INTERIM STUDY PROPOSAL 2013-008

State of Arkansas *As Engrossed: S2/4/13*

89th General Assembly **A Bill**

Regular Session, 2013 SENATE BILL 149

By: Senator Files

Filed with: Interim Senate Committee on Public Health, Welfare and Labor pursuant to A.C.A. §10-3-217.

For An Act To Be Entitled

AN ACT TO REGULATE THE SUBSTITUTION OF BIOSIMILAR BIOLOGICAL PRODUCTS FOR CERTAIN PRESCRIBED PRODUCTS; AND FOR OTHER PURPOSES.

Subtitle

TO REGULATE THE SUBSTITUTION OF BIOSIMILAR BIOLOGICAL PRODUCTS FOR CERTAIN PRESCRIBED PRODUCTS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 17, Chapter 92, is amended to add an additional subchapter to read as follows:

Subchapter 5 — Biosimilar Biological Products

17-92-507. Biosimilar biological products.

(a) As used in this section:

(1) "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", and "reference product" have the meanings established under Section 351 of the Public Health Service Act, 42 U.S.C. § 262; and

(2) "Prescription" means a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353(b).

(b)(1) Except as provided in subsection (c) of this section, when a pharmacist receives a prescription for a biological product, the pharmacist may dispense a lower cost interchangeable biosimilar drug product.

(2) The total amount charged for the substituted interchangeable biosimilar product or for dispensing the prescribed product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that prescribed product or for the dispensing of the prescribed product.

(3) A pharmacist, a pharmacist's employee, or agent of a pharmacist shall notify the prescriber of the substitution of an interchangeable biosimilar product, including the full name and manufacturer, in writing or electronically not later than three (3) days after the date the product is dispensed.

(4) A pharmacist, the pharmacist's employee, or agent of a pharmacist, before dispensing an interchangeable biosimilar as a substitute for the prescribed biological product, shall inform the person for whom the medication is prescribed and the label of the dispensed shall appropriately indicate the substitution.

(5) A pharmacist shall record and retain for a period of two (2) years such records, the substitution of a reference product, including the full name and manufacturer of the prescribed product and of the interchangeable biosimilar product substituted for the prescribed product.

(c) A pharmacist shall not dispense an interchangeable biosimilar product under subsection (b) of this section:

(1) Unless the purchaser agrees to the total charge, if the total charge for the interchangeable biosimilar product exceeds the total charge of the prescribed product originally prescribed;

(2) For a prescription in writing signed by the prescriber, if the prescriber indicates in his or her own handwriting by name or initial that a substitution shall not be made;

(3) For a prescription other than one in writing signed by the prescriber, if the prescriber expressly indicates that the prescription is to be dispensed as communicated;

(4) If the individual for whom the reference product is prescribed indicates that the prescription shall be dispensed as written or communicated; or

(5) If the Arkansas State Board of Pharmacy has determined that the product shall not be substituted and has notified all pharmacists of that determination.

(d) The Arkansas State Board of Pharmacy shall:

(1)(A) Determine which biosimilar biological products are interchangeable.

(B) The Arkansas State Board of Pharmacy shall make the determination under subdivision (d)(1)(A) of this section on the basis of the determination of the United States Food and Drug Administration regarding interchangeability with the prescribed biological product; and

(2) Notify each licensed pharmacist and the Arkansas State Medical Board of the determination and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

/s/Files

Referred by the Arkansas Senate
Prepared by: MGF/VJF