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SENATE BILL 6021

State of Washington 54th Legislature 1995 Regular Session

By Senators Moyer, Prentice, Palmer, Franklin, Fairley, Winsley, C. Anderson, McAuliffe, Deccio, Snyder, McDonald, Sellar, Kohl, Schow, Johnson, Wood, A. Anderson, Pelz, Bauer, Drew and Oke

Read first time 02/23/95. Referred to Committee on Health & Long-Term Care.

AN ACT Relating to health care entity authority regarding drugs; amending RCW 18.64.011 and 18.64.255; reenacting and amending RCW 18.64.165; and adding new sections to chapter 18.64 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

Sec. 1. RCW 18.64.011 and 1989 1st ex.s. c 9 s 412 are each amended to read as follows:

Unless the context clearly requires otherwise, definitions of terms shall be as indicated when used in this chapter.

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

(2) "Board" means the Washington state board of pharmacy.

(3) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia or the official homeopathic pharmacopoeia of the United States;

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

(c) Substances (other than food) intended to affect the structure or any function of the body of man or other animals; or

(d) Substances intended for use as a component of any substances specified in (a), (b), or (c) of this subsection, but not including devices or their component parts or accessories.

(4) "Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (a) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, or (b) to affect the structure or any function of the body of man or other animals.

(5) "Nonlegend" or "nonprescription" drugs means any drugs which may be lawfully sold without a prescription.

(6) "Legend drugs" means any drugs which are required by any applicable federal or state law or regulation to be dispensed on prescription only or are restricted to use by practitioners only.

(7) "Controlled substance" means a drug or substance, or an immediate precursor of such drug or substance, so designated under or pursuant to the provisions of chapter 69.50 RCW.

(8) "Prescription" means an order for drugs or devices issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe drugs or devices in the course of his or her professional practice for a legitimate medical purpose.

(9) "Practitioner" means a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

(10) "Pharmacist" means a person duly licensed by the Washington state board of pharmacy to engage in the practice of pharmacy.

(11) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

(12) "Pharmacy" means every place properly licensed by the board of pharmacy where the practice of pharmacy is conducted.

(13) The words "drug" and "devices" shall not include surgical or dental instruments or laboratory materials, gas and oxygen, therapy equipment, X-ray apparatus or therapeutic equipment, their component parts or accessories, or equipment, instruments, apparatus, or contrivances used to render such articles effective in medical, surgical, or dental treatment, or for use or consumption in or for mechanical, industrial, manufacturing, or scientific applications or purposes, nor shall the word "drug" include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended, nor medicated feed intended for and used exclusively as a feed for animals other than man.

(14) The word "poison" shall not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(15) "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.

(16) "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.

(17) "Distribute" means the delivery of a drug or device other than by administering or dispensing.

(18) "Compounding" shall be the act of combining two or more ingredients in the preparation of a prescription.

(19) "Wholesaler" shall mean a corporation, individual, or other entity which buys drugs or devices for resale and distribution to corporations, individuals, or entities other than consumers.

(20) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of a practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, prepares, compounds, packages, or labels such substance or device.

(21) "Manufacturer" shall mean a person, corporation, or other entity engaged in the manufacture of drugs or devices.

(22) "Labeling" shall mean the process of preparing and affixing a label to any drug or device container. The label must include all information required by current federal and state law and pharmacy rules.

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

(24) "Master license system" means the mechanism established by chapter 19.02 RCW by which master licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a master application and a master license expiration date common to each renewable license endorsement.

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

(26) "Secretary" means the secretary of health or the secretary's designee.

(27) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state. Health care entity includes a free-standing outpatient surgery center, a free-standing cardiac care center, or a kidney dialysis center. It does not include an individual practitioner's office or a multipractitioner clinic.

NEW SECTION. **Sec. 2.** A new section is added to chapter 18.64 RCW to read as follows:

(1) In order for a health care entity to purchase, administer, dispense, and deliver legend drugs, the health care entity must be licensed by the department.

(2) In order for a health care entity to purchase, administer, dispense, and deliver controlled substances, the health care entity must annually obtain a license from the department in accordance with the board's rules.

(3) The receipt, administration, dispensing, and delivery of legend drugs or controlled substances by a health care entity must be performed under the supervision or at the direction of a pharmacist.

(4) A health care entity may only administer, dispense, or deliver legend drugs and controlled substances to patients who receive care within the health care entity and in compliance with rules of the board. Nothing in this subsection shall prohibit a practitioner, in carrying out his or her licensed responsibilities within a health care

entity, from dispensing or delivering to a patient of the health care entity drugs for that patient's personal use in an amount not to exceed seventy-two hours of usage.

NEW SECTION. **Sec. 3.** A new section is added to chapter 18.64 RCW to read as follows:

(1) The owner of a health care entity shall pay an original license fee to be determined by the secretary, and annually thereafter, on or before a date to be determined by the secretary, a fee to be determined by the secretary, for which he or she shall receive a license of location, which shall entitle the owner to purchase legend drugs or controlled substances at the location specified for the period ending on a date to be determined by the secretary. A declaration of ownership and location filed with the department under this section shall be deemed presumptive evidence of ownership of the health care entity.

(2) The owner shall immediately notify the department of any change of location or ownership in which case a new application and fee shall be submitted.

(3) It shall be the duty of the owner to keep the license of location or the renewal license properly exhibited in the health care entity.

(4) Failure to comply with this section is a misdemeanor and each day that the failure continues is a separate offense.

(5) In the event that a license fee remains unpaid after the date due, no renewal or new license may be issued except upon payment of the license renewal fee and a penalty fee equal to the original license fee.

Sec. 4. RCW 18.64.165 and 1989 1st ex.s. c 9 s 404 and 1989 c 352 s 4 are each reenacted and amended to read as follows:

The board shall have the power to refuse, suspend, or revoke the license of any manufacturer, wholesaler, pharmacy, shopkeeper, itinerant vendor, peddler, poison distributor, health care entity, or precursor chemical distributor upon proof that:

(1) The license was procured through fraud, misrepresentation, or deceit;

(2) The licensee has violated or has permitted any employee to violate any of the laws of this state or the United States relating to

drugs, controlled substances, cosmetics, or nonprescription drugs, or has violated any of the rules and regulations of the board of pharmacy or has been convicted of a felony.

NEW SECTION. **Sec. 5.** A new section is added to chapter 18.64 RCW to read as follows:

Every proprietor or manager of a health care entity shall keep readily available a suitable record of drugs, which shall preserve for a period of not less than two years the record of every drug used at such health care entity. The record shall be maintained either separately from all other records of the health care entity or in such form that the information required is readily retrievable from ordinary business records of the health care entity. All record-keeping requirements for controlled substances must be complied with. Such record of drugs shall be for confidential use in the health care entity, only. The record of drugs shall be open for inspection by the board of pharmacy, who is authorized to enforce chapter 18.64, 69.41, or 69.50 RCW.

Sec. 6. RCW 18.64.255 and 1984 c 153 s 14 are each amended to read as follows:

Nothing in this chapter shall operate in any manner:

(1) To restrict the scope of authorized practice of any practitioner other than a pharmacist, duly licensed as such under the laws of this state. However, a health care entity shall comply with all state and federal laws and rules relating to the dispensing of drugs and the practice of pharmacy; or

(2) In the absence of the pharmacist from the hospital pharmacy, to prohibit a registered nurse designated by the hospital and the responsible pharmacist from obtaining from the hospital pharmacy such drugs as are needed in an emergency: PROVIDED, That proper record is kept of such emergency, including the date, time, name of prescriber, the name of the nurse obtaining the drugs, and a list of what drugs and quantities of same were obtained; or

(3) To prevent shopkeepers, itinerant vendors, peddlers, or salesmen from dealing in and selling nonprescription drugs, if such drugs are sold in the original packages of the manufacturer, or in packages put up by a licensed pharmacist in the manner provided by the

state board of pharmacy, if such shopkeeper, itinerant vendor, salesman, or peddler shall have obtained a registration.

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