AMCP Academy of Managed Care Pharmacy®

February 27, 2018

The Honorable Representative Eric Barlow
Chairman, Joint Labor, Health and Social Services Committee
213 State Capitol Building
Cheyenne, WY 82001

RE: Senate File 75 – Authorizing Pharmacists to Dispense Specified Biological Products

Dear Representative Barlow:

The Academy of Managed Care Pharmacy (AMCP) writes to support and express concerns with specific provisions of Senate File 75. This legislation would regulate biological products and 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 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 Wyoming, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

Senate File 75 Should Reference the FDA "Purple Book" not the "Orange Book"

The language in section 33-24-147 (a) (vii) defines an "an interchangeable biological product" as (A) "Licensed and determined meets the standards for interchangeability under 42 U.S.C 262 (k) (4); or (B) Determined is therapeutically equivalent to the prescription ordered or prescribed, as set forth in the latest edition or supplement to the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) issued by the United States food and drug administration." We are concerned with this section for the following reasons:

- Section A should include a reference to the FDA Purple Book: Lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations.
- Section B should be deleted because it refers to drugs (FDA Orange Book) that are approved under the Food, Drug and Cosmetics Act pathway
- Reference information for all licensed biologics, including biosimilars and interchangeable biologics under the BPCIA pathway, is only available in the Purple Book.

Senate File 75 creates administrative burdens on Wyoming pharmacists

Section 33-24-149 (f) 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 Wyoming law for any other FDA approved drug category.

FDA guidance not yet final on interchangeable biological products

Although it was released more than a year ago, the FDA draft guidance 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. Once FDA draft guidance is final, AMCP encourages the Wyoming legislature to review it and determine whether additional legislation is necessary.

In conclusion, we urge you to amend section 33-24-147 (a) (vii) to include the "Purple Book" and strike the reference to the "Orange Book" for previously discussed reasons; and strike section 33-24-149 (f) which imposes additional administrative burdens on pharmacists. If you have any questions about our position, please contact AMCP's Director of Legislative Affairs, Reginia Benjamin, at (703) 684-2620, or rbenjamin@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer