S-0630.1

SENATE BILL 5713

State of Washington 53rd Legislature 1993 Regular Session

By Senators Wojahn and West

Read first time 02/10/93. Referred to Committee on Health & Human Services.

AN ACT Relating to drug dispensing outlets; adding new sections to chapter 18.64 RCW; and prescribing penalties.

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

NEW SECTION. **Sec. 1.** LEGISLATIVE FINDINGS. The legislature finds that:

(1) A number of prescribers dispense drugs and devices.

(2) The difference between administration and dispensing is related to the number of dosage units given, in other words, administration involves a single dose, while dispensing involves multiple doses.

(3) There is no Washington law prohibiting the dispensing of drugs or devices by prescribers, and historically a small number of prescribers have also dispensed, that is practiced pharmacy.

(4) For the most part, dispensing prescribers have not maintained updated knowledge of the many professional and legal requirements involved in the dispensing of drugs and devices.

(5) Dispensing by the prescriber deprives the patient of the checks-and-balances gained in the prescriber-pharmacist-patient relationship.

(6) The prescriber who dispenses must, at least, meet the legal requirements, and is obliged to meet the professional requirements of the pharmacist in the act of dispensing drugs and devices.

NEW SECTION. **Sec. 2.** DEFINITIONS. Unless the context clearly requires otherwise, definitions in this section apply throughout this chapter.

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

(2) "Compounding" means the preparation, mixing, assembling, packaging, or labeling or a combination of these activities, of a drug or device:

(a) As a result of a prescribing practitioner’s prescription or order for her or his patient; or

(b) For the purpose of or as an incident to research, teaching, or chemical analysis and not for sale or dispensing.

(3) "Controlled substances" means a drug or substance, or an immediate precursor of the drug or substance, as designated under the provisions of chapter 69.50 RCW.

(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) "Department" means the department of health.

(6) "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 people or animals; or

(b) To affect the structure or function of the body of a person or an animal.

(7) "Disciplinary authority" means the entity or authority responsible for the discipline of the involved prescriber.

(8) "Dispense" means the interpretation of a prescription or order for a drug, biological, or device, or combination of 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.

(9) "Dispenser" means a practitioner who is legally authorized to dispense.

(10) "Drug dispensing outlet" means a separate drug room or similar approved facility where a health care practitioner, authorized by her or his license to prescribe, shall store drugs to be dispensed by the practitioner to her or his patients, only.

(11) "Drugs" means:

(a) Articles recognized in the official United States pharmacopoeia/national formulary or the official homeopathic pharmacopoeia of the United States or any supplement to them;

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

(c) Substances, other than food, intended to affect the structure or function of the body of a person or an animal;

(d) Oxygen USP and other gases intended for treatment of, or administration to people or animals; or

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

(12) "Labeling" means the process of preparing and affixing a label to a drug or device container. The label must include all information required by federal and state laws and rules.

(13) "Legend drugs" means drugs that are required by applicable federal or state law or rule to be dispensed on prescription only or are restricted to use by practitioners only, pursuant to chapter 69.41 RCW.

(14) "Order" of a drug or device for an individual patient, whether transmitted orally, in writing, or by some other means, is a prescription for that patient, and may only be issued by an individual authorized by law or rule as an independent or dependent prescriber.

(15) "Practice of pharmacy" includes the practice of and responsibility for: Interpreting prescription orders, the compounding, dispensing, labeling, administrating, 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 her or his practice by a practitioner authorized to prescribe drugs; the participation in drug utilization reviews and drug product selection; and includes the practice of and responsibility for assuring optimal therapeutic outcomes, and includes prevention of suboptimal therapeutic outcomes through misuse associated with legend and nonlegend drugs, and additionally it includes activities necessary to achieve those

outcomes, for example physical assessment, drug administration, laboratory or analytical processes, phlebotomy, or other activities; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs that may include, but is not limited to, the advising of therapeutic values, hazards, and uses of drugs and devices.

(16) "Person" means the individual licensed health care practitioner that is authorized, by state law or rule, to prescribe drugs or devices, or both, for their patients.

(17) "Practitioner" means a person duly authorized by law or rule in the state of Washington to prescribe or dispense drugs.

(18) "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 within the scope of her or his professional practice for a legitimate medical purpose.

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

NEW SECTION. **Sec. 3.** DRUG DISPENSING OUTLET--LICENSE. (1) The individual prescribing practitioner owner of each drug dispensing outlet 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, pay a fee to be determined by the secretary, for which he or she shall receive a license of location. The license of location entitles the owner to operate the drug dispensing outlet at the location specified, or a temporary location as the secretary may approve, for the period ending on a date to be determined by the secretary. Each such owner shall at the time of payment of the fee file with the secretary, on a blank therefore provided, a declaration of ownership and location. The declaration of ownership and location, if filed, is deemed presumptive evidence of ownership of the dispensing drug outlet.

(2) It is the duty of the owner to immediately notify the department of a change of location or cessation of operation and to keep the license of location or the renewal of the license properly exhibited in the public access area associated with the drug dispensing outlet.

(3) If the renewal fee is not paid by the date due, no renewal license may be issued except upon payment of the license renewal fee and a penalty equal to the original license fee.

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

NEW SECTION. **Sec. 4.** ENFORCEMENT PROVISIONS. The disciplinary authority of the licensee shall have the authority to refuse, suspend, or revoke the license of a drug dispensing outlet upon proof that:

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

(2) The licensee has violated or has permitted an employee to violate federal or state laws or rules relating to drugs or devices, the dispensing of drugs or devices, or the practice of pharmacy, or has been convicted of a felony;

(3) The disciplinary authority shall consult with the board of pharmacy regarding the board's standard penalties assigned for the various violations; and

(4) The investigators assigned to inspect pharmacies shall also be assigned to inspecting dispensing drug outlets, under an agreement reached between the disciplining authority and the board of pharmacy.

NEW SECTION. **Sec. 5.** LABELING--SAFETY STANDARD CAPS. To every box, bottle, jar, tube, or other container of a prescription that is dispensed, there shall be fixed a label bearing the name and address of the drug dispensing outlet where the prescription is compounded, the directions, the name of the medicine and the strength per unit dose, unless there is a reason not to do so, name of the patient, date filled or refilled, the expiration date, the initials of the authorized dispenser who has dispensed the prescription, and a serial number or some other code to permit tracing of prescriptions filled. Combination products shall be labeled by the active ingredients or the trade name of the product. The security of the cover or cap on every bottle or jar shall meet the safety standards adopted by the board of pharmacy.

NEW SECTION. **Sec. 6.** RECORDS REQUIRED. (1) The authorized dispenser of a drug dispensing outlet shall keep readily available a suitable record of every prescription dispensed at the dispensing drug outlet, which shall be preserved for a period of not less than two

years, either with serial numbers or with other codes that will supply information regarding patients, dates, drugs, and quantity dispensed, and shall produce the records in court or before a grand jury whenever lawfully required to do so. All federal and state recordkeeping requirements for controlled substances must be complied with. All records relating to prescriptions are for confidential use in the dispensing drug outlet only.

(2) The authorized dispenser of a dispensing drug outlet shall maintain invoices or other records as are necessary to account for the receipt and disposition of all drugs, which shall be maintained for at least two years.

(3) The records cited in subsections (1) and (2) of this section shall be maintained either separately from all other records, or in a form that the information required is readily retrievable from ordinary business records of the dispensing drug outlet.

(4) The records cited in subsections (1) and (2) of this section shall be available for inspection by an authorized representative of the board of pharmacy or an officer of the law who is conducting an active investigation and who is authorized to enforce chapter 18.64, 69.41, or 69.50 RCW.

NEW SECTION. **Sec. 7.** Sections 1 through 6 of this act are each added to chapter 18.64 RCW and codified with the subchapter heading "DRUG DISPENSING OUTLETS."

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