Academy of Managed Care Pharmacy®

February 12, 2018

The Honorable Robin Vos
Speaker of the Assembly
State Capitol Room 217 West
P.O Box 8953
Madison, WI 53708

RE: Assembly Bill 679 and Senate Bill 575 – Interchangeable Biological Products

Dear Speaker Vos:

The Academy of Managed Care Pharmacy (AMCP) is writing to express concerns with specific provisions of Assembly Bill 679 and Senate Bill 575. 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 allow 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 Wisconsin, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Assembly Bill 679 and Senate Bill 575 Should Reference the FDA "Purple Book" not the "Orange Book"

The language in Section 450.135 (1) defines "interchangeable biological product" as "-a biological product that the federal food and drug administration has licensed and has determined meets the standards for interchangeability pursuant to 42 USC 262 (k) (4) or has determined is 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 underlined language in Section 450.135(1) is a reference to the FDA Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book", which lists approved products under the Food, Drug and Cosmetics Act pathway. Therefore, the reference to the Orange book should be deleted because it does not contain information on interchangeable biological products.

Reference information for all licensed biologics, including biosimilars and interchangeable biologics, is only available in the Purple Book: Lists of licensed biological products with reference product

exclusivity and biosimilarity or interchangeability evaluations. Therefore, we recommend that the language proposed in Section 450.135 (1) be amended to reference the Purple Book. Interchangeable biologic products will be approved under the BPCIA pathway.

Assembly Bill 679 and Senate Bill 575 create administrative burdens on Wisconsin pharmacists

Section 450.135 (5) (b) 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 Wisconsin law for any other FDA approved drug category.

FDA guidance not yet final on interchangeable biological products

To date, the FDA draft guidance released January 17, 2017, 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.

In conclusion, we urge you to amend section 450.135 (1) to include the "Purple Book" for previously discussed reasons and strike the reference to the "Orange Book" in that section; and strike section 450.135 (5) (b) which imposes additional administrative burdens on pharmacists. Once FDA draft guidance is final, AMCP encourages the Wisconsin legislature to review it and determine whether additional legislation is 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,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer