



Academy of
Managed Care
Pharmacy®

February 28, 2018

The Honorable William Lippert
Chair, House Committee on Healthcare
115 State Street
Montpelier, VT 05633

RE: Senate Bill 92 – Relating to Interchangeable Biological Products

Dear Representative Lippert:

The Academy of Managed Care Pharmacy (AMCP) writes to support and express concerns with specific provisions of Senate Bill 92. This legislation would regulate biological products and substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in the bills that allows a pharmacist to substitute an FDA approved “interchangeable biological product”. That language is consistent with the Biologics Price Competition and Innovation Act (BPCIA) which allows a pharmacist to substitute an interchangeable biologic product without the intervention of the health care provider who prescribed the “reference product”.

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.

Senate Bill 92 Should Reference the FDA “Purple Book” not the “Orange Book”

The amended language in section 18 V.S.A §4601 (5) defines an “an interchangeable biological product” as “-a biological product that the federal Food and Drug Administration has: (A) licensed and determined pursuant to 42 U.S.C section 262(k)(4) to be interchangeable with reference product against which it was evaluated or; (B) determined to be therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book)”. The underlined language is a reference to what is commonly referred to as the “[Orange Book](#)”. We are concerned with this section for the following reasons:

- Section A should include a reference to the FDA [Purple Book](#): Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations.
- Section B should be deleted because it refers to drugs (FDA Orange Book) that are approved under the Food, Drug and Cosmetics Act pathway

- Reference information for all licensed biologics, including biosimilars and interchangeable biologics under the BPCIA pathway, is only available in the Purple Book.

Senate Bill 92 creates administrative burdens on Vermont pharmacists

Section 18 V.S.A. §4605 (e)(1) requires pharmacists to communicate with the prescriber within 5 days of dispensing a biological product, which creates an additional administrative record keeping and post-dispensing communication requirement for dispensing an interchangeable biological product that is unnecessary and not required under Vermont law for any other FDA approved drug category.

FDA guidance not yet final on interchangeable biological products

Although it was released more than a year ago, the FDA draft guidance titled “[Considerations in Demonstrating Interchangeability with a Reference Product](#)” is not final. The FDA will not accept an application for approval of an interchangeable biological product until the guidance is final. Once FDA draft guidance is final, AMCP encourages the Vermont legislature to review it and determine whether additional legislation is necessary.

In conclusion, we urge you to amend section 18 V.S.A §4601 (5) to include the “Purple Book” and strike the reference to the “Orange Book” for previously discussed reasons; and strike section 18 V.S.A. §4605 (e)(1) which imposes additional administrative burdens on pharmacists. If you have any questions about our position, please contact AMCP’s Director of Legislative Affairs, Regina Benjamin, at (703) 684-2620, or rbenjamin@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer