AMCP Academy of Managed Care Pharmacy®

August 9, 2016

The Honorable Robert A. DeLeo
Speaker of the House
Massachusetts House of Representatives
Room 356
24 Beacon Street
Boston, MA 02133

RE: House Bill 976 - Regulating the Substitution of Interchangeable Biosimilars

Dear Speaker DeLeo:

The Academy of Managed Care Pharmacy (AMCP) opposes House Bill 976. This bill would amend Chapter 112 Section 12EE (a) by replacing the words "biosimilar and interchangeable" in the definition of "interchangeable biologic product" with the words "therapeutically equivalent to". This new proposed definition is inconsistent with existing Massachusetts law, which follows the language in the Biologics and Price Competition and Innovation Act (BPCIA). The BPCIA implements an approval pathway for biosimilar and interchangeable products with oversight by the Food and Drug Administration (FDA). Accordingly, BPCIA identifies the standard for review and approval for a biosimilar to be "highly similar" to the reference product [42 U.S. § 262i(2)]. The BPCIA also establishes the standard of review for interchangeability to include biosimilarity to the reference product and can be expected to duplicate the same clinical result as the reference product [42 U.S. § 262 k(2)].

The Food and Drug Administration (FDA), which has oversight of approval for biologic and biosimilar approval pathways, is expected to issue guidance on substitution of interchangeable products. When this occurs, the ability of pharmacists to substitute interchangeable products will be compromised in Massachusetts unless the state maintains its current terminology which is consistent with the BPCIA. Biologic products have an important role in today's health care system. Yet, the high costs of many of these products continue to threaten patient access to important therapies and place a strain on payers. Since the introduction of biosimilars more than 10 years ago, the European Union (EU) 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. The United States health care system should have the opportunity to benefit from similar savings experienced by the EU.

AMCP is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's nearly 8,000 members, including 239 living and practicing in Massachusetts, develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

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Consistent with the BPCIA, and the FDA Purple Book, a biosimilar product is a biological product that is highly similar to the reference product, notwithstanding minor differences in clinically inactive components. Biologics, biosimilars and interchangeables are considered to be complex large molecule medication products. For this reason, biosimilars have a different approval processes than other types of products. The BPCIA specifies the approval pathway for biosimilars. This pathway includes a specific definition of interchangeable products whereby the pharmacist may substitute for the reference product without additional intervention by the prescriber. On the other hand, the term "therapeutically equivalent" relates to small molecule medication products approved under the U.S. Food, Drug and Cosmetic Act, and listed in the FDA's Orange Book. House Bill 976 erroneously seeks to apply the Food, Drug and Cosmetic Act standard to biologics approved under a different pathway, i.e. BPCIA and as a result adopting the proposed definition could result in less adoption of safe and effective biosimilars and interchangeable products in Massachusetts.

Therefore, AMCP respectfully urges you to vote against House Bill 976. This bill would create a new standard of approval for "biosimilar and interchangeable with" that is not consistent with the BPCIA pathway for approval of these drug products. If you have any questions, you may AMCP's Massachusetts advocacy leader, Dennis Lyons at (617) 312-5906 or hiddgl@gmail.com. You may also contact the AMCP Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer