INTERIM STUDY PROPOSAL 2017-007

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
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:
   (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:

(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
Prepared by: VJF