AMCP Academy of Managed Care Pharmacy®

May 15, 2017

The Honorable Joe Aresimowicz
Speaker of the House
Legislative Office Building, Room 4105
Hartford, CT 06106

RE: Substitute Bill No. 7118 – Biological Product Substitutions

Dear Speaker Aresimowicz:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Substitute Bill No.7118 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in the Substitute Bill that allows a pharmacist to substitute an FDA approved "interchangeable biological product". That language is consistent with 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". However, we oppose the language that defines an interchangeable biological product as therapeutically equivalent and imposes administrative requirements to dispense an interchangeable biological product that are different from existing requirements for all other classes of medications. We also are concerned about enacting 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 Connecticut, 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 In fact, the FDA released draft guidance on January 17 titled "Considerations in Demonstrating Interchangeability With a Reference Product" and the comment period closes on May 19, 2017.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 Biologic Products

The FDA 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 20-619(a)(4)(A) should include the following language at the end of that paragraph: as set forth in the "Purple Book". We also recommend that Section 20-619 (a)(4)(B), which references the Orange Book, should be deleted entirely. 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.

Additional administrative burdens on pharmacists

Specifically, the proposed language in Section 20-619(d) is problematic because it is inconsistent with existing law under Section 20-619(b). Existing law states that the pharmacist shall inform the patient and the practitioner of the substitution at the *earliest reasonable time.* The proposed language in Section 20-619(d) would require notification by the pharmacist to the prescriber and the patient not later than seventy-two hours following the dispensing. We recommend that you correct this internal inconsistency by striking Section 20-619(d) entirely, as it would set an arbitrary notification timeframe not required for any other class or category of drugs approved by the FDA. This provision would also be 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 language provides 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 Connecticut law to allow for the substitution of biologic products with FDA approved interchangeable biological products. We also urge you to delete the following provisions: the language in Section 20-619(d) because it adds requirements different from any other class of FDA approved drugs and is inconsistent with Connecticut law; and the paragraph that references the Orange Book in Section 20-619 (a)(4)(B). Lastly, once the draft FDA interchangeability guidance is final, AMCP 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 Connecticut advocacy leader Daniel C. Shan, PharmD at Daniel.shan@shire.com or 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