



Academy of  
Managed Care  
Pharmacy®

March 9, 2017

The Honorable Jeff Wardlaw, Chair  
House Public Health, Welfare and Labor Committee  
Room 130, State Capitol  
Little Rock, Arkansas

**RE: House Bill 1204 –Biological Product Substitutions**

Dear Representative Wardlaw:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of House Bill 1204 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in House Bill 1204 that amends Section 17-92-101 (25) (A) and defines “interchangeable biologic product” consistent with the Biologics Competition and Innovation Act (BPCIA) and the proposed language in Section 17-92-503 (a) (1) that allows a pharmacist to substitute a FDA approved “interchangeable biological product”. However, we oppose the language that defines an interchangeable biological product as therapeutically equivalent in Section 17-92-101 (25)(B) and the proposed provisions later in that section that impose additional administrative requirements to dispense an interchangeable biological that are different from existing requirements for all other classes of medications. We also concerned about enacting additional requirements prior to the FDA finalizing guidance on interchangeable biological products.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners, including members in Arkansas, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

*FDA guidance not yet final on interchangeable biological products*

To date, the FDA has not finalized guidance on the determination of interchangeability. In fact, the FDA released draft guidance on January 17 titled “Considerations in Demonstrating Interchangeability With a Reference Product” and the comment period closes on March 20, 2017. The FDA will not accept an application for approval of an interchangeable biological product until the guidance document is final.

The FDA Purple Book: Designated List of Biologic Products

The FDA has already created a publically available reference document: The Purple Book: Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations. When the draft guidance on interchangeability is finalized, the FDA will begin accepting applications and information will be available on licensed products in the Purple Book. Therefore, we recommend that the language proposed to amend Arkansas Code § 17-92-101 (25) (A) should include the title of the reference, i.e., the “Purple Book”. We also recommend that paragraph (25) (B), which references the Orange Book, should be deleted entirely. The Orange Book is the FDA’s list of drug products approved under the Food, Drug and Cosmetic Act. As previously mentioned applications for and approval of interchangeable biological products are only authorized under the BPCIA and will be listed in the Purple Book.

Additional administrative burdens on pharmacists

The language proposed in Section 17-92-101(d)(1)-(4) and (6), is problematic because it requires additional notification by the pharmacist to the prescriber and additional record keeping not required for any other class or category of drugs approved by the FDA. These provisions are unduly burdensome and time consuming for pharmacists and there are no proposed amendments that require the prescriber to maintain a record of the required notifications. Although the proposed amendments provide that notification can take place via the use of electronic systems in subdivision (d) (2), the primary mode of communication between prescribers and pharmacists is not via an electronic system.

In conclusion, we support adoption of the language that updates the Arkansas Code to allow for the substitution of biologic products with FDA approved interchangeable biological products and language that includes the FDA Purple Book reference. However, we oppose the amended language in Section 17-92-101(d) (1)-(4) and (6) that would add additional dispensing requirements not required for any other class of FDA approved drugs. We also urge you to delete the paragraph that references the Orange Book (Section 17-92-101 (25) (B)). Lastly, AMCP encourages the legislature to compare the final FDA guidance and at that time determine whether additional legislation is necessary. If you have any questions about our position, please contact AMCP’s Director of Legislative Affairs, Regina Benjamin, at (703) 683-8416 or [rbenjamin@amcp.org](mailto:rbenjamin@amcp.org).

Sincerely,



Susan A. Cantrell, RPh, CAE  
Chief Executive Officer