ENGROSSED SENATE BILL 5935

AS AMENDED BY THE HOUSE

Passed Legislature - 2015 Regular Session

State of Washington 64th Legislature 2015 Regular Session

By Senators Parlette and Frockt

Read first time 02/11/15. Referred to Committee on Health Care.

AN ACT Relating to biological products; amending RCW 69.41.110, 69.41.120, 69.41.150, and 69.41.160; adding new sections to chapter 69.41 RCW; and providing expiration dates.

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

Sec. 1. RCW 69.41.110 and 1979 c 110 s 1 are each amended to read as follows:

As used in RCW 69.41.100 through 69.41.180, the following words shall have the following meanings:

(1) "Brand name" means the proprietary or trade name selected by the manufacturer and placed upon a drug, its container, label, or wrapping at the time of packaging;

(2) "Generic name" means the official title of a drug or drug ingredients published in the latest edition of a nationally recognized pharmacopoeia or formulary;

(3) "Substitute" means to dispense, with the practitioner's authorization, a "therapeutically equivalent" drug product ((~~of the identical base or salt as the specific drug product prescribed: PROVIDED, That with the practitioner's prior consent, therapeutically equivalent drugs other than the identical base or salt may be dispensed~~)) or "interchangeable biological" drug product;

(4) "Therapeutically equivalent" means a drug product of the identical base or salt as the specific drug product prescribed with essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen; ((~~and~~))

(5) "Practitioner" means a physician, osteopathic physician and surgeon, dentist, veterinarian, or any other person authorized to prescribe drugs under the laws of this state;

(6) "Biological product" 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, blood component, or derivative; (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; and

(7) "Interchangeable" means a biological product:

(a) Licensed by the federal food and drug administration and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or

(b) Approved based on an application filed under section 505(b) of the federal food, drug, and cosmetic act that is determined by the federal food and drug administration to be therapeutically equivalent to an approved 505(b) biological product and is included in the 505(b) list maintained by the pharmacy quality assurance commission pursuant to section 5 of this act.

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

(1) Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological 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 biological product unless otherwise instructed by the practitioner through the use of the words "dispense as written", words of similar meaning, or some other indication.

(2) 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 biological product may be substituted in its place. The pharmacist shall note the instructions on the file copy of the prescription.

(3) The pharmacist shall note the manufacturer of the drug dispensed on the file copy of a written or oral prescription.

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

NEW SECTION. **Sec. 3.** A new section is added to chapter 69.41 RCW to read as follows:

Unless the prescribed biological product is requested by the patient or the patient's representative, if "substitution permitted" is marked on the prescription as provided in RCW 69.41.120, the pharmacist must substitute an interchangeable biological product that he or she has in stock for the biological product prescribed if the wholesale price for the interchangeable biological product to the pharmacist is less than the wholesale price for the biological product prescribed.

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

(1) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee must make an entry of the specific product provided to the patient, including either the name of the product and the manufacturer or the federal food and drug administration's national drug code, provided that the name of the product and the name of the manufacturer are accessible to a practitioner in an electronic records system that can be electronically accessed by the patient's practitioner through:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing technology;

(c) A pharmacy benefit management system; or

(d) A pharmacy record.

(2) Entry into an electronic records system, as described in subsection (1) of this section, is presumed to provide notice to the practitioner. Otherwise, the pharmacist must communicate to the practitioner the specific product provided to the patient, including the name of the product and manufacturer, using facsimile, telephone, electronic transmission, or other prevailing means.

(3) No entry or communication pursuant to this section is required if:

(a) There is no interchangeable biological product for the product prescribed;

(b) A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or

(c) The pharmacist or the pharmacist's designee and the practitioner communicated before dispensing and the communication included confirmation of the specific product to be provided to the patient, including the name of the product and the manufacturer.

(4) This section expires August 1, 2020.

NEW SECTION. **Sec. 5.** A new section is added to chapter 69.41 RCW to read as follows:

The pharmacy quality assurance commission shall maintain a link on its web site to the current list of all biological products determined by the federal food and drug administration as interchangeable. The commission shall maintain a list of all biological products approved as therapeutically equivalent by the federal food and drug administration through the approval process specified in 505(b) of the federal food, drug, and cosmetic act. The commission shall make the 505(b) list accessible to pharmacies.

Sec. 6. RCW 69.41.150 and 2003 1st sp.s. c 29 s 6 are each amended to read as follows:

(1) A practitioner who authorizes a prescribed drug shall not be liable for any side effects or adverse reactions caused by the manner or method by which a substituted drug product is selected or dispensed.

(2) A pharmacist who substitutes ((~~an~~)) a therapeutically equivalent drug product pursuant to RCW 69.41.100 through 69.41.180

as now or hereafter amended assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

(3) A pharmacist who substitutes a preferred drug for a nonpreferred drug pursuant to RCW 69.41.190 assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name.

(4) A pharmacist who selects an interchangeable biological product to be dispensed pursuant to RCW 69.41.100 through 69.41.180, and the pharmacy for which the pharmacist is providing service, assumes no greater liability for selecting the interchangeable biological product than would be incurred in filling a prescription for the interchangeable biological 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 biological product under this section.

Sec. 7. RCW 69.41.160 and 1979 c 110 s 6 are each amended to read as follows:

Every pharmacy shall post a sign in a location at the prescription counter that is readily visible to patrons stating, "Under Washington law, ((~~an equivalent but~~)) a less expensive interchangeable biological product or equivalent drug may in some cases be substituted for the drug prescribed by your doctor. Such substitution, however, may only be made with the consent of your doctor. Please consult your pharmacist or physician for more information."

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