



Academy of  
Managed Care  
Pharmacy®

February 28, 2018

The Honorable Tim Armstead  
Speaker of the House of Delegates  
Room 228 Building 1  
State Capitol Complex  
Charleston, WV 25305

**RE: House Bill 4524 – Establishing Guidelines for the Substitution of Certain Biological Pharmaceuticals by Pharmacists**

Dear Speaker Armstead:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of House Bill 4524. This legislation would regulate biological products and substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in the bill that allows a pharmacist to substitute an FDA approved “interchangeable biological product”. That language is consistent with the Biologics Price Competition and Innovation Act (BPCIA) which allows a pharmacist to substitute an interchangeable biologic product without the intervention of the health care provider who prescribed the “reference product”.

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 West Virginia, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

**House Bill 4524 Should Reference the FDA “Purple Book” not the “Orange Book”**

The language in Article 5 amending 30-5-4 (36) defines an “interchangeable biologic product” as “a biological product that the federal food and drug administration has: (A) licensed; and (B) determined meets standards for interchangeability pursuant to 42 U.S.C §262 (k) (4); or (ii) determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal food and drug administration’s approved drug products with therapeutic equivalence evaluations.” The underlined language above references what is commonly referred to as the “[Orange Book](#)”. We are concerned with this section for the following reasons:

- Section B should include a reference to the FDA [Purple Book](#): Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations.
- Section B (ii) should be deleted because it refers to drugs (FDA Orange Book) that are approved under the Food, Drug and Cosmetics Act pathway
- Reference information for all licensed biologics, including biosimilars and interchangeable biologics under the BPCIA pathway, is only available in the Purple Book.

**House Bill 4524 creates administrative burdens on West Virginia pharmacists**

Section 30-5-12c (c) requires pharmacists to communicate with the prescriber within 5 days of dispensing a biological product, which creates an additional post-dispensing communication requirement that is unnecessary and not required under West Virginia law for any other FDA approved drug category.

**FDA guidance not yet final on interchangeable biological products**

Although it was released more than a year ago, the FDA draft guidance titled “[Considerations in Demonstrating Interchangeability with a Reference Product](#)” is not final. The FDA will not accept an application for approval of an interchangeable biological product until the guidance is final. Once FDA draft guidance is final, AMCP encourages the West Virginia legislature to review it and determine whether additional legislation is necessary.

In conclusion, we urge you to amend section 30-5-4 (36) to include the “Purple Book” and strike the reference to the “Orange Book” for previously discussed reasons; and strike section 30-5-12c (c) which imposes additional administrative burdens on pharmacists. If you have any questions about our position, please contact AMCP’s Director of Legislative Affairs, Reginia Benjamin, at (703) 684-2620, or [rbenjamin@amcp.org](mailto:rbenjamin@amcp.org).

Sincerely,



Susan A. Cantrell, RPh, CAE  
Chief Executive Officer