H-0702.3

HOUSE BILL 1675

State of Washington 64th Legislature 2015 Regular Session

By Representatives Sullivan, Schmick, Cody, Harris, and Tharinger

Read first time 01/26/15. Referred to Committee on Health Care & Wellness.

AN ACT Relating to the prescription of biological products and interchangeable biological products; amending RCW 69.41.110, 69.41.120, 69.41.130, 69.41.150, and 69.41.160; and adding a new section to chapter 69.41 RCW.

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

Sec. 1. RCW 69.41.110 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 <u>or interchangeable "biological product"</u> prescribed: PROVIDED, That with the practitioner's prior consent, therapeutically equivalent drugs other than the identical base or salt may be dispensed;

(4) "Therapeutically equivalent" means 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" has the same meaning as defined in 42 U.S.C. Sec. 262(i), relating to regulation of biological products; and

(7) "Interchangeable" means (a) a biological product 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) a biological product determined by the federal food and drug administration to be therapeutically equivalent as set forth in the latest edition or supplement of the federal food and drug administration approved drug products with therapeutic equivalence evaluations, sometimes referred to as the "orange book."

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 the manufacturer and name of the drug or biological product dispensed.

(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:

(1) Within a reasonable time following the dispensing of a biological product, the dispensing pharmacist or pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry in an interoperable electronic medical records system or through an electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

(a) There is no federal food and drug administration approved interchangeable biological product for the product prescribed; or

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

(2) 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.

Sec. 4. 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. 5. 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, as now or hereafter amended, 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. 6. 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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