



Academy of
Managed Care
Pharmacy®

May 30, 2017

The Honorable Hank Vaupel, Chair
House Health Policy Committee
N-896 House Office Building
P.O. Box 30014
Lansing, MI 48909

RE: House Bill 4472 – Interchangeable Biological Products

Dear Representative Vaupel:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of House Bill 4472 regarding the regulation of biological products and the substitution of interchangeable biological products when dispensed by pharmacists. We strongly support the language in the 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 implementing 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 Michigan, 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 In fact, the FDA released draft guidance on January 17 titled “Considerations in Demonstrating Interchangeability with a Reference Product” and the comment period closed on May 19, 2017. The FDA will not accept an application for approval of an interchangeable biological product until the guidance document is final.

BPCIA is the sole statutory authority for the approval of interchangeable biological products

The language in Section 17704(5)(B) is problematic because it creates a definition of “interchangeable”. Specifically, it defines it as – “A biological drug product that is approved by the FDA pursuant to an application filed under 21 USC 355 (B)(2) and that the FDA has determined to be therapeutically equivalent to the prescribed drug product.” We recommend that Section 17704(5)(B) be deleted. The only statutory authority for the filing of an

application and approval of an interchangeable biological product is under the BCPIA in 42 USC 262(k)(4) as referenced in Section 17704 (5)(A).

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. FDA has indicated that it will not accept applications for interchangeable biological products until it releases final guidance. Reference information for all licensed biologics, including biosimilars and interchangeable biologics, will be available in the Purple Book. Therefore, we recommend that the language proposed in Section 17704(5)(A) should include a reference to the “Purple Book”.

Additional administrative burdens on pharmacists

Finally, Section 17755(5) requires the pharmacist 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 the dispensing of an interchangeable biological product that is unnecessary and not required under Michigan law for any other FDA drug category.

Although the proposed amendments provide that notification can take place via the use of electronic methods, written or telephone communications continue to be the primary mode of communication. The proposed amendments would add unnecessary and time consuming duties to an already busy pharmacy dispensing setting. Also the proposed legislation does not contain any requirements that the prescriber maintain this information or record it.

In conclusion, we urge you to adopt the bill language that updates Michigan law to allow for the substitution of biologic products with FDA approved interchangeable biological products. We also urge you to delete the following proposed provisions: Sections 17704(5)(B) and 17755(5) for the reasons previously discussed. Lastly, once the draft FDA interchangeability guidance is final, AMCP encourages the legislature to review it and determine whether additional legislation is necessary. If you have any questions about our position, please contact our Michigan advocacy leader, Manjula Jayabalan, PharmD, MBA at mjayabalan@mail.usciences.edu 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