

September 26, 2017

John C. Kirtley, PharmD
Executive Director
Arkansas State Board of Pharmacy
322 South Main Street, Suite 600
Little Rock, AR 72201

Re: Proposed Changes to Regulation 7 – Drug Products/Prescriptions

Dear Dr. Kirtley:

The Academy of Managed Care Pharmacy (AMCP) thanks the Arkansas State Board of Pharmacy (Board) for the opportunity to provide comments on the proposed changes to *Regulation 7 – Drug Products/Prescriptions* as they relate to biosimilar products. The introduction of biosimilars in the United States marketplace has the potential to save the United States healthcare industry billions of dollars in annual expenditures, and encourages a competitive marketplace that could result in substantial savings to patients and public and private payers. AMCP supports the implementation of a robust biosimilars pathway at the federal and state level to ensure that Americans continue to receive access to safe, effective, and affordable biologics and biosimilars.

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 Arkansas, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

The proposed changes update several definitions, including biological product, biosimilar, and biosimilar product, to align with the Food and Drug Administration's (FDA) definitions of these terms. AMCP supports adoption of the FDA definition of these terms in state regulations to minimize confusion to prescribers, pharmacists, and patients and minimize differences between state and federal regulations. However, AMCP is concerned that the proposed changes include 'biological products' within the definition of 'drug.' By FDA definition, a biological product is not a drug and therefore this may result in unintended confusion for prescribers, pharmacists, and patients. AMCP recommends that the Board reconsider the inclusion of 'biological product' within the definition of 'drug' and maintain them as separate definitions to be consistent with the FDA and federal regulations.

The proposed changes would also allow the dispensing of an interchangeable biological product when available unless the provider specifically indicates that substitution is not permitted, which is consistent with the Biologics Price Competition and Innovation Act (BPCIA). AMCP supports the automatic substitution, without additional restrictions or recordkeeping requirements, of interchangeable biological products that are licensed by the FDA and determined to meet the safety standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4). Therefore, AMCP urges the Board to move forward with finalizing the proposed rule regarding interchangeability.

To make the interchangeability provisions more definitive, AMCP recommends that the Board consider revising *Section 07-00-0006—GENERIC AND BIOLOGICAL SUBSTITUTION* into two sub-sections, the first discussing generic substitution and the second discussing biological interchangeability. As written, the section may be confusing with its multiple references and therefore AMCP suggests dividing it to minimize any potential confusion and misinterpretation, especially regarding when the Orange Book versus the Purple Book is the appropriate reference.

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with the Arkansas State Board of Pharmacy. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell", with a long horizontal flourish extending to the right.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer