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HOUSE BILL 2326

State of Washington 63rd Legislature 2014 Regular Session

By Representatives Cody, Schmick, Harris, Morrell, Ross, Manweller, Sullivan, Ryu, and Jinkins

Read first time 01/15/14. 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, 69.41.150, 69.41.130, 69.41.160, and 69.41.050; 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 prescribed~~)) or

"interchangeable biological" drug product: 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 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 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~~)) on the file copy of a written or oral prescription the manufacturer of the drug product dispensed, the brand name or, if there is not a brand name, the nonproprietary name.

(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) If a biological product is dispensed, the pharmacist or the pharmacist's designee shall within a reasonable time but not to exceed ten days following the dispensing, record the name and manufacturer of the product dispensed in an interoperable health records system shared with the prescribing practitioner, to the extent such a system is available; or, in the case that an interoperable electronic health

records system is not in place, communicate to the prescribing practitioner the name and the manufacturer of the biological product dispensed to the patient. No communication to the prescribing practitioner is required under this subsection where there is no interchangeable biological product for the prescribed biological product, or for a refill prescription that is not changed from the product originally dispensed.

(2) The pharmacy quality commission shall maintain a link on its web site to the current list of all biological products determined by the United States food and drug administration to be interchangeable with a specific reference biological product.

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 the same responsibility for selecting the interchangeable biological product as the pharmacist does 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. 5. 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 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. 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."

Sec. 7. RCW 69.41.050 and 2003 c 53 s 325 are each amended to read as follows:

(1) To every box, bottle, jar, tube, or other container of a legend drug, which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label bearing the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of the manufacturer, name of patient and date: PROVIDED, That the practitioner may omit the name and dosage of the drug if he or she determines that his or her patient should not have this information and that, if the drug dispensed is a trial sample in its original package and which is labeled in accordance with federal law or regulation, there need be set forth additionally only the name of the issuing practitioner and the name of the patient.

(2) A violation of this section is a misdemeanor.

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