



Academy of
Managed Care
Pharmacy®

February 16, 2017

The Honorable Merv Riepe, Chairperson
Senate Health and Human Services Committee
Room #1402
P.O. Box 94604
Lincoln, NE 68509

RE: LB 481 – Biological Product Substitutions

Dear Senator Riepe:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of LB 481 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in LB 481 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 additional administrative requirements to dispense an interchangeable biological product prior to the Food and Drug Administration finalizing draft guidance on this topic and the implementation of requirements that are different from existing requirements for all other classes of medications.

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 Nebraska, 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 In fact, the FDA released a draft guidance on January 17 titled “Considerations in Demonstrating Interchangeability With a Reference Product” and the comment period closes on March 20, 2017.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.

Additional administrative burdens on pharmacists

Specifically, the language proposed to amend Section 38-28-111, paragraph (4), Reissue Revised Statutes of Nebraska, 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.

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 Section 38-28-110, section (11), Reissue Revised Statutes of Nebraska, paragraph (1) should include the title of the reference, i.e., the “Purple Book” and that the reference in paragraph (2) which is to the 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 in the Purple Book.

In conclusion, AMCP encourages the legislature to maintain the language in LB 481 that is consistent with your legislative intent to update Nebraska statutes to allow for the substitution of biologic products only with FDA approved interchangeable biological products. We support that intent but those provisions that go beyond the intent and create barriers to substitution by adding additional requirements for dispensing, we cannot support.

We urge you to adopt the language that achieves the legislative intent and to delete the additional requirements and the reference to the Orange Book. AMCP encourages the legislature to compare the final guidance and at that time determine whether additional amendments are 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,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer