S-3651.1

SENATE BILL 6203

State of Washington 64th Legislature 2016 Regular Session

By Senators Parlette, Becker, Keiser, and Conway

Read first time 01/12/16. Referred to Committee on Health Care.

AN ACT Relating to updating statutes relating to the practice of pharmacy including the practice of pharmacy in long-term care settings; amending RCW 18.64.011, 69.50.308, 74.42.230, 69.41.032, 69.41.042, 69.41.044, 69.41.055, 69.41.220, 18.64.245, and 18.64.500; reenacting and amending RCW 69.41.010 and 69.41.030; adding new sections to chapter 18.64 RCW; and adding a new section to chapter 69.41 RCW.

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

Sec. 1. RCW 18.64.011 and 2015 c 234 s 3 are each 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, a residential treatment facility, and a freestanding cardiac care center. "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 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.

(28) "Administrative long-term care pharmacy personnel" means pharmacy ancillary personnel in a closed door long-term care pharmacy who perform administrative tasks not associated with immediate dispensing of drugs, whether or not the ancillary personnel is registered under chapter 18.64A RCW. Administrative tasks include, but are not limited to, medical records maintenance, billing, prepackaging unit dose drugs, inventory control, delivery, and processing returned drugs, in a long-term care pharmacy or other health systems settings.

(29) "Chart order" means a lawful order for a drug or device entered on the chart or medical record of an inpatient or resident of an institutional facility by a practitioner or his or her designated agent.

(30) "Closed door long-term care pharmacy" means a pharmacy that provides pharmaceutical care to a defined and exclusive group of patients who have access to the services of the pharmacy because they are treated by or have an affiliation with a long-term care facility or hospice program, and that is not a retailer of goods to the general public.

(31) "Hospice program" means a hospice program certified or paid by medicare under Title XVIII of the federal social security act, or a hospice program licensed under chapter 70.127 RCW.

(32) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services including, but not limited to, services in a hospital, long-term care facility, hospice program, mental health facility, drug abuse treatment center, residential

habilitation center, or a local, state, or federal correction facility.

(33) "Long-term care facility" means a nursing home licensed under chapter 18.51 RCW, an assisted living facility licensed under chapter 18.20 RCW, or an adult family home licensed under chapter 70.128 RCW.

(34) "Shared pharmacy services" means a system that allows a participating pharmacist or pharmacy pursuant to a request from another participating pharmacist or pharmacy to process or fill a prescription or drug order, which may include but is not necessarily limited to preparing, packaging, labeling, data entry, compounding for specific patients, dispensing, performing drug utilization reviews, conducting claims adjudication, obtaining refill authorizations, reviewing therapeutic interventions, or reviewing chart orders.

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

(1) A chart order must be considered a prescription if it contains:

(a) The full name of the patient;

(b) The date of issuance;

(c) The name, strength, and dosage form of the drug prescribed;

(d) Directions for use; and

(e) An authorized signature:

(i) For written orders, the order must contain the prescribing practitioner's signature or the signature of the practitioner's authorized agent, including the name of the prescribing practitioner; or

(ii) For electronic or digital orders, the order must contain the prescribing practitioner's electronic or digital signature, or the electronic or digital signature of the practitioner's authorized agent, including the name of the prescribing practitioner.

(2) A licensed nurse, pharmacist, or physician practicing in a long-term care facility or hospice program may act as the practitioner's agent for purposes of this chapter, without need for a written agency agreement, to document a chart order in the patient's medical record on behalf of the prescribing practitioner pending the prescribing practitioner's signature; or to communicate a prescription to a pharmacy whether telephonically, via facsimile, or

electronically. The communication of a prescription to a dispenser by the prescriber's agent has the same force and effect as if communicated directly by the authorized practitioner.

(3) Nothing in this chapter prevents an authorized credentialed employee of a long-term care facility from transmitting a chart order pursuant to RCW 74.42.230, or transmitting a prescription on behalf of a resident to the extent otherwise authorized by law.

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

(1) A pharmacy or pharmacist may provide a limited quantity of drugs to a nursing home or hospice program without a prescription for emergency administration by authorized personnel of the facility or program pursuant to a valid prescription. The drugs so provided must be limited to those required to meet the immediate therapeutic needs of residents or patients and may not be available from another authorized source in sufficient time to prevent risk of harm by delay resulting from obtaining drugs from another source. Emergency kits must be secured in a locked room, container, or device to prevent unauthorized access and to ensure the proper environment for preservation of the drugs.

(2) In addition to or in connection with the emergency kit authorized under subsection (1) of this section, a nursing home that employs a unit dose drug distribution system may maintain a supplemental dose kit for supplemental nonemergency drug therapy. Supplemental dose kits must be secured in a locked room, container, or device to prevent unauthorized access, and to ensure the proper environment for preservation of the drugs. Administration of drugs from a supplemental dose kit must be under a valid prescription or chart order.

(3) The types and quantity of drugs appropriate to serve the resident or patient population of a nursing home or hospice program using an emergency kit or supplemental dose kit and procedures for the proper storage and security of drugs must be determined by a pharmaceutical services committee that includes a pharmacist licensed under this chapter, a physician licensed under chapter 18.71 RCW, or an osteopathic physician licensed under chapter 18.57 RCW, and appropriate clinical or administrative personnel of the nursing home or hospice program as set forth in rules adopted by the pharmacy quality assurance commission.

(4) A registered nurse or licensed practical nurse operating under appropriate direction and supervision by a pharmacist may restock an emergency kit or supplemental dose kit to provide for safe and timely patient access.

NEW SECTION. **Sec. 4.** A new section is added to chapter 18.64 RCW to read as follows:

(1) A pharmacy may resupply a legend drug to a patient at a long-term care facility or hospice program pursuant to a valid chart order that is signed by the prescribing practitioner, is not time limited, and has not been discontinued.

(2) A pharmacy may outsource shared pharmacy services for a long-term care facility or hospice program to another pharmacy if the outsourcing pharmacy:

(a) Obtains approval from the long-term care facility or hospice program to outsource shared pharmacy services for the facility's or program's residents or patients; and

(b) Provides a copy of the prescription or order to the pharmacy providing the shared pharmacy services.

(3) Shared pharmacy services may be used for, but are not limited to, the purpose of ensuring that drugs or devices are attainable to meet the immediate needs of residents of the long-term care facility or hospice program, or when the outsourcing pharmacy cannot provide services on an ongoing basis. Where a pharmacy uses shared pharmacy services to have a second pharmacy provide a first dose or partial fill of a prescription or drug order to meet a patient's or resident's immediate needs, the second supplying pharmacy may dispense the first dose or partially filled prescription on a satellite basis without the outsourcing pharmacy being required to fully transfer the prescription to the supplying pharmacy. The supplying pharmacy must retain a copy of the prescription or order on file, a copy of the dispensing record or fill, and must notify the outsourcing pharmacy of the service and quantity provided.

(4) A pharmacy may repackage and dispense unused drugs returned by a long-term care facility or hospice program to the pharmacy in per-use, blister packaging, whether in unit dose or modified unit dose form. The commission must adopt rules providing for the safe and efficient repackaging and reuse of unused drugs returned to a pharmacy from a long-term care facility or hospice program.

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

The commission must adopt reasonable, task-based standards regarding the ratio of pharmacists to pharmacy ancillary personnel in a closed door long-term care pharmacy. For the purpose of such standards, administrative long-term care pharmacy personnel may not be considered to be practicing as pharmacy technicians or pharmacy assistants requiring pharmacist oversight while performing administrative tasks.

NEW SECTION. **Sec. 6.** A new section is added to chapter 18.64 RCW to read as follows:

The commission may adopt rules implementing sections 2 through 5 of this act.

NEW SECTION. **Sec. 7.** A new section is added to chapter 69.41 RCW to read as follows:

(1) A pharmacy may dispense legend drugs to the resident of a long-term care facility or hospice program on the basis of a written or digitally signed prescription or chart order sent via facsimile copy by the prescriber to the long-term care facility or hospice program, and communicated or transmitted to the pharmacy pursuant to section 3 of this act.

(2) For the purpose of this section, the terms "long-term care facility," "hospice program," and "chart order" have the meanings provided in RCW 18.64.011.

Sec. 8. RCW 69.50.308 and 2013 c 276 s 3 are each amended to read as follows:

(a) A controlled substance may be dispensed only as provided in this section. Prescriptions electronically communicated must also meet the requirements under RCW 69.50.312.

(b) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule II may not be dispensed without the written or electronically communicated prescription of a practitioner.

(1) Schedule II narcotic substances may be dispensed by a pharmacy pursuant to a facsimile prescription under the following circumstances:

(i) The facsimile prescription is transmitted by a practitioner to the pharmacy; and

(ii) The facsimile prescription is for a patient in a long-term care facility or a hospice program ((~~certified or paid by medicare under Title XVIII of the federal social security act. "Long-term care facility" means nursing homes licensed under chapter 18.51 RCW, assisted living facilities licensed under chapter 18.20 RCW, and adult family homes licensed under chapter 70.128 RCW; or~~

~~(iii) The facsimile prescription is for a patient of a hospice program licensed by the state~~)); and

((~~(iv)~~)) (iii) The practitioner or the practitioner's agent notes on the facsimile prescription that the patient is a long-term care or hospice patient.

(2) Injectable Schedule II narcotic substances that are to be compounded for patient use may be dispensed by a pharmacy pursuant to a facsimile prescription if the facsimile prescription is transmitted by a practitioner to the pharmacy.

(3) Under (1) and (2) of this subsection the facsimile prescription shall serve as the original prescription and shall be maintained as other Schedule II narcotic substances prescriptions.

(c) In emergency situations, as defined by rule of the commission, a substance included in Schedule II may be dispensed upon oral prescription of a practitioner, reduced promptly to writing and filed by the pharmacy. Prescriptions shall be retained in conformity with the requirements of RCW 69.50.306.

(d) A prescription for a substance included in Schedule II may not be refilled. A prescription for a substance included in Schedule II may not be filled more than six months after the date the prescription was issued.

(e) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written, oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing.

(f) A written, oral, or electronically communicated prescription for a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, for a resident in a long-term care facility or hospice program may be communicated

to the pharmacy by an authorized agent of the prescriber. A registered nurse, pharmacist, or physician practicing in a long-term care facility or hospice program may act as the practitioner's agent for purposes of this section, without need for a written agency agreement.

(g) The prescription for a substance included in Schedule III, IV, or V may not be filled or refilled more than six months after the date issued by the practitioner or be refilled more than five times, unless renewed by the practitioner.

((~~(g)~~)) (h) A valid prescription or lawful order of a practitioner, in order to be effective in legalizing the possession of controlled substances, must be issued in good faith for a legitimate medical purpose by one authorized to prescribe the use of such controlled substance. An order purporting to be a prescription not in the course of professional treatment is not a valid prescription or lawful order of a practitioner within the meaning and intent of this chapter; and the person who knows or should know that the person is filling such an order, as well as the person issuing it, can be charged with a violation of this chapter.

((~~(h)~~))(i) A substance included in Schedule V must be distributed or dispensed only for a medical purpose.

((~~(i)~~)) (j) A practitioner may dispense or deliver a controlled substance to or for an individual or animal only for medical treatment or authorized research in the ordinary course of that practitioner's profession. Medical treatment includes dispensing or administering a narcotic drug for pain, including intractable pain.

((~~(j)~~)) (k) No administrative sanction, or civil or criminal liability, authorized or created by this chapter may be imposed on a pharmacist for action taken in reliance on a reasonable belief that an order purporting to be a prescription was issued by a practitioner in the usual course of professional treatment or in authorized research.

((~~(k)~~)) (l) An individual practitioner may not dispense a substance included in Schedule II, III, or IV for that individual practitioner's personal use.

(4) For the purposes of this section, the terms "long-term care facility" and "hospice program" have the meaning provided in RCW 18.64.011.

Sec. 9. RCW 74.42.230 and 1994 sp.s. c 9 s 751 are each amended to read as follows:

(1) The resident's attending or staff physician or authorized practitioner approved by the attending physician shall order all medications for the resident. The order may be oral or written and shall be limited by time, unless specified as continuing in effect until discontinued by a physician or authorized practitioner. An "authorized practitioner," as used in this section, is a registered nurse under chapter 18.79 RCW when authorized by the nursing care quality assurance commission, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the committee of osteopathic examiners, ((~~or~~)) a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or a pharmacist under chapter 18.64 RCW when authorized by the pharmacy quality assurance commission.

(2) An oral order shall be given only to a licensed nurse, pharmacist, or another physician. The oral order shall be recorded and physically or electronically signed immediately by the person receiving the order. The attending physician shall sign the record of the oral order in a manner consistent with good medical practice.

(3) A licensed nurse, pharmacist, or another physician receiving and recording an oral order may, if so authorized by the physician or authorized practitioner, communicate that order to a pharmacy on behalf of the physician or authorized practitioner. The order may be communicated verbally by telephone, by facsimile manually signed by the person receiving the order pursuant to subsection (2) of this section, or by electronic transmission pursuant to RCW 69.41.055. The communication of a resident's order to a pharmacy by a licensed nurse, pharmacist, or another physician acting at the prescriber's direction has the same force and effect as if communicated directly by the delegating physician or authorized practitioner. Nothing in this provision limits the authority of a licensed nurse, pharmacist, or physician to delegate to an authorized agent, including but not limited to delegation of operation of a facsimile machine by credentialed facility staff, to the extent consistent with his or her professional license.

Sec. 10. RCW 69.41.010 and 2013 c 276 s 1 and 2013 c 19 s 55 are each reenacted and amended to read as follows:

As used in this chapter, the following terms have the meanings indicated unless the context clearly requires otherwise:

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

(a) A practitioner; or

(b) The patient or research subject at the direction of the practitioner.

(2) "Community-based care settings" include: Community residential programs for persons with developmental disabilities, certified by the department of social and health services under chapter 71A.12 RCW; adult family homes licensed under chapter 70.128 RCW; and assisted living facilities licensed under chapter 18.20 RCW. Community-based care settings do not include acute care or skilled nursing facilities.

(3) "Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a legend drug, 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 legend drug 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) "Dispenser" means a practitioner who dispenses.

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

(8) "Distributor" means a person who distributes.

(9) "Drug" means:

(a) Substances recognized as drugs in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or any supplement to any of them;

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

(c) Substances (other than food, minerals or vitamins) intended to affect the structure or any function of the body of human beings or animals; and

(d) Substances intended for use as a component of any article specified in (a), (b), or (c) of this subsection. It does not include devices or their components, parts, or accessories.

(10) "Electronic communication of prescription information" means the transmission of a prescription or refill authorization for a drug of a practitioner using computer systems. The term does not include a prescription or refill authorization transmitted verbally by telephone nor a facsimile manually signed by the practitioner.

(11) "In-home care settings" include an individual's place of temporary and permanent residence, but does not include acute care or skilled nursing facilities, and does not include community-based care settings.

(12) "Legend drugs" means any drugs which are required by state law or regulation of the pharmacy quality assurance commission to be dispensed on prescription only or are restricted to use by practitioners only.

(13) "Legible prescription" means a prescription or medication order issued by a practitioner that is capable of being read and understood by the pharmacist filling the prescription or the nurse or other practitioner implementing the medication order. A prescription must be hand printed, typewritten, or electronically generated.

(14) "Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, and such other means of medication assistance as defined by rule adopted by the department. A nonpractitioner may help in the preparation of legend drugs or controlled substances for self-administration where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate. Medication assistance shall not include assistance with intravenous medications or injectable medications, except prefilled insulin syringes.

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

(16) "Practitioner" means:

(a) 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 registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW, an optometrist under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, an osteopathic physician assistant under chapter 18.57A RCW, a physician assistant under chapter 18.71A RCW, a naturopath licensed under chapter 18.36A RCW, a pharmacist under chapter 18.64 RCW, or, when acting under the required supervision of a dentist licensed under chapter 18.32 RCW, a dental hygienist licensed under chapter 18.29 RCW;

(b) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to, or to administer a legend drug in the course of professional practice or research in this state; and

(c) A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery in any state, or province of Canada, which shares a common border with the state of Washington.

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

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

Sec. 11. RCW 69.41.030 and 2013 c 71 s 1 and 2013 c 12 s 1 are each reenacted and amended to read as follows:

(1) It shall be unlawful for any person to sell, deliver, or possess any legend drug except upon the order or prescription of a physician under chapter 18.71 RCW, an osteopathic physician and surgeon under chapter 18.57 RCW, an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010, 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 commissioned medical or dental officer in the United States armed forces or 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 by the nursing care quality assurance commission, a pharmacist licensed under chapter 18.64 RCW to the extent permitted by drug therapy guidelines or protocols established under RCW 18.64.011 and authorized by the ((~~board of pharmacy~~)) commission and approved by a practitioner authorized to prescribe drugs, an osteopathic physician assistant under chapter 18.57A RCW when authorized by the board of osteopathic medicine and surgery, a physician assistant under chapter 18.71A RCW when authorized by the medical quality assurance commission, or any of the following professionals in any province of Canada that shares a common border with the state of Washington or in any state of the United States: A physician licensed to practice medicine and surgery or a physician licensed to practice osteopathic medicine and surgery, a dentist licensed to practice dentistry, a podiatric physician and surgeon licensed to practice podiatric medicine and surgery, a licensed advanced registered nurse practitioner, a licensed physician assistant, a licensed osteopathic physician assistant, or a veterinarian licensed to practice veterinary medicine: PROVIDED, HOWEVER, That the above provisions shall not apply to sale, delivery, or possession by drug wholesalers or drug manufacturers, or their agents or employees, or to any practitioner acting within the scope of his or her license, or to a common or contract carrier or warehouse operator, or any employee thereof, whose possession of any legend drug is in the usual course of business or employment: PROVIDED FURTHER, That nothing in this chapter or chapter 18.64 RCW shall prevent a family planning clinic that is under contract with the health care authority from selling, delivering, possessing, and dispensing commercially prepackaged oral contraceptives prescribed by authorized, licensed health care practitioners.

(2)(a) A violation of this section involving the sale, delivery, or possession with intent to sell or deliver is a class B felony punishable according to chapter 9A.20 RCW.

(b) A violation of this section involving possession is a misdemeanor.

Sec. 12. RCW 69.41.032 and 1987 c 41 s 2 are each amended to read as follows:

This chapter shall not prevent a medicare-approved dialysis center or facility operating a medicare-approved home dialysis program from selling, delivering, possessing, or dispensing directly

to its dialysis patients, in case or full shelf lots, if prescribed by a physician licensed under chapter 18.57 or 18.71 RCW, those legend drugs determined by the ((~~board~~)) commission pursuant to rule.

Sec. 13. RCW 69.41.042 and 1989 1st ex.s. c 9 s 405 are each amended to read as follows:

A pharmaceutical manufacturer, wholesaler, pharmacy, or practitioner who purchases, dispenses, or distributes legend drugs shall maintain invoices or such other records as are necessary to account for the receipt and disposition of the legend drugs.

The records maintained pursuant to this section shall be available for inspection by the ((~~board~~)) commission and its authorized representatives and shall be maintained for two years.

Sec. 14. RCW 69.41.044 and 2005 c 274 s 328 are each amended to read as follows:

All records, reports, and information obtained by the ((~~board~~)) commission or its authorized representatives from or on behalf of a pharmaceutical manufacturer, representative of a manufacturer, wholesaler, pharmacy, or practitioner who purchases, dispenses, or distributes legend drugs under this chapter are confidential and exempt from public inspection and copying under chapter 42.56 RCW. Nothing in this section restricts the investigations or the proceedings of the ((~~board~~)) commission so long as the ((~~board~~)) commission and its authorized representatives comply with the provisions of chapter 42.56 RCW.

Sec. 15. RCW 69.41.055 and 1998 c 222 s 2 are each amended to read as follows:

(1) Information concerning an original prescription or information concerning a prescription refill for a legend drug may be electronically communicated between an authorized practitioner and a pharmacy of the patient's choice with no intervening person having access to the prescription drug order pursuant to the provisions of this chapter if the electronically communicated prescription information complies with the following:

(a) Electronically communicated prescription information must comply with all applicable statutes and rules regarding the form, content, recordkeeping, and processing of a prescription or order for a legend drug;

(b) The system used for transmitting electronically communicated prescription information and the system used for receiving electronically communicated prescription information must be approved by the ((~~board~~)) commission. This subsection does not apply to currently used facsimile equipment transmitting an exact visual image of the prescription. The ((~~board~~)) commission shall maintain and provide, upon request, a list of systems used for electronically communicating prescription information currently approved by the ((~~board~~)) commission;

(c) An explicit opportunity for practitioners must be made to indicate their preference on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. This section does not limit the ability of practitioners and pharmacists to permit substitution by default under a prior-consent authorization;

(d) Prescription drug orders are confidential health information, and may be released only to the patient or the patient's authorized representative, the prescriber or other authorized practitioner then caring for the patient, or other persons specifically authorized by law to receive such information;

(e) To maintain confidentiality of prescription records, the electronic system shall have adequate security and systems safeguards designed to prevent and detect unauthorized access, modification, or manipulation of these records. The pharmacist in charge shall establish or verify the existence of policies and procedures which ensure the integrity and confidentiality of prescription information transmitted to the pharmacy by electronic means. All managers, employees, and agents of the pharmacy are required to read, sign, and comply with the established policies and procedures; and

(f) The pharmacist shall exercise professional judgment regarding the accuracy, validity, and authenticity of the prescription drug order received by way of electronic transmission, consistent with federal and state laws and rules and guidelines of the ((~~board~~)) commission.

(2) The electronic or digital signature of the prescribing practitioner's agent on behalf of the prescribing practitioner, pursuant to a valid order and authorization, constitutes a valid electronic communication of prescription information. An authorized signature and transmission does not constitute an intervening person having access to the prescription drug order.

(3) The ((~~board~~)) commission may adopt rules implementing this section.

Sec. 16. RCW 69.41.220 and 1989 1st ex.s. c 9 s 428 are each amended to read as follows:

Each manufacturer and distributor shall publish and provide to the ((~~board~~)) commission by filing with the department printed material which will identify each current imprint used by the manufacturer or distributor. The ((~~board~~)) commission shall be notified of any change by the filing of any change with the department. This information shall be provided by the department to all pharmacies licensed in the state of Washington, poison control centers, and hospital emergency rooms.

Sec. 17. RCW 18.64.245 and 2013 c 19 s 17 are each amended to read as follows:

(1) Every proprietor or manager of a pharmacy shall keep readily available a suitable record of prescriptions which shall preserve for a period of not less than two years the record of every prescription dispensed at such pharmacy which shall be numbered, dated, and filed, and shall produce the same in court or before any grand jury whenever lawfully required to do so. The record shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy. All recordkeeping requirements for controlled substances must be complied with. Such record of prescriptions shall be for confidential use in the pharmacy, only. The record of prescriptions shall be open for inspection by the commission or any officer of the law, who is authorized to enforce this chapter ((~~18.64,~~)) or chapter 69.41((~~,~~)) or 69.50 RCW.

(2) When a pharmacy receives a prescription in digital or electronic format through facsimile equipment transmitting an exact visual image of the prescription, or through electronic communication of prescription information, the digital or electronic record of every such prescription dispensed at the pharmacy constitutes a suitable record of prescriptions, provided that the original or direct copy of the prescription is electronically or digitally numbered or referenced, dated, and filed in a form that permits the information required to be readily retrievable.

(3) A person violating this section is guilty of a misdemeanor.

Sec. 18. RCW 18.64.500 and 2013 c 19 s 30 are each amended to read as follows:

(1) ((~~Effective July 1, 2010,~~)) Every prescription written in this state by a licensed practitioner must be written on a tamper-resistant prescription pad or paper approved by the commission.

(2) A pharmacist may not fill a written prescription from a licensed practitioner unless it is written on an approved tamper-resistant prescription pad or paper, except that a pharmacist may provide emergency supplies in accordance with the commission and other insurance contract requirements.

(3) If a hard copy of an electronic prescription is given directly to the patient, the manually signed hard copy prescription must be on approved tamper-resistant paper that meets the requirements of this section.

(4) For the purposes of this section, "tamper-resistant prescription pads or paper" means a prescription pad or paper that has been approved by the commission for use and contains the following characteristics:

(a) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;

(b) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription form by the practitioner; and

(c) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

(5) Practitioners shall employ reasonable safeguards to assure against theft or unauthorized use of prescriptions.

(6) All vendors must have their tamper-resistant prescription pads or paper approved by the commission prior to the marketing or sale of pads or paper in Washington state.

(7) The commission shall create a seal of approval that confirms that a pad or paper contains all three industry-recognized characteristics required by this section. The seal must be affixed to all prescription pads or paper used in this state.

(8) The commission may adopt rules necessary for the administration of chapter 328, Laws of 2009.

(9) The tamper-resistant prescription pad or paper requirements in this section shall not apply to:

(a) Prescriptions that are transmitted to the pharmacy by telephone, facsimile, or electronic means; or

(b) Prescriptions written for inpatients of a hospital, outpatients of a hospital, residents of a ((~~nursing home~~)) long-term care facility, patients of a hospice program, inpatients or residents of a mental health facility, or individuals incarcerated in a local, state, or federal correction facility, when the health care practitioner authorized to write prescriptions, or his or her authorized agent, writes the order into the patient's medical or clinical record, the order is given directly to the pharmacy, and the patient never has the opportunity to handle the written order.

(10) All acts related to the prescribing, dispensing, and records maintenance of all prescriptions shall be in compliance with applicable federal and state laws, rules, and regulations.

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