

January 19, 2016

The Honorable Mike Shirkey
Chair
Health Policy Committee
Michigan Senate
P.O. Box 30036
Lansing, MI 48909

RE: Substitute for House Bill 4812

Dear Senator Shirkey:

The Academy of Managed Care Pharmacy (AMCP) is opposed to the Substitute for House Bill 4812 because the U.S. Food and Drug Administration (FDA) has not released guidance on how applicants can demonstrate interchangeability. In addition, the legislation modifies the Biologics Price Competition and Innovation Act (BPCIA) definition of an interchangeable, and it includes provisions that would place unnecessary requirements on pharmacists when a product determined by FDA to be interchangeable with the reference biologic product is dispensed.

AMCP is a professional association of pharmacists and other practitioners, including 180 members in Michigan, who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

Biologic products already have an important role in today's health care system, both in terms of scientific improvements in the treatment of disease and in increased drug costs. The high costs of many of these products threaten patient access to important therapies and place a strain on payers trying to manage prescription drug spending. Since the introduction of biosimilars almost 10 years ago, the European Union has experienced an average price reduction of 30 percent for products with competition from biosimilars, and it is reasonable to expect a similar impact in the United States.

It was the intent of Congress when it passed the BPCIA to foster competition and improve choices for American patients. AMCP supported its adoption and is a strong advocate for the biosimilars pathway established under the BPCIA. The United States health care system should have the opportunity to benefit from similar savings experienced by the European Union, as the cost of certain drug products continue to rise in the United States.

The language in Section 17704(5) is problematic for several reasons. Specifically, its definition of “interchangeable” is a modification of the BPCIA definition, and the FDA has not issued guidance on demonstrating interchangeability to the reference product.

Section 17704(5) states that an “interchangeable biological drug product” means either of the following:

(A) A biological product that is licensed by the FDA and determined to be interchangeable with the prescribed drug product pursuant to 42 USC 262 (k)(4);

(B) 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.

* The FDA definition of the term ‘interchangeable’ or ‘interchangeability’ is found in 42 U.S.C. 262 (i)(3) and reads as follows: ‘interchangeable’ or ‘interchangeability’ in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

- Although Section 42 U.S.C. 262(i)(3) defines interchangeable, as previously mentioned, the FDA has not released guidance on demonstrating interchangeability. Until the FDA issues guidance on demonstrating interchangeability, Paragraph (A) is premature. In fact, during a Congressional hearing on September 17, 2015, Janet Woodcock, Director, Center for Drug Evaluation and Research at the FDA, received questions regarding the timeframe for a FDA determination of interchangeability requirements and declined to provide a specific deadline. AMCP continues to advocate that the FDA must provide guidance regarding interchangeability requirements prior to states enacting laws that add unnecessary burdens to the dispensing of interchangeables.
- We were unable to find the reference cited in paragraph (B) of the legislation, [21 U.S.C. 355 (B)(2)]. Perhaps the intended reference is 21 U.S.C. 355(b)(2). Section 355 considers applications for new drugs, not biologic products or biosimilars. Thus, a state mandate that defines products approved as drugs under Section 355 as interchangeable pursuant to the approval for pathway for biosimilars and interchangeables under Section 351 of the Public Health Service Act (42 U.S.C. 262) would appear to be beyond the scope of state legislative authority. The biosimilar pathway under Section 351 of the Food, Drug and Cosmetic Act grants the FDA some authority to approve a biosimilar that was approved as a new drug under the Section 355, but it does not specifically indicate whether the product would automatically be considered interchangeable. This determination would only be within the authority of the FDA, not within state law; therefore, paragraph (5)(B) would appear to be outside of state legislative authority.

Finally, Section 17755(5) requires the pharmacist to communicate with the prescriber within 5 days of dispensing a biological product, which adds an additional administrative record keeping and post-dispensing communication requirement for the dispensing of an interchangeable biological product that is unnecessary and not required for any other FDA drug category.

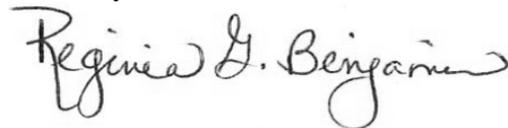
The post-dispensing communication may be through the use of electronic methods. While the health care industry continues to increase its use of electronic technology, it has not yet reached a level of participation by a majority of prescribers and pharmacies. At this time, the use of an interoperable health records system or other means of electronic interchange between prescribers and pharmacists is not the primary method of communication. In fact, written or telephonic communications continue to be the primary record in health care settings. This presents an added duty in an already busy pharmacy dispensing setting. Additional communication from the pharmacist is not necessary, and the proposed legislation does not contain any requirements that the prescriber has to maintain that information or record it.

The FDA has designated the “Purple Book” as the resource to list biologic products, including any biosimilar and interchangeable biologic products licensed by the FDA. Biosimilar and interchangeable biologic products will be listed under the reference product to which biosimilarity or interchangeability was demonstrated. Prescribers will have access to the Purple Book. Therefore, when the prescriber writes the prescription and does not indicate, “dispense as written,” she will already have access to the information in the Purple Book of the licensed products to which interchangeability has been demonstrated. Prescribers have been using the “Orange Book of Approved Drug Products with Therapeutic Equivalence Evaluations” for years as a reference for small molecule drugs, so they are familiar with this type of FDA resource.

Contrary to the congressional intent in passing the BPCIA, this legislation has the potential to increase prescription costs to patients and payers and, thereby, threatens patient access to more affordable treatments. Biosimilars will bring value to your constituents as patients and payers by enhancing access to FDA approved, safe and effective, lower cost medications.

We appreciate the opportunity to share our views on Substitute for House Bill 4812. We respectfully urge you oppose this legislation. If you have any additional questions, you may contact our local advocacy leader, Cheryl Kaltz of Northville, MI, at (586) 904-0820 or cheryl.kaltz@att.net. You may also contact me at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

A handwritten signature in cursive script that reads "Regina G. Benjamin". The signature is written in black ink and is positioned below the word "Sincerely,".

Reginia Grayson Benjamin, JD
Director of Legislative Affairs

cc: Members of the Senate Health Policy Committee