolees.

(b) Personal information in files maintained for employees, appointees, or elected officials of any public agency to the extent that disclosure would violate their right to privacy.

(c) Information required of any taxpayer in connection with the assessment or collection of any tax if the disclosure of the information to other persons would (i) be prohibited to such persons by RCW 82.32.330 or (ii) violate the taxpayer's right to privacy or result in unfair competitive disadvantage to the taxpayer.

(d) Specific intelligence information and specific investigative records compiled by investigative, law enforcement, and penology agencies, and state agencies vested with the responsibility to discipline members of any profession, the nondisclosure of which is essential to effective law enforcement or for the protection of any person's right to privacy.

(e) Information revealing the identity of persons who file complaints with investigative, law enforcement, or penology agencies, other than the public disclosure commission, if disclosure would endanger any person's life, physical safety, or property: PROVIDED, That if at the time the complaint is filed the complainant indicates a desire for disclosure or nondisclosure, such desire shall govern: PROVIDED, FURTHER, That all complaints filed with the public disclosure commission about any elected official or candidate for public office must be made in writing and signed by the complainant under oath.

(f) Test questions, scoring keys, and other examination data used to administer a license, employment, or academic examination.

(g) Except as provided by chapter 8.26 RCW, the contents of real estate appraisals, made for or by any agency relative to the acquisition or sale of property, until the project or prospective sale is abandoned or until such time as all of the property has been acquired or the property to which the sale appraisal relates is sold, but in no event shall disclosure be denied for more than three years after the appraisal.

(h) Valuable formulae, designs, drawings, and research data obtained by any agency within five years of the request for disclosure when disclosure would produce private gain and public loss.

(i) Preliminary drafts, notes, recommendations, and intra-agency memorandums in which opinions are expressed or policies formulated or recommended except that a specific record shall not be exempt when publicly cited by an agency in connection with any agency action.

(j) Records which are relevant to a controversy to which an agency is a party but which records would not be available to another party under the rules of pretrial discovery for causes pending in the superior courts.

(k) Records, maps, or other information identifying the location of archaeological sites in order to avoid the looting or depredation of such sites.

(l) Any library record, the primary purpose of which is to maintain control of library materials, or to gain access to information, which discloses or could be used to disclose the identity of a library user.

(m) Financial information supplied by or on behalf of a person, firm, or corporation for the purpose of qualifying to submit a bid or proposal for (a) a ferry system construction or repair contract as required by RCW 47-.60.680 through 47.60.750 or (b) highway construction or improvement as required by RCW 47.28.070.

(n) Railroad company contracts filed with the utilities and transportation commission under RCW 81.34.070, except that the summaries of the contracts are open to public inspection and copying as otherwise provided by this chapter.

(o) Financial and commercial information and records supplied by private persons pertaining to export services provided pursuant to chapter 53-.31 RCW.

(p) Financial disclosures filed by private vocational schools under chapter 28C.10 RCW.

(q) Information obtained by the board of pharmacy as provided in section 9 of this 1987 act.

(2) Except for information described in subsection (1)(c)(i) of this section and confidential income data exempted from public inspection pursuant to RCW 84.40.020, the exemptions of this section are inapplicable to the extent that information, the disclosure of which would violate personal privacy or vital governmental interests, can be deleted from the specific records sought. No exemption may be construed to permit the nondisclosure of statistical information not descriptive of any readily identifiable person or persons.

(3) Inspection or copying of any specific records exempt under the provisions of this section may be permitted if the superior court in the county in which the record is maintained finds, after a hearing with notice thereof to every person in interest and the agency, that the exemption of such records is clearly unnecessary to protect any individual's right of privacy or any vital governmental function.

(4) Agency responses refusing, in whole or in part, inspection of any public record shall include a statement of the specific exemption authorizing the withholding of the record (or part) and a brief explanation of how the exemption applies to the record withheld.

NEW SECTION. Sec. 11. Sections 1 through 9 of this act shall constitute a new chapter in Title 69 RCW.

NEW SECTION. Sec. 12. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

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