AMCP Academy of Managed Care Pharmacy®

April 29, 2016

The Honorable Ronald Kouchi
President, Senate
Hawaii State Capitol, Room 409
Honolulu, HI 96813

The Honorable Joseph M. Souki
Speaker, House of Representatives
Hawaii State Capitol, Room 431
Honolulu, HI 96813

RE: H.B. No. 254 (H.D. 2; S.D. 1; C.D. 1) – Biosimilar Medicines; Interchangeable Biological Products

Dear President Kouchi and Speaker Souki:

The Academy of Managed Care Pharmacy (AMCP) is writing to express its opposition to certain provisions of H.B. No. 254. AMCP opposes the practitioner notification requirements, which would place an unnecessary burden on the substitution of an interchangeable biological drug product. In addition, AMCP also opposes the new definition of "interchangeable biological product" included in the bill, which is not consistent with the Food and Drug Administration (FDA) definition. According to FDA, an interchangeable biological drug product is a biological product that may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product [42 U.S. Code Section 262 (i)(3)].

AMCP is a national professional association of pharmacists and other health care practitioners, including members in Hawaii, 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 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.

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 medication 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 in 2006, 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. Interchangeable products are also expected to be less costly than the reference product. Therefore, ensuring that laws and regulations encourage patient access to these medications is critical to successful adoption of interchangeable biological products when approved by the FDA.

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AMCP recommends the following provisions in H.B. No. 254 be amended:

Section 3.1 would add a new definition of "interchangeable biological product" to Section 328.91 to mean a biological product that is biosimilar to, and therefore interchangeable with, the biological product identified in the prescription and with respect to which there are no other clinically significant differences in terms of safety or effectiveness. This definition modifies the Biologics Price Competition and Innovation Act (BPCIA) definition of an interchangeable, which is found in 42 U.S.C. 262 (i)(3), 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. AMCP respectfully requests that this definition be amended to be consistent with the BPCIA definition of interchangeable.

Section 4 would add paragraph (d) to Section 328-92, to require the dispensing pharmacist or the pharmacists' designee to communicate to the prescribing practitioner information regarding the specific product provided to the patient, including the name of the product and the manufacturer within two days of dispensing the biological product. These additional requirements following the dispensing of an interchangeable biological drug product are not required for any other category of drugs dispensed and place an undue burden on the dispensing pharmacist.

Section 4 would also add a paragraph (e) to Section 328-92, to require the pharmacist to enter certain information into an interoperable health record system, if available, or if not by facsimile, telephone, or email. While the overall healthcare 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 electronic technology, including interoperable health records system between prescribers and pharmacists is not the primary method of communication. Further, the requirement to use electronic technology is not required for any other category of drug dispensed and, as mentioned, is not reflective of the electronic transmission capability of many prescribers and pharmacists.

For these reasons, AMCP believes these burdensome practitioner notification requirements will discourage substitution, which only benefits those entities offering more costly biologic drugs and, conversely, potentially increases medication costs to patients and payers and, thereby, threatens patient access to more affordable treatments.

AMCP recommends that you include a reference to the FDA's Purple book in H.B. No. 254. 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," he or 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.

AMCP supports the proposed amendment to Section 328-98, which provides: "A pharmacist who selects an equivalent <u>generic</u> drug product <u>or an interchangeable biological product</u> pursuant to this part assumes no

greater liability for selecting the dispensed drug product than would be incurred for filling a prescription for a drug product prescribed by its established name."

Since the FDA has not issued any guidance on the application process for an interchangeable, AMCP would urge you to consider this type of legislation after the FDA issues guidance. However, if you decide to move forward then AMCP would encourage you to remove the practitioner notification requirements and amend the definition of interchangeable biological product to be consistent with the BPCIA definition. We appreciate the opportunity to share AMCP's views on H.B. No. 254. If you have any additional questions, you may 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