



Academy of
Managed Care
Pharmacy®

February 27, 2017

The Honorable Claire Ayer, Chair
Senate Health and Welfare Committee
Room 17
115 State Street
Montpelier, VT 05633-5301

RE: Senate Bill 92 – Biological Product Substitutions

Dear Senator Ayer:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Senate Bill 92 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the statement of purpose of this bill to direct pharmacists to fill prescriptions for biological products with an interchangeable biological product unless otherwise specified by the prescriber or the purchaser. However, we oppose the additional administrative communication requirements to dispense an interchangeable biological product that are different from existing requirements for all other classes of medications and since the Food and Drug Administration has not issued final guidance on this topic, we believe those additional administrative requirements warrant further consideration by the legislature.

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 In fact, the FDA released a draft guidance on January 17 titled "Considerations in Demonstrating Interchangeability With a Reference Product" and the comment period closes on March 20, 2017.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

The language proposed to amend 18 V.S.A. § 4605(e)(1) and (e)(3), 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 rather it remains by telephone or facsimile.

The FDA Purple Book: Designated List of Biologic Products

As you are aware, 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 18 V.S.A. § 4601(5)(A) should include the title of the reference, i.e., the “Purple Book”, consistent with the proposed language in 18 V.S.A. § 4605(a)(2).

We also recommend that the references in 18 V.S.A. § 4601(5)(B) and 18 V.S.A. § 4605(a)(1) which are 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 Senate Bill 92 that is consistent with your statement of purpose (lines 7-10) directing pharmacists to fill prescriptions for biological products with an interchangeable biological product unless otherwise specified by the prescriber or the purchaser. We support that purpose, but we cannot support the provisions that go beyond the purpose and create barriers to substitution by adding additional requirements for dispensing.

We urge you to adopt the language that achieves your statement of purpose and to delete the additional communication requirements for dispensing and all references to the Orange Book. Lastly, AMCP also encourages the legislature to compare 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, Regina Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer