INTERIM STUDY PROPOSAL 2017-007

State of Arkansas *As Engrossed: H2/8/17*

91st General Assembly **A Bill**

Regular Session, 2017 HOUSE BILL 1204

By: Representative Magie

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

For An Act To Be Entitled

AN ACT TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL PRODUCT SUBSTITUTIONS; AND FOR OTHER PURPOSES.

Subtitle

TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL PRODUCT SUBSTITUTIONS.

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

SECTION 1. Arkansas Code § 17-92-101, concerning the definitions relating to pharmacists, pharmacies, and the practice of pharmacy, is amended to add new subdivisions to read as follows:

(24) "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein that is not chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any trivalent organic sersenic compound applicable to the prevention, treatment, or cure of a disease or condition of a human being; and

(25) "Interchangeable biological product" means a biological product that the United States Food and Drug Administration has:

(A) Licensed and determined to meet the standards of interchangeability established by 42 U.S.C. § 262(k)(4), as existing on January 1, 2017; or

(B) Determined to be therapeutically equivalent to another biological product as set forth in the United States Food and Drug

Administration's "Approved Drug Products with Therapeutic Equivalence Evaluations", also known as the "Orange Book", as existing on January 1, 2017.

SECTION 2. Arkansas Code § 17-92-503 is amended to read as follows:

17-92-503. Generic drug product and biological product substitutions.

(a)(1) Except as provided in subsection (b) of this section, when a pharmacist receives a prescription for a brand or trade name drug product or biological product, the pharmacist may dispense a lower cost generically equivalent drug product or interchangeable biological product.

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

(3) A pharmacist may not dispense a drug product or interchangeable biological product with a total charge that exceeds the total charge of the drug product *or biological product* originally prescribed unless agreed to by the purchaser.

(b) The pharmacist shall not dispense a generically equivalent drug product or interchangeable biological product under subsection (a) of this section if:

(1) The prescriber, in the case of a prescription in writing signed by the prescriber, indicates in his or her own handwriting by name or initial that no substitution shall be made;

(2) The prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates that the prescription is to be dispensed as communicated;

(3) The person for whom the drug product or biological product is prescribed indicates that the prescription is to be dispensed as written or communicated; or

(4) The Arkansas State Board of Pharmacy has determined that the drug product or biological product should not be substituted and has notified all pharmacists of that determination.

(c)(1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent as defined in § 17-92-101, relying on standards scientifically supported and generally accepted in the field of pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.

(2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

(d)(1) Within five (5) business days after dispensing a biological product, the dispensing pharmacist or his or her designee shall enter the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product.

(2) The entry shall be electronically accessible to the prescriber through:

(A) An interoperable electronic medical records system;

(B) An electronic prescribing technology;

(C) A pharmacy benefit management system; or

(D) A pharmacy record.

(3) If the pharmacist is unable to make an entry as described in subdivision (d)(2) of this section, a pharmacist shall communicate to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means the biological product dispensed.

(4) An entry made into an electronic records system as described in subdivision (d)(2) or subdivision (d)(3) of this section is presumed to provide notice to the prescriber of the dispensing of the biological product.

(5) A communication is not required when:

(A) An interchangeable biological product does not exist for the prescribed biological product; or

(B) A refill prescription for a biological product is not substituted for an interchangeable biological product on a subsequent filling of the prescription.

(6) The pharmacist or pharmacy shall maintain a record of biological products dispensed for at least two (2) years.

SECTION 3. Arkansas Code § 17-92-505 is amended to read as follows:

17-92-505. Labeling.

(a)(1) The pharmacist filling a prescription for dispensing to an ultimate patient may affix to the container a label showing:

(A) The pharmacy name, address, and telephone number;

(B) The date of dispensing;

(C) The serial number of the prescription;

(D) The name of the patient;

(E) The name of the prescribing practitioner;

(F) The trade name of the ~~medication~~ drug product, if any, or the generic name and identity of the manufacturer of the dispensed ~~medication~~ drug product, if the medication appears generically listed on the drug formulary list as established by this subchapter, or in the case of a biological product, the trade name of the biological product, if any, or the proper name of the biological product and identity of the manufacturer of the dispensed biological product;

(G) The strength per unit dose of the medication;

(H) The quantity of the medication; and

(I) Directions for use.

(2) If a pharmacist dispenses a generically equivalent product, the person for whom the medication is prescribed shall be informed prior to dispensing or the label should appropriately indicate the substitution.

(3) However, this subsection shall not apply to the dispensing of medication to inpatients in hospitals.

(4) ~~Further, in an appropriate manner,~~ In the case of dispensing *a drug product*, the prescribing practitioner may indicate that the name, manufacturer, and strength of the medication dispensed shall be deleted from the label.

(b)(1) ~~Any authorized person filling a prescription~~ An authorized person who fills a prescription for dispensing to an ultimate patient shall affix to the container a label showing the trade name of the medication or the generic name of the medication unless directed to the contrary by the physician.

(2) Failure to comply with this subsection shall be grounds for disciplinary action.

(c) An authorized person who fills a prescription for dispensing to a patient shall affix to the container a label showing the trade name, if any, or the proper name of the biological product.

(2) Failure to comply with this subsection shall be grounds for disciplinary action.

SECTION 4. Arkansas Code § 17-92-506 is amended to read as follows:

17-92-506. ~~Price~~ Available drug product and biological product lists.

(a)(1) A pharmacist may display, within the confines of the pharmacy, lists of available drug products and biological products, other than controlled substances, and current charges for the drug products or biological products or for the dispensing of the drug products or biological products in specified quantities.

(2) Upon request, a pharmacy may make such lists available to its customers and other members of the public.

(b) The Arkansas State Board of Pharmacy shall maintain on the website of the board a link to the list of all interchangeable biological products approved by the United States Food and Drug Administration.

/s/Magie

Referral requested by: Representative Stephen Magie

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