ESSB 5460 - H COMM AMD
By Committee on Health Care & Wellness

ADOPTED AND ENGROSSED 4/13/2015

Strike everything after the enacting clause and insert the following:

"NEW SECTION. **Sec. 1.** A new section is added to chapter 70.41 RCW to read as follows:

(1) The legislature finds that high quality, safe, and compassionate health care services for patients of Washington state must be available at all times. The legislature further finds that there is a need for patients being released from hospital emergency departments to maintain access to emergency medications when community or hospital pharmacy services are not available. It is the intent of the legislature to accomplish this objective by allowing practitioners with prescriptive authority to prescribe limited amounts of prepackaged emergency medications to patients being discharged from hospital emergency departments when access to community or outpatient hospital pharmacy services is not otherwise available.

(2) A hospital may allow a practitioner to prescribe prepackaged emergency medications and allow a practitioner or a registered nurse licensed under chapter 18.79 RCW to distribute prepackaged emergency medications to patients being discharged from a hospital emergency department during times when community or outpatient hospital pharmacy services are not available within fifteen miles by road or when, in the judgment of the practitioner and consistent with hospital policies and procedures, a patient has no reasonable ability to reach the local community or outpatient pharmacy. A hospital may only allow this practice if: The director of the hospital pharmacy, in collaboration with appropriate hospital medical staff, develops policies and procedures regarding the following:

(a) Development of a list, preapproved by the pharmacy director, of the types of emergency medications to be prepackaged and distributed;

(b) Assurances that emergency medications to be prepackaged pursuant to this section are prepared by a pharmacist or under the supervision of a pharmacist licensed under chapter 18.64 RCW;

(c) Development of specific criteria under which emergency prepackaged medications may be prescribed and distributed consistent with the limitations of this section;

(d) Assurances that any practitioner authorized to prescribe prepackaged emergency medication or any nurse authorized to distribute prepackaged emergency medication is trained on the types of medications available and the circumstances under which they may be distributed;

(e) Procedures to require practitioners intending to prescribe prepackaged emergency medications pursuant to this section to maintain a valid prescription either in writing or electronically in the patient's records prior to a medication being distributed to a patient;

(f) Establishment of a limit of no more than a forty-eight hour supply of emergency medication as the maximum to be dispensed to a patient, except when community or hospital pharmacy services will not be available within forty-eight hours. In no case may the policy allow a supply exceeding ninety-six hours be dispensed;

(g) Assurances that prepackaged emergency medications will be kept in a secure location in or near the emergency department in such a manner as to preclude the necessity for entry into the pharmacy; and

(h) Assurances that nurses or practitioners will distribute prepackaged emergency medications to patients only after a practitioner has counseled the patient on the medication.

(3) The delivery of a single dose of medication for immediate administration to the patient is not subject to the requirements of this section.

(4) For purposes of this section:

(a) "Emergency medication" means any medication commonly prescribed to emergency room patients, including those drugs, substances or immediate precursors listed in schedules II through V of the uniform controlled substances act, chapter 69.50 RCW, as now or hereafter amended.

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

(c) "Practitioner" means any person duly authorized by law or rule in the state of Washington to prescribe drugs as defined in RCW 18.64.011(24).

(d) "Nurse" means a registered nurse as defined in RCW 18.79.020.

NEW SECTION. **Sec. 2.** A new section is added to chapter 70.41 RCW to read as follows:

(1) The legislature recognizes that in order for hospitals to ensure drugs are accessible to patients and the public to meet hospital and community health care needs, certain transfers of drugs must be authorized between hospitals and their affiliated or related companies under common ownership and control of the corporate entity and for emergency medical reasons.

(2) A licensed hospital pharmacy is permitted, without a wholesaler license, to:

(a) Engage in intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent company, affiliated company, or related company under common ownership and control of the corporate entity, unless the transfer occurs between a wholesale distributor and a health care entity or practitioner; and

(b) Sell, purchase, or trade a drug or offer to sell, purchase, or trade a drug for emergency medical reasons. For the purposes of this subsection, "emergency medical reasons" includes transfers of prescription drugs to alleviate a temporary shortage, except that the gross dollar value of the transfers may not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

Sec. 3. RCW 18.64.011 and 2013 c 146 s 1, 2013 c 144 s 13, and 2013 c 19 s 7 are each reenacted and amended to read as follows:

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

(1) "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.

(2) "Business licensing system" means the mechanism established by chapter 19.02 RCW by which business licenses, endorsed for individual state-issued licenses, are issued and renewed utilizing a

business license application and a business license expiration date common to each renewable license endorsement.

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

(4) "Compounding" means the act of combining two or more ingredients in the preparation of a prescription.

(5) "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.

(6) "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.

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

(8) "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 human beings or other animals, or (b) to affect the structure or any function of the body of human beings or other animals.

(9) "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.

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

(11) "Drug" and "devices" do 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. "Drug" also does not 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 human beings.

(12) "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 human beings or other animals;

(c) Substances (other than food) intended to affect the structure or any function of the body of human beings 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.

(13) "Health care entity" means an organization that provides health care services in a setting that is not otherwise licensed by the state to acquire or possess legend drugs. Health care entity includes a freestanding outpatient surgery center ((~~or~~)), a residential treatment facility, and a freestanding cardiac care center. ((~~It~~)) "Health care entity" does not include an individual practitioner's office or a multipractitioner clinic, regardless of ownership, unless the owner elects licensure as a health care entity. "Health care entity" also does not include an individual practitioner's office or multipractitioner clinic identified by a hospital on a pharmacy application or renewal pursuant to RCW 18.64.043.

(14) "Labeling" means 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.

(15) "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.

(16) "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, personally prepares, compounds, packages, or labels such substance or device. "Manufacture" includes the distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the ((~~board [commission]~~)) commission. The term does not include:

(a) The activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;

(b) The practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;

(c) The distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or

(d) The delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

(17) "Manufacturer" means a person, corporation, or other entity engaged in the manufacture of drugs or devices.

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

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

(20) "Pharmacist" means a person duly licensed by the commission to engage in the practice of pharmacy.

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

(22) "Poison" does not include any article or mixture covered by the Washington pesticide control act (chapter 15.58 RCW), as enacted or hereafter amended.

(23) "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.

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

(25) "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.

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

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

Sec. 4. RCW 18.64.043 and 1996 c 191 s 43 are each amended to read as follows:

(1) The owner of each pharmacy 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 operate such pharmacy at the location specified, or such other temporary location as the secretary may approve, for the period ending on a date to be determined by the secretary as provided in RCW 43.70.250 and 43.70.280, and each such owner shall at the time of filing proof of payment of such fee as provided in RCW 18.64.045 as now or hereafter amended, file with the department on a blank therefor provided, a declaration of ownership and location, which declaration of ownership and location so filed as aforesaid shall be deemed presumptive evidence of ownership of the pharmacy mentioned therein. For a hospital licensed under chapter 70.41 RCW, the license of location provided under this section may include any individual practitioner's office or multipractitioner clinic owned and operated by a hospital, and identified by the hospital on the pharmacy application or renewal. A hospital that elects to include one or more offices or clinics under this subsection on its pharmacy application must maintain the office or clinic under its pharmacy license through at

least one pharmacy inspection or twenty-four months. However, the department may, in its discretion, allow a change in licensure at an earlier time. The secretary may adopt rules to establish an additional reasonable fee for any such office or clinic.

(2) It shall be the duty of the owner to immediately notify the department of any change of location or ownership and to keep the license of location or the renewal thereof properly exhibited in said pharmacy.

(3) Failure to comply with this section shall be deemed a misdemeanor, and each day that said failure continues shall be deemed a separate offense.

(4) In the event such license fee remains unpaid on the date due, no renewal or new license shall be issued except upon compliance with administrative procedures, administrative requirements, and fees determined as provided in RCW 43.70.250 and 43.70.280.

NEW SECTION. **Sec. 5.** Section 1 of this act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately."

Correct the title.

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