ARIZONA STATE SENATE

Fifty-Second Legislature, Second Regular Session

AMENDED

FACT SHEET FOR H.B. 2310

biological products; prescription orders

Purpose

Permits a pharmacist to substitute a biological product for a prescribed biological product if certain conditions are met, and outlines requirements relating to the substitution.

Background

Biological products (biologics) are medical products derived from living organisms and used for prevention or treatment of a disease, including human growth hormone, injectable treatments for arthritis and psoriasis, the hepatitis B vaccine and stem cell therapy.

According to the U.S. Food and Drug Administration (FDA), a biosimilar product is a biologic that is approved based on the demonstration that it is highly similar to an FDA-approved biologic, and has no clinically meaningful differences in terms of safety and effectiveness and only minor differences in clinically inactive components. An interchangeable biologic is a biosimilar product that meets additional standards for interchangeability. These products may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

In March of 2015, the FDA approved the first biosimilar, Zarxio, for Neupogen. Of the list of licensed biologics provided by both the Center for Drug Evaluation and Research and Center for Biologic Evaluation and Research, Zarxio remains the only approved biosimilar. There are currently no approved interchangeable biologics.

Pursuant to A.R.S. § 32-1963.01, a pharmacist is permitted to fill a prescription with a generic equivalent drug, if a medical practitioner prescribes a brand name drug and does not indicate an intent to prevent substitution. Prescriptions to be dispensed as written must clearly display *DAW*, *dispense as written*, or other statements that indicate intent to prevent substitution.

Pharmacists are required to notify recipients of the price difference between the brand name and generic equivalent drug, in situations where the medical practitioner does not prevent substitution and the purchase is not subject to third-party reimbursement. Labels are required to contain the phrase *generic equivalent for* followed by the brand name of the product that is being replaced. The liability of a pharmacist in substituting is no greater than that incurred in the filling of a generically written prescription.

There is no anticipated fiscal impact to the state General Fund associated with this legislation.

Provisions

1. Permits a pharmacist to substitute a biological product for a prescribed biological product if:
   a) the FDA has determined the substituted product to be an interchangeable biological product;
   b) the prescribing physician does not designate in writing or electronically that substitution is prohibited;
   c) the pharmacy informs the patient or person presenting the prescription of the substitution;
   d) the pharmacy retains a record of the biological product dispensed; and
   e) within five business days after dispensing a biological product, the dispensing pharmacist or the pharmacist's designee makes an entry of the specific product provided to the patient, including the name of the product and the manufacturer.

2. Requires the communication from the dispensing pharmacist to be conveyed by making an entry that is electronically accessible to the prescriber through an interoperable electronic medical records system, an electronic prescribing technology, a pharmacy benefit manager system or a pharmacy record. Entry is presumed to provide notice to the prescriber, otherwise the pharmacist is required to communicate the biological product dispensed to the prescriber.

3. Specifies that communication is not required if:
   a) there is no interchangeable biological product approved by the FDA for the product prescribed; or
   b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

4. Requires the pharmacist to notify the person presenting the prescription of the amount of price difference between the biological product prescribed and the interchangeable biological product, if:
   a) the medical practitioner does not indicate an intent to prevent substitution with an interchangeable biological product; and
   b) the transaction is not subject to third-party reimbursement.

5. Requires the pharmacist to place on the container the name of the biological product dispensed followed by the words "interchangeable biological product for" followed by the brand or trade name of the product that is being replaced by the interchangeable biological product.

6. Prohibits an employer or agent of an employer of a pharmacist from requiring the pharmacist to dispense any specific interchangeable biological product or to substitute any interchangeable biological product for a biological product against the professional judgment of the pharmacist or the order of the prescriber.

7. Prohibits a pharmacist from making a substitution unless the manufacturer or distributor of the interchangeable biological product has shown that:
   a) all products dispensed have an expiration date on the original package; and
   b) the manufacturer or distributor maintains recall and return capabilities for unsafe or defective biological products.

8. Requires the Board of Pharmacy to maintain on its public website a link to the current list of each biological product determined by the FDA to be an interchangeable biological product.

9. Defines *biological product* as a virus, therapeutic serum, toxin, antitoxin, vaccine, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment or cure of a disease or condition of human beings.

10. Defines *interchangeable biological product* as a biological product that either:
    a) the FDA has licensed and determined meets the safety standards for determining interchangeability; or
    b) is determined to be therapeutically equivalent as set forth in the latest edition of the supplement to the FDA's approved drug products with therapeutic equivalence evaluations.

11. Makes technical and conforming changes.

12. Becomes effective on January 1, 2017.

Amendments Adopted by Committee

- Delays the effective date to January 1, 2017.

House Action				Senate Action			
Health	1/26/16	DP	5-0-0-1	HHS	3/9/16	DPA	6-0-1
3rd Read	2/04/16		56-1-3-0				

Prepared by Senate Research
March 9, 2016
EM/ls