

INTERIM STUDY PROPOSAL 2017-007

State of Arkansas  
91st General Assembly  
Regular Session, 2017

*As Engrossed: H2/8/17*

**A Bill**

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

1 Administration's "Approved Drug Products with Therapeutic Equivalence  
2 Evaluations", also known as the "Orange Book", as existing on January 1,  
3 2017.

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

6 17-92-503. Generic drug product and biological product substitutions.

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

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

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

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

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

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

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

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

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

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

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

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

- 18 (A) An interoperable electronic medical records system;
- 19 (B) An electronic prescribing technology;
- 20 (C) A pharmacy benefit management system; or
- 21 (D) A pharmacy record.

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

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

29 (5) A communication is not required when:

- 30 (A) An interchangeable biological product does not exist  
31 for the prescribed biological product; or
- 32 (B) A refill prescription for a biological product is not  
33 substituted for an interchangeable biological product on a subsequent filling  
34 of the prescription.

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

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

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

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

7 (B) The date of dispensing;

8 (C) The serial number of the prescription;

9 (D) The name of the patient;

10 (E) The name of the prescribing practitioner;

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

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

19 (H) The quantity of the medication; and

20 (I) Directions for use.

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

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

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

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

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

