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**JOHN CLAY KIRTLEY, Pharm.D.**  
**EXECUTIVE DIRECTOR**

To Whom It May Concern,

I am writing today to simply address information you have been provided in opposition to proposed regulation 7 of the Arkansas State Board of Pharmacy.

Any and all opposition to this rule change focus on one issue so we would start by pointing out the following:

1. The rule changes surrounding biologics only affect biosimilars deemed “Interchangeable” which is a much higher bar than any current biosimilar has achieved to date.
2. To be deemed “Interchangeable” a biosimilar must prove that there are no clinical differences or additional risks to the patient if switched once or multiple times between the innovator and the “Interchangeable” biologic.
3. This rule will ensure that your constituents have access to the lowest cost drug that is proven to be equivalent and therefore “Interchangeable” by the FDA without any bureaucratic delays or obstacles.

I will also attempt to answer 3 specific things. Who is in favor of this, why this is important now and if the Board has authority to make this regulatory change over drugs also called biologics, biosimilars and interchangeable biologics.

First of all, who is in favor of the changes to Regulation 7?

The Arkansas Pharmacists Association

Wal-Mart stores, Inc. and their more than 130 Walmart and Sam’s Club Pharmacies operated in Arkansas

Academy of Managed Care Pharmacy – 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 who utilize evidence and value-based strategies and practices to manage medication therapies for the 270 million Americans served by health plans, Pharmacy Benefit Managers (PBMs), emerging care models and government.

Walgreens and their 80+ pharmacies owned and operated in Arkansas

Express Scripts

CVS/Caremark

Various Pharmacy Benefit Managers

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It is important to note that we have also received word from Express Scripts, CVS, Walmart, Walgreens and the Arkansas Pharmacists Association as well as individual pharmacy owners/representatives that any Active, Manual Notifications or communication requirements will be vehemently opposed as it could represent a significant financial impact and regulatory burden to pharmacies/pharmacists as well as an increased risk of audit issues if the pharmacy cannot prove that notification was received. This would also represent a risk to prescribers who would need to do something with the information received such as chart it or make note of it in the patient's file.

## Excerpts of letters of support:



As BIO, the trade association that represents the biologic manufacturers, noted in their letter to the Arkansas State Board of Pharmacy (obtained through FOI) "the standard for interchangeability in the law is stringent and consistent with the FDA's role in protecting patient safety." BIO goes further to correctly state the heightened scrutiny that interchangeable biosimilars must achieve before receiving interchangeable status from the FDA by stating "if a patient switches between two products, the FDA must determine that there is *no* (*emphasis added*) additional risk in such switching compared to using the reference product alone."

Simply put, for the FDA to approve a product as an interchangeable biosimilar, the risk posed to the patient between switching between the originator product and the interchangeable biosimilar must not be greater than the risk posed to a patient by continuing the originator product, which could include changing between various lots of the originator. This will necessarily require interchangeable biosimilar manufacturers to perform switching studies to obtain an approval for an interchangeable biosimilar. Absent these studies, the FDA would never allow a non-single dose biosimilar to ever obtain interchangeable status.

APA supports Congress' and the FDA's regulatory framework for determining interchangeability for biologic drugs and we do not believe any additional state-based regulatory burden should be placed on pharmacists, physicians or patients. We therefore are supportive of the changes to the Arkansas State Board of Pharmacy's Regulation 7.

## *Walgreens*

On behalf of the 80 pharmacies owned and operated by Walgreen Co. in the state of Arkansas, we would like to provide this letter of support for Regulation 7 – Drug Products/Prescriptions as passed by the Board of Pharmacy (BoP) on September 26<sup>th</sup>, 2017 regarding prescription drug products and pharmacists' ability to substitute products that are either generically equivalent, interchangeable biological products, or manufacturer authorized generics.

Any changes to this proposed regulation requiring active, manual communications to prescribers of substitution for interchangeable biologics would be opposed as a costly, unnecessary measure.

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On behalf of the 396 chain pharmacies operating in the state of Arkansas, the National Association of Chain Drugs Stores (NACDS) is writing in support of the Arkansas Board of Pharmacy (BOP) Regulation 7 regarding prescription drug products and pharmacists' ability to substitute products that are either generically equivalent, interchangeable biological products, or manufacturer authorized generics.

Lastly, it is important to note that while we support Regulation 7 as currently written, we strongly oppose any proposals that would adopt special prescriber or active notification provisions that would require a manual call, fax, letter or other manual notification when pharmacists substitute products that are either generically equivalent or an interchangeable biologic. Special notification requirements would create otherwise unnecessary distractions from the important communications already initiated by pharmacists when there are pressing healthcare issues to address. For example, pharmacists commonly reach out to physicians regarding potential drug interactions, patient allergies to medications, and formulary issues. These additional communications would increase the volume of information flowing from pharmacies to physicians' offices, detracting focus from important patient care issues that need resolution and inundating physicians with information that is likely irrelevant for the overwhelming majority of patients.



September 26, 2017

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 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.

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## Why is this regulation change important now?

This regulation change does several things related to drug substitution beyond and in addition to a reference to Purple Book or “Interchangeable” biologics:

1. Answers the mandate of Act 820 of 2017 in reference to limiting the amount of Schedule II narcotics that may be dispensed by licensees of the board to match any limitations set by other prescribing boards in Arkansas.
2. Adds federal definitions and glossary terms that have been the point of much misinformation regarding biologics and drugs.
3. Clarifies appropriate terminology for Green Book (animal designated drugs)
4. Clarifies that pharmacists can substitute “Manufacturer Authorized Generics” which would be drugs such as branded \$600 EpiPens vs the \$300 manufacturer authorized generic. This is the same product by the same company with a different sticker on it which we need to show can be substituted. This type of issue cost the state EBD plan roughly \$1,000,000 in a year due to paying for the higher cost, identical product. There is a 90+ page list of these types of products currently.
5. Limit any biologic substitution to only those that are deemed ‘Interchangeable’ by FDA and reflected that way in the Purple Book.
6. Prevent biosimilars that are not deemed ‘Interchangeable’ from being automatically substituted in the dispensing process as it is arguable that this is not currently the case.
7. Protect and preserve the right of a prescriber to say “Do Not Substitute” on biologic products
8. Protect and preserve the right of a patient to refuse product substitution
9. Protect the patient by requiring that products may only be substituted automatically if they are at a lower cost to the patient unless the patient agrees otherwise
10. Require appropriate labeling of the product dispensed
11. Maintain pharmacy records on biologic dispensing for a minimum of 2 years
12. Communication of dispensing or substitution for an Interchangeable Biologic Product is accomplished by the dispensing pharmacist or his or her designee entering the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product into one or more of the following systems which should be electronically accessible to the prescriber:
  - (A) An interoperable electronic medical records system (EMR);
  - (B) An electronic prescribing technology;
  - (C) A pharmacy benefit management system (PBM); or
  - (D) An electronic pharmacy record system.

Furthermore: FDA has finally issued guidance regarding the requirements to achieve the designation of interchangeable showing that manufacturers must prove that there are no clinical differences or additional risks to a patient to use one product or the other. States that have previously adopted guidelines or statutes on this issue have done so without knowing what the requirements and patient safety measures would be from the federal government in order to achieve the designation of interchangeable. It is obvious from not only the federal government but from many other sources that have published and opined since draft guidance was published this year. It is clear that you will repeatedly see the following: This will and has already resulted in states that have had bad or incomplete policy adopted by statute that either has already been changed or will need to be going forward.

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Does the Board of Pharmacy have rulemaking authority over Biologics?

The Board of Pharmacy's authority for proposed changes to Regulation 7 involving Biologic Drugs, Biosimilars and Interchangeable Biologics is quite clear. The Board of Pharmacy is the agency of Drug Experts, Drug regulations and the agency charged with the mission statement of:

"The purpose of the Arkansas State Board of Pharmacy is to promote, preserve, and protect the public health, safety, and welfare by and through the effective regulation of the many aspects of the drug delivery system. The agency licenses and regulates not only pharmacists and pharmacies, but also the distribution system where there is sale, delivery, or distribution of prescription drugs, medical gases, durable medical equipment, and legend devices."

Authority granted by the legislature is both directly clear and intentional to show that the Board of Pharmacy has authority over drugs and sole authority granted by the state in determining equivalency of drugs including the ability to use nationally recognized reference sources in making these determinations. These statutes in fact do not require the Board to promulgate rules or regulations to delineate this but rather require the Board to notify pharmacists and the Arkansas State Medical Board of their determinations in this area. A large part of discussion on this topic and opposition to the regulations being proposed by the Board of Pharmacy surround the incorrect thought process that Biologics are not drugs. This is patently erroneous as quickly seen when reviewing the federal Food and Drug Administration definition of Drug (included below) as well as when reviewing United States Pharmacopeia – National Formulary language (included below). Simply put, federal definitions of drug or drugs includes biologics as they are a subset of drugs even though they are different than most common drugs we see through experience. Biologics have been around for nearly 100 years as drugs and will continue to exist as drugs going forward.

My notes on this are below and I am available to answer any questions that may arise on this issue.

Sincerely,



John Clay Kirtley, Pharm D  
Executive Director, Arkansas State Board of Pharmacy

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Does the Board of Pharmacy have rulemaking authority over Biologics?

The following three things are true and directed by the legislature:

1. Generic equivalency by statute is to be determined by the Board of Pharmacy (17-92-503) as defined in § 17-92-101.
2. § 17-92-101 defines a drug as including all medicines and preparations recognized by the United States Pharmacopeia or National Formulary (USP-NF) \*Link to USP who defines Biologics as a whole as a subset of drugs no matter which route they gain approval through at FDA and FDA glossary definition of Drug as shown in our proposed regulation
3. 17-92-205 (a)(1) grants the Board of Pharmacy rulemaking authority on issues relating to pharmacy

17-92-205. Rules and regulations- Enforcement

(a) (1) The Arkansas State Board of Pharmacy shall have authority to make reasonable rules and regulations, not inconsistent with law, to carry out the purposes and intentions of this chapter and the pharmacy laws of this state that the board deems necessary to preserve and protect the public health.

17-92-503. Generic substitutions.

(c) (1) The Arkansas State Board of Pharmacy shall determine which drugs are generically equivalent as defined in § 17-92-101, relying on standards scientifically supported and generally accepted in the field of pharmacy, and shall notify each licensed pharmacist and the Arkansas State Medical Board of this determination.

(2) In making this determination, the Arkansas State Board of Pharmacy may use a nationally recognized reference source that meets the requirements of this act, notifying each licensed pharmacist and the Arkansas State Medical Board of the reference source to be used and any additions or deletions the Arkansas State Board of Pharmacy may make in its discretion.

17-92-101. Definitions.

(5) "Drug" shall include all medicines and preparations recognized in the United States Pharmacopeia or the National Formulary as substances intended to be used for the care, mitigation, or prevention of disease of either man or other animals;

(6) "Generically equivalent" means a drug that is pharmaceutically and therapeutically equivalent to the drug prescribed;

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United State Pharmacopeia

<http://www.usp.org/about/legal-recognition/standard-categories#biologics>

“Biologics—In the United States, all biologics are considered a subset of drugs, whether they are approved by FDA under the FD&C Act [and receive a new drug application (NDA)] or under the Public Health Service Act [PHS Act, where they receive a biologics license application (BLA)]. As a result, all PHS Act biologics are subject to the drug regulatory requirements of the FD&C Act, which means they are required to comply with the adulteration and misbranding provisions of the FD&C Act, including USP–NF compendial requirements. This is equally so for biologics approved under the longstanding PHS Act "351(a)" pathway, as well as the new "351(k)" pathway for biosimilars added by the 2010 healthcare reform legislation.”

FDA Glossary of terms from [www.fda.gov](http://www.fda.gov) under Drugs@FDA Glossary of Terms

## **Drug**

A drug is defined as:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

At least every 12 months all prescriptions for legend drugs which are not controlled substances when refilled must be verified by the prescribing practitioner, a new prescription written, and a new prescription number assigned to the prescription. The prescription number of the updated prescription shall be recorded on the new prescription.

Provided, however, this regulation recognizes, and in no way affects, the six-month and five-refill limit on controlled drug prescriptions pursuant to A.C.A. 5-64 308(c). (10/09/80, Revised 12/12/86)

#### **07-00-0006—GENERIC AND BIOLOGICAL SUBSTITUTION**

The Arkansas State Board of Pharmacy recognizes the Federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book), Approved Animal Drug Products (The Green Book), Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (The Purple Book) and their list of authorized generics as the basis for the determination of generic equivalency within the limitations stipulated in that publication. If the Federal Food and Drug Administration approves a drug product as bioequivalent and publishes that product with an "A" (AA, AB, AN, AO, AP, and AT) rating in the Approved Drug Products with Therapeutic Equivalence Evaluations (The Orange Book or The Green Book), lists the drug (biological product) as being interchangeable (The Purple Book), or lists the drug as an authorized generic, an Arkansas pharmacist, or any pharmacist dispensing drugs to patients in Arkansas, may substitute that product consistent with law. Conversely, if the drug product is not listed in this manner, the pharmacist may not substitute without the consent of the prescribing practitioner. When a pharmacist substitutes a drug product for the drug prescribed, the patient shall be notified of the substitution by a pharmacist involved in the dispensing process.

Communication regarding the substitution of any interchangeable biological product will be made to the prescriber upon dispensing. Communication should include the specific biological product provided to the patient, including without limitation the name of the biological product and the manufacturer of the biological product and should be recorded in an electronic system such as:

- (a) An interoperable electronic medical records system;
- (b) An electronic prescribing technology;
- (c) A pharmacy benefit management system; or
- (d) A pharmacy record.

An entry made into an electronic records system as described in this section is presumed to provide notice to the prescriber of the dispensing of the interchangeable biological product.

(6/21/2001, Amended 5/31/2014 and 12/31/2017)

#### **07-00-0007—A PHARMACIST SHALL NOT DISPENSE A GENERICALLY EQUIVALENT OR INTERCHANGEABLE BIOLOGICAL DRUG PRODUCT UNDER ACA § 17-92-503 (a) AND (b) OF THE GENERIC SUBSTITUTION ACT IF:**

- (a) In the case of a written prescription, on the prescription the prescriber writes in his or her own handwriting words that specify that no substitution shall be made and then also signs the prescription.