AMCP | Academy of Managed Care Pharmacy®

February 27, 2017

The Honorable Mia Costello, Chair
Senate Labor and Commerce Committee
State Capitol Room 504
Juneau, Alaska, 99801

RE: Senate Bill No. 32 – Biological Product Substitutions

Dear Senator Costello:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Senate Bill No. 32 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the Biologics Competition and Innovation Act (BPCIA) definition of "interchangeable biologic product" which allows a pharmacist to substitute an interchangeable biologic product without the intervention of the health care provider who prescribed the "reference product". Senate Bill No. 32 includes an amendment to AS. 08.80.295 which allows the pharmacist to substitute an interchangeable biological product with the consent of the patient, we support that amendment because it is consistent with the BPCIA and Alaska law.

However, we oppose the additional administrative requirements in Senate Bill No. 32 to dispense an interchangeable biological product that differ from existing requirements in Alaska for all other classes of FDA approved medications. We are also concerned about enacting additional requirements prior to the Food and Drug Administration (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 Alaska, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Additional administrative burdens on pharmacists

The language proposed to amend AS 08.80.295 in sections (c) and (f), 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. These provisions are not consistent with the intent of the BPCIA, which was to create an

abbreviated pathway for approval of these products by balancing innovation and consumer interests. These provisions create barriers to substitution by adding requirements for dispensing, and we cannot support them.

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 a 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 language proposed to amend AS 08.80.480 (38)(A) should include the title of the reference, i.e., the "Purple Book".

The reference in AS 08.80.480 (38)(B) to the "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.

In conclusion, we urge you to adopt the language that updates Alaska statutes to allow for the substitution of biologic products with FDA approved interchangeable biological products and to provide the liability protections for pharmacists dispensing those products. However, we urge you delete the additional administrative 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 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 Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE
Chief Executive Officer