



Academy of
Managed Care
Pharmacy®

February 27, 2017

The Honorable April Weaver, Chair
House Health Committee
11 South Union Street
Suite 417-J
Montgomery, Alabama

RE: House Bill 82 –Biological Product Substitutions

Dear Representative Weaver:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of House Bill 82 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 82 that is consistent with the Biologics Competition and Innovation Act (BPCIA) definition of “interchangeable biologic product” and the language 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 and imposes 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 Alabama, 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 In fact, the FDA released draft guidance on January 17 titled “Considerations in Demonstrating Interchangeability With a Reference Product” and the comment period closes on March 20, 2017.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 Biological Products

The FDA has already created a publically available reference document: The Purple Book: Lists of Licensed Biological Products (Purple Book) 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 new language in Section 34-23-1, paragraph (9)(a) should include the title of the reference, i.e., as set forth in the latest edition of the “Purple Book”.

However, the language proposed to amend Section 34-23.1, paragraph (9)(b) which is to the latest edition of the FDA’s “Approved Drug Products with therapeutic equivalence evaluations” which is commonly referred to as the FDA Orange Book, should be deleted. 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 only in the Purple Book.

Additional administrative burdens on pharmacists

Specifically, the language proposed to amend section 34-23-8 paragraphs 5 (a) and 5(b), 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, the primary mode of communication between prescribers and pharmacists is not via an electronic system.

In conclusion, we urge you to adopt the language that updates Alabama statutes to allow for the substitution of biologic products with FDA approved interchangeable biological products. However, we urge you delete the additional requirements not required for any other class of FDA approved drugs and the paragraph that references the Orange Book. Lastly, AMCP also encourages the legislature to compare the final FDA guidance and at that time determine whether additional legislation is necessary.

We urge you to delete the additional requirements and the reference to the Orange Book. AMCP also encourages the legislature to review 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 Alabama advocacy leader Gregory O. Kitchens, PharmD at gokitchens@artiasolutions.com or AMCP’s Director of Legislative Affairs, Regina Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer