S-0225.3

SENATE BILL 5469

State of Washington 63rd Legislature 2013 Regular Session

By Senators Frockt, Rivers, Hobbs, Keiser, Hatfield, Ericksen, Kohl-Welles, and Delvin

AN ACT Relating to the prescription of biological products and interchangeable biosimilar products; amending RCW 69.41.010, 69.41.120, and 69.41.190; and adding a new section to chapter 69.41 RCW.

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 for a legend drug between an authorized practitioner and a pharmacy or the transfer of prescription information for a legend drug from one pharmacy to another pharmacy.

(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.

(18) "Biological product" has the same meaning as provided in 42 U.S.C. Sec. 262(i)(1), and means any of the following, when applied to the prevention, treatment, or cure of a disease or condition of human beings:

(a) A virus;

(b) A therapeutic serum;

(c) A toxin;

(d) An antitoxin;

(e) A vaccine;

(f) Blood;

(g) An allergenic product;

(h) A protein, other than a chemically synthesized polypeptide, or an analogous product; or

(i) Arsphenamine, a derivative of arsphenamine, or any trivalent organic arsenic compound.

(19) "Biosimilar product" means a biological product licensed by the federal food and drug administration pursuant to 42 U.S.C. Sec. 262(k)(3)(A)(i).

(20) "Interchangeable" means, in reference to a biological product, that the federal food and drug administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. Sec. 262(k)(4).

Sec. 2. RCW 69.41.120 and 2000 c 8 s 3 are each amended to read as follows:

Every drug or biological product prescription shall contain an

instruction on whether or not a therapeutically equivalent generic drug or interchangeable biosimilar product may be substituted in its place, unless substitution is permitted under a prior-consent authorization.

If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words "DISPENSE AS WRITTEN". Under the line at the left side shall be clearly printed the words "SUBSTITUTION PERMITTED". The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. In the case of a prescription issued by a practitioner in another state that uses a one-line prescription form or variation thereof, the pharmacist may substitute a therapeutically equivalent generic drug or interchangeable biosimilar product unless otherwise instructed by the practitioner through the use of the words "dispense as written", words of similar meaning, or some other indication.

If an oral prescription is involved, the practitioner or the practitioner's agent shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biosimilar product may be substituted in its place. The pharmacist shall note the instructions on the file copy of the prescription.

The pharmacist shall note ((~~the manufacturer of the drug dispensed~~)) on the file copy of a written or oral prescription the manufacturer of the drug dispensed or, if an interchangeable biosimilar product is dispensed, the brand name or, if there is not a brand name, the nonproprietary name, the strength, and the name of the manufacturer or distributor of the product.

The pharmacist shall retain the file copy of a written or oral prescription for at least the same period of time specified in RCW 18.64.245 for retention of prescription records.

Sec. 3. RCW 69.41.190 and 2011 1st sp.s. c 15 s 80 are each amended to read as follows:

(1)(a)(i) Except as provided in subsection (2) of this section, any pharmacist filling a prescription under a state purchased health care program as defined in RCW 41.05.011((~~(2)~~)) (21) shall substitute, where identified, a preferred drug or biological product for any nonpreferred

drug or biological product in a given therapeutic class, unless the endorsing practitioner has indicated on the prescription that the nonpreferred drug or biological product must be dispensed as written, or the prescription is for a refill of an antipsychotic, antidepressant, antiepileptic, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of a immunomodulator/antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks but no more than forty-eight weeks, in which case the pharmacist shall dispense the prescribed nonpreferred drug or biological product.

(ii) In the case of a biological product, any pharmacist filling a prescription for a specific biological product may substitute a biosimilar product for the prescribed biological product only if the federal food and drug administration has determined that the biosimilar product is interchangeable with the prescribed biological product.

(b) When a substitution is made under (a) of this subsection, the dispensing pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed.

(c) If a pharmacist dispenses an interchangeable biosimilar product that is not the biological product prescribed, the pharmacist shall notify the patient or the patient's representative and the prescribing practitioner. The notification to the prescribing practitioner must:

(i) Be transmitted in writing or electronically;

(ii) Identify the brand name or, if there is not a brand name, the nonproprietary name, strength, and manufacturer or distributor of the interchangeable biosimilar product dispensed to the patient; and

(iii) Be transmitted to the prescribing practitioner not later than the third day after the date the interchangeable biosimilar product is dispensed.

(2)(a) A state purchased health care program may impose limited restrictions on an endorsing practitioner's authority to write a prescription to dispense as written only under the following circumstances:

(i) There is statistical or clear data demonstrating the endorsing practitioner's frequency of prescribing dispensed as written for nonpreferred drugs or biological products varies significantly from the prescribing patterns of his or her peers;

(ii) The medical director of a state purchased health program has: (A) Presented the endorsing practitioner with data that indicates the endorsing practitioner's prescribing patterns vary significantly from his or her peers, (B) provided the endorsing practitioner an opportunity to explain the variation in his or her prescribing patterns to those of his or her peers, and (C) if the variation in prescribing patterns cannot be explained, provided the endorsing practitioner sufficient time to change his or her prescribing patterns to align with those of his or her peers; and

(iii) The restrictions imposed under ((~~(a) of~~)) this subsection (2)(a) must be limited to the extent possible to reduce variation in prescribing patterns and shall remain in effect only until such time as the endorsing practitioner can demonstrate a reduction in variation in line with his or her peers.

(b) A state purchased health care program may immediately designate an available, less expensive, equally effective generic product in a previously reviewed drug class as a preferred drug, without first submitting the product to review by the pharmacy and therapeutics committee established pursuant to RCW 70.14.050.

(c) For a patient's first course of treatment within a therapeutic class of drugs or biological products, a state purchased health care program may impose limited restrictions on endorsing practitioners' authority to write a prescription to dispense as written, only under the following circumstances:

(i) There is a less expensive, equally effective therapeutic alternative generic product or interchangeable biosimilar product available to treat the condition;

(ii) The drug use review board established under WAC 388-530-4000 reviews and provides recommendations as to the appropriateness of the limitation;

(iii) Notwithstanding the limitation set forth in (c)(ii) of this subsection (2), the endorsing practitioner shall have an opportunity to request as medically necessary, that the brand name drug or biological product be prescribed as the first course of treatment;

(iv) The state purchased health care program may provide, where available, prescription, emergency room, diagnosis, and hospitalization history with the endorsing practitioner; and

(v) Specifically for antipsychotic restrictions, the state purchased health care program shall effectively guide good practice without interfering with the timeliness of clinical decision making. Health care authority prior authorization programs must provide for responses within twenty-four hours and at least a seventy-two hour emergency supply of the requested drug or biological product.

(d) If, within a therapeutic class, there is an equally effective therapeutic alternative over-the-counter drug available, a state purchased health care program may designate the over-the-counter drug as the preferred drug.

(e) A state purchased health care program may impose limited restrictions on endorsing practitioners' authority to prescribe pharmaceuticals to be dispensed as written for a purpose outside the scope of their approved labels only under the following circumstances:

(i) There is a less expensive, equally effective on-label product available to treat the condition;

(ii) The drug use review board established under WAC 388-530-4000 reviews and provides recommendations as to the appropriateness of the limitation; and

(iii) Notwithstanding the limitation set forth in (e)(ii) of this subsection (2), the endorsing practitioner shall have an opportunity to request as medically necessary, that the drug or biological product be prescribed for a covered off-label purpose.

(f) The provisions of this subsection related to the definition of medically necessary, prior authorization procedures and patient appeal rights shall be implemented in a manner consistent with applicable federal and state law.

(3) Notwithstanding the limitations in subsection (2) of this section, for refills for an antipsychotic, antidepressant, antiepileptic, chemotherapy, antiretroviral, or immunosuppressive drug, or for the refill of an immunomodulator antiviral treatment for hepatitis C for which an established, fixed duration of therapy is prescribed for at least twenty-four weeks by no more than forty-eight weeks, the pharmacist shall dispense the prescribed nonpreferred drug or biological product.

(4) If the federal food and drug administration makes available a current list of biosimilar products determined by the federal food and

drug administration to be interchangeable with specific biological products, the state board of pharmacy shall maintain on its web site a link to the list.

NEW SECTION. **Sec. 4.** A new section is added to chapter 69.41 RCW to read as follows:

If a pharmacist fills a prescription not covered under a state purchased health care program, the following apply:

(1) If a pharmacist dispenses an interchangeable biosimilar product that is not the biological product prescribed, the pharmacist shall notify the patient or the patient's representative and the prescribing practitioner. The notification to the prescribing practitioner must:

(a) Be transmitted in writing or electronically;

(b) Identify the brand name or, if there is not a brand name, the nonproprietary name, strength, and manufacturer or distributor of the interchangeable biosimilar product dispensed to the patient; and

(c) Be transmitted to the prescribing practitioner not later than the third day after the date the interchangeable biosimilar product is dispensed.

(2) A pharmacist who selects an interchangeable biosimilar product to be dispensed under this section assumes the same responsibility for selecting the interchangeable biosimilar product as the pharmacist does in filling a prescription for the interchangeable biosimilar product when prescribed by name. The prescribing practitioner is not liable for a pharmacist's act or omission in selecting, preparing, or dispensing an interchangeable biosimilar product under this section.

--- END ---