



Academy of
Managed Care
Pharmacy®

June 1, 2017

The Honorable Kenneth P. LaValle, Chair
Senate Higher Education Committee
Legislative Office Building, Room 806
Albany, NY 12247

RE: Senate Bill 4788 – Biological Product Substitutions

Dear Senator LaValle:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Senate Bill 4788 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in Senate Bill 4788 which amends Section 6802 of the education law by adding subdivisions 28 lines 6-12 because it defines “interchangeable biologic product” consistent with the Biologics Competition and Innovation Act (BPCIA) and also references the FDA “Purple Book”. However, we oppose the language that begins on line 12 and ends on line 16 which defines an interchangeable biological product as “therapeutically equivalent” and refers to the Orange Book. That language is not consistent with the BPCIA.

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 373 members in New York, 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 In fact, the FDA released draft guidance on January 17 titled “Considerations in Demonstrating Interchangeability With a Reference Product” and the comment period recently closed on May 19, 2017. The FDA will not accept applications for interchangeable biological products until it releases final guidance. Therefore, AMCP recommends that the legislature continue to monitor the status of the guidance and not approve legislation that may not be consistent with FDA final guidance.

The FDA Orange Book is not the FDA recognized source of interchangeable drug products

As previously referenced, the language in lines 12 -16 is problematic because it creates a definition of “interchangeable” that is not consistent with the BPCIA. Specifically, it defines “interchangeable” as therapeutically equivalent as set forth in the “Orange Book”. We recommend those lines be deleted. The sole statutory authority for the filing of an application and approval of an interchangeable biological product is under the BCPIA pursuant to 42 USC 262(k)(4) as referenced in lines 7-8 of the bill. Reference information for all licensed biologics, including biosimilars and interchangeable biologics, will only be available in the Purple Book.

Additional administrative burdens on pharmacists

The language proposed to amend Section 6816-a subdivision 4 of the education law, 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. Also these additional administrative requirements to dispense an interchangeable biological are different from existing requirements for all other classes of medications. We are also concerned with enacting additional requirements prior to the FDA finalizing guidance on interchangeable biological products.

In conclusion, we strongly support adoption of the language that amends New York law to allow a pharmacist to substitute an FDA approved interchangeable biological product for a biologic product which is consistent with the BPCIA. However, we oppose the proposed language in Sections 6802 lines 12-16 and 6816-a subdivision 4 of the education law which is not consistent with the BPCIA for the above referenced reasons. Lastly, AMCP encourages the legislature to review the FDA guidance once it is final, and then determine if additional legislation is necessary. If you have any questions about our position, please contact AMCP's New York advocacy leader Lee Marks at lee.marks@orexo.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