

2 State of Arkansas
3 91st General Assembly
4 Third Extraordinary Session, 2018

A Bill

JMB/JMB
HOUSE BILL

5
6 By: Representative Magic

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

For An Act To Be Entitled

9
10 AN ACT TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL
11 PRODUCT SUBSTITUTIONS; AND FOR OTHER PURPOSES.

Subtitle

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15 TO ALLOW PHARMACISTS TO MAKE BIOLOGICAL
16 PRODUCT SUBSTITUTIONS.

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

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

24 (25) "Biological product" means a biological product as defined
25 by 42 U.S.C. 262(i)(1), as existing on January 1, 2019; and

26 (26) "Interchangeable biological product" means a biological
27 product that is interchangeable as defined by 42 U.S.C. 262(i)(3), as
28 existing on January 1, 2019.

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

31 17-92-503. Generic drug product and biological product substitutions.

32 (a)(1)(A) Except as provided in subsection (b) of this section, when a
33 pharmacist receives a prescription for a brand or trade name drug product or
34 biological product, the pharmacist may dispense a ~~lower cost~~ generically
35 equivalent drug product or interchangeable biological product only when there
36 will be a cost savings for the patient.

1 (B) The pharmacist shall disclose the amount of the cost
2 savings at the request of the patient.

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

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

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

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

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

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

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

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

34 (2) In making this determination, the Arkansas State Board of
35 Pharmacy may use a nationally recognized reference source that meets the
36 requirements of this act, notifying each licensed pharmacist and the Arkansas

1 State Medical Board of the reference source to be used and any additions or
2 deletions the Arkansas State Board of Pharmacy may make in its discretion.

3 (d)(1) Within three (3) business days after dispensing an
4 interchangeable biological product that has been substituted for a biological
5 product, the dispensing pharmacist or his or her designee shall record the
6 specific interchangeable biological product provided to the patient,
7 including without limitation the name of the interchangeable biological
8 product and the manufacturer of the interchangeable biological product.

9 (2) The record shall be electronically accessible to the
10 prescriber through:

11 (A) An interoperable electronic medical records system;

12 (B) An electronic prescribing technology;

13 (C) A pharmacy benefit management system; or

14 (D) A pharmacy record.

15 (3) If requested by a prescriber, a pharmacist shall communicate
16 to the prescriber using facsimile, telephone, electronic transmission, or
17 other prevailing means that an interchangeable biological product has been
18 dispensed.

19 (4) A communication is not required when:

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

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

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

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28 SECTION 3. Arkansas Code § 17-92-505 is amended to read as follows:
29 17-92-505. Labeling.

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

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

33 (B) The date of dispensing;

34 (C) The serial number of the prescription;

35 (D) The name of the patient;

36 (E) The name of the prescribing practitioner;

(F) Either:

(i) 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 drug product appears generically
listed on the drug formulary list as established by this subchapter; or

(ii) 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
or interchangeable biological product, the person for whom the medication is
prescribed shall be informed ~~prior to~~ before dispensing or the label should
appropriately indicate the substitution.

(3) ~~However, this subsection shall~~ This subsection does 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 or biological product, the prescribing practitioner may
indicate that the name, manufacturer, and strength of the medication
dispensed shall be deleted from the label.

(b) ~~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:

(1) ~~the~~ The trade name of the medication or the generic name of
the medication unless directed to the contrary by the ~~physician. Failure to~~
~~comply with this subsection shall be grounds for disciplinary action.~~
prescribing practitioner; or

(2) The trade name, if any, or the proper name of the biological
product unless directed to the contrary by the prescribing practitioner.

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

1 biological products or for the dispensing of the drug products or biological
2 products in specified quantities.

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

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

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10 Referred by Representative Magie

11 Prepared by: JMB/JMB

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