H-0340.2

HOUSE BILL 1679

State of Washington 64th Legislature 2015 Regular Session

By Representatives Moeller and Harris

AN ACT Relating to the prescribing of biological products; and amending RCW 69.41.110, 69.41.120, 69.41.130, 69.41.150, and 69.41.160.

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;

(7) "Biosimilar product" means a biological product licensed by the federal food and drug administration pursuant to 42 U.S.C. Sec. 262(i)(2); and

(8) "Interchangeable" means, in reference to a biological product, that the federal food and drug administration has determined that a biological product meets the safety standards set forth in 42 U.S.C. Sec. 262(k)(4) and may be substituted for the reference product without notification or the intervention of the health care provider who prescribed the reference product.

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 electronically in the patient's health records or 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.

Sec. 3. RCW 69.41.130 and 2012 c 117 s 365 are each amended to read as follows:

Unless the brand name drug or biological product is requested by the patient or the patient's representative, the pharmacist shall substitute ((~~an~~)) a therapeutically equivalent drug product or interchangeable biological product, which he or she has in stock if its wholesale price to the pharmacist is less than the wholesale price of the prescribed drug product, and at least sixty percent of the savings shall be passed on to the purchaser.

Sec. 4. 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 under this section assumes no greater liability for selecting the interchangeable biological product as the pharmacist does in filling a prescription for the interchangeable biological product when prescribed by name.

Sec. 5. 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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