INTERIM STUDY PROPOSAL 2011-227

State of Arkansas
89th General Assembly
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A Bill

DRAFT MGF/NJR
SENATE BILL

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 13 — 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 and Service Act, 42 U.S.C. § 262, as it existed on January 1, 2013; 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), as it existed on January 1, 2013.

(b)(1) Except as provided in subsection (c) of this section, when a pharmacist receives a prescription for a reference 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 reference product shall not exceed the amount normally and regularly charged under comparable circumstances by the pharmacist for that reference product or for the dispensing of the reference product.

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

(4) A pharmacist shall record the substitution of a reference product in the manner required under § 17-92-410.

(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 reference 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 no substitution shall be made;

(3) For a prescription other than one in writing signed by the prescriber, unless 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 reference biological product for the specified indicated use, as the determination existed on January 1, 2013; 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.

Referral requested by: Senator Percy Malone

Prepared by: MGF/jlc