Z-0213.1

SENATE BILL 5416

State of Washington 63rd Legislature 2013 Regular Session

By Senators Bailey, Schlicher, Becker, and Keiser; by request of Department of Health

Read first time 01/29/13. Referred to Committee on Health Care .

AN ACT Relating to prescription information; amending RCW 69.41.010, 69.50.308, and 69.50.312; and reenacting and amending RCW 69.50.101.

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

Sec. 1. RCW 69.41.010 and 2012 c 10 s 44 are each 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 the developmentally disabled, 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 ((~~communication of prescription information by computer, or the~~)) transmission of ((~~an exact visual image of~~)) a prescription ((~~by facsimile,~~)) or ((~~other electronic means for original prescription information or prescription~~)) refill ((~~information~~)) authorization for a ((~~legend~~)) drug ((~~between an authorized~~)) of a practitioner ((~~and a pharmacy or the transfer of prescription information for a legend drug from one pharmacy to another pharmacy~~)) 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 state board of pharmacy 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.

Sec. 2. RCW 69.50.101 and 2012 c 8 s 1 are each reenacted and amended to read as follows:

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

(a) "Administer" means to apply a controlled substance, whether by injection, inhalation, ingestion, or any other means, directly to the body of a patient or research subject by:

(1) a practitioner authorized to prescribe (or, by the practitioner's authorized agent); or

(2) the patient or research subject at the direction and in the presence of the practitioner.

(b) "Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseperson, or employee of the carrier or warehouseperson.

(c) "Board" means the state board of pharmacy.

(d) "Controlled substance" means a drug, substance, or immediate precursor included in Schedules I through V as set forth in federal or state laws, or federal or board rules.

(e)(1) "Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and:

(i) that has a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II; or

(ii) with respect to a particular individual, that the individual represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance included in Schedule I or II.

(2) The term does not include:

(i) a controlled substance;

(ii) a substance for which there is an approved new drug application;

(iii) a substance with respect to which an exemption is in effect for investigational use by a particular person under Section 505 of the federal Food, Drug and Cosmetic Act, 21 U.S.C. Sec. 355, to the extent conduct with respect to the substance is pursuant to the exemption; or

(iv) any substance to the extent not intended for human consumption before an exemption takes effect with respect to the substance.

(f) "Deliver" or "delivery," means the actual or constructive transfer from one person to another of a substance, whether or not there is an agency relationship.

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

(h) "Dispense" means the interpretation of a prescription or order for a controlled substance and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery.

(i) "Dispenser" means a practitioner who dispenses.

(j) "Distribute" means to deliver other than by administering or dispensing a controlled substance.

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

(l) "Drug" means (1) a controlled substance recognized as a drug in the official United States pharmacopoeia/national formulary or the official homeopathic pharmacopoeia of the United States, or any supplement to them; (2) controlled substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals; (3) controlled substances (other than food)

intended to affect the structure or any function of the body of individuals or animals; and (4) controlled substances intended for use as a component of any article specified in (1), (2), or (3) of this subsection. The term does not include devices or their components, parts, or accessories.

(m) "Drug enforcement administration" means the drug enforcement administration in the United States Department of Justice, or its successor agency.

(n) "Electronic communication of prescription information" means the communication of prescription information by computer, or the transmission of an exact visual image of a prescription by facsimile, or other electronic means for original prescription information or prescription refill information for a Schedule III-V controlled substance between an authorized practitioner and a pharmacy or the transfer of prescription information for a controlled substance from one pharmacy to another pharmacy.

(o) "Immediate precursor" means a substance:

(1) that the state board of pharmacy has found to be and by rule designates as being the principal compound commonly used, or produced primarily for use, in the manufacture of a controlled substance;

(2) that is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance; and

(3) the control of which is necessary to prevent, curtail, or limit the manufacture of the controlled substance.

(p) "Isomer" means an optical isomer, but in subsection (r)(5) of this section, RCW ((~~69.50.101(r)(5),~~)) 69.50.204(a) (12) and (34), and 69.50.206(b)(4), the term includes any geometrical isomer; in RCW 69.50.204(a) (8) and (42)((~~,~~)) and 69.50.210(c) the term includes any positional isomer; and in RCW 69.50.204(a)(35), 69.50.204(c), and 69.50.208(a) the term includes any positional or geometric isomer.

(q) "Manufacture" means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly or by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. The term does not include the preparation, compounding,

packaging, repackaging, labeling, or relabeling of a controlled substance:

(1) by a practitioner as an incident to the practitioner's administering or dispensing of a controlled substance in the course of the practitioner's professional practice; or

(2) by a practitioner, or by the practitioner's authorized agent under the practitioner's supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(r) "Marijuana" or "marihuana" means all parts of the plant Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. The term does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

(s) "Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium, opium derivative, and any derivative of opium or opium derivative, including their salts, isomers, and salts of isomers, whenever the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation. The term does not include the isoquinoline alkaloids of opium.

(2) Synthetic opiate and any derivative of synthetic opiate, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of the isomers, esters, ethers, and salts is possible within the specific chemical designation.

(3) Poppy straw and concentrate of poppy straw.

(4) Coca leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives or ecgonine or their salts have been removed.

(5) Cocaine, or any salt, isomer, or salt of isomer thereof.

(6) Cocaine base.

(7) Ecgonine, or any derivative, salt, isomer, or salt of isomer thereof.

(8) Any compound, mixture, or preparation containing any quantity of any substance referred to in subparagraphs (1) through (7).

(t) "Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. The term includes opium, substances derived from opium (opium derivatives), and synthetic opiates. The term does not include, unless specifically designated as controlled under RCW 69.50.201, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). The term includes the racemic and levorotatory forms of dextromethorphan.

(u) "Opium poppy" means the plant of the species Papaver somniferum L., except its seeds.

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

(w) "Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

(x) "Practitioner" means:

(1) A physician under chapter 18.71 RCW; a physician assistant under chapter 18.71A RCW; an osteopathic physician and surgeon under chapter 18.57 RCW; an osteopathic physician assistant under chapter 18.57A RCW who is licensed under RCW 18.57A.020 subject to any limitations in RCW 18.57A.040; an optometrist licensed under chapter 18.53 RCW who is certified by the optometry board under RCW 18.53.010 subject to any limitations in 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 registered nurse, advanced registered nurse practitioner, or licensed practical nurse under chapter 18.79 RCW; a naturopathic physician under chapter 18.36A RCW who is licensed under RCW 18.36A.030 subject to any limitations in RCW 18.36A.040; a pharmacist under chapter 18.64 RCW or a scientific investigator under this chapter, licensed, registered or otherwise permitted insofar as is consistent with those licensing laws to

distribute, dispense, conduct research with respect to or administer a controlled substance in the course of their professional practice or research in this state.

(2) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a controlled substance in the course of professional practice or research in this state.

(3) A physician licensed to practice medicine and surgery, 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, an advanced registered nurse practitioner licensed to prescribe controlled substances, or a veterinarian licensed to practice veterinary medicine in any state of the United States.

(y) "Prescription" means an order for controlled substances issued by a practitioner duly authorized by law or rule in the state of Washington to prescribe controlled substances within the scope of his or her professional practice for a legitimate medical purpose.

(z) "Production" includes the manufacturing, planting, cultivating, growing, or harvesting of a controlled substance.

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

(bb) "State," unless the context otherwise requires, means a state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, or a territory or insular possession subject to the jurisdiction of the United States.

(cc) "Ultimate user" means an individual who lawfully possesses a controlled substance for the individual's own use or for the use of a member of the individual's household or for administering to an animal owned by the individual or by a member of the individual's household.

(dd) "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 verbally transmitted by telephone nor a facsimile manually signed by the practitioner.

Sec. 3. RCW 69.50.308 and 2012 c 10 s 46 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 certified or paid for by medicare under Title XVIII; or~~

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

((~~(v)~~)) (iv) 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 state board of pharmacy, 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. ((~~A prescription for a substance included in Schedule II may not be refilled.~~))

(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 ((~~or~~)), IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written ((~~or~~)), oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing. ((~~The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.~~

~~(e)~~)) (f) 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) 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.

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

((~~(g)~~)) (i) 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.

((~~(h)~~)) (j) 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.

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

Sec. 4. RCW 69.50.312 and 1998 c 222 s 4 are each amended to read as follows:

(1) Information concerning ((~~an original~~)) a prescription for a controlled substance included in Schedules II through V, or information concerning a ((~~prescription~~)) refill authorization for a controlled substance included in Schedules III through V may be electronically communicated to a pharmacy of the patient's choice 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 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 and in accordance with federal rules for electronically communicated prescriptions for controlled substance included in Schedules II through V, as set forth in Title 21 CFR Parts 1300, 1304, 1306, and 1311. This subsection does not apply to currently used facsimile equipment transmitting an exact visual image of the prescription. The board shall maintain and provide, upon request, a list of systems used for electronically communicating prescription information currently approved by the board;

(c) An explicit opportunity for practitioners must be made to indicate their preference on whether a therapeutically equivalent generic drug may be substituted;

(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.

(2) The board may adopt rules implementing this section.

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