AN ACT relating to biosimilar medicines.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 304.17A-163 is amended to read as follows:

(1) As used in this section and KRS 304.17A-1631, unless the context requires otherwise:

(a) "Clinical practice guidelines" means a systematically developed statement to assist decision making by health care providers and patients about appropriate healthcare for specific clinical circumstances and conditions;

(b) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by the insurer, health plan, pharmacy benefit manager, or private review agent to determine the medical necessity and appropriateness of health care services;

(c) "Health plan":

1. Means any state-regulated policy, certificate, contract, or plan that offers or provides coverage in this state, by direct payment, reimbursement, or otherwise, for prescription drugs pursuant to a step therapy protocol, regardless of whether the protocol is described as a step therapy protocol; and

2. Shall include but not be limited to a health benefit plan;

(d) "Pharmacy benefit manager" has the same meaning as in KRS 304.9-020;

(e) "Private review agent" has the same meaning as in KRS 304.17A-600;

(f) "Step therapy exception" means a determination that a step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug; and

(g) "Step therapy protocol" means a protocol, policy, or program that establishes the specific sequence in which prescription drugs that are for a specified medical condition and medically appropriate for a particular insured are

covered by an insurer or health plan.

(2) (a) Except as provided in paragraph (b) of this subsection, clinical review criteria developed by an insurer, health plan, pharmacy benefit manager, or private review agent to establish a step therapy protocol shall be based on clinical practice guidelines that:

1. Recommend that prescription drugs be taken in the specific sequence required by the step therapy protocol;

2. Are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among the members of the writing and review groups by:

a. Requiring members to:

i. Disclose any potential conflict of interests with entities, including insurers, health plans, and pharmaceutical manufacturers; and

ii. Recuse himself or herself from voting if the member has a conflict of interest;

b. Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus; and

c. Offering opportunities for public review and comments;

3. Are based on high quality studies, research, and medical practice;

4. Are created by an explicit and transparent process that:

a. Minimizes biases and conflicts of interest;

b. Explains the relationship between treatment options and outcomes;

c. Rates the quality of the evidence supporting recommendations; and

d. Considers relevant patient subgroups and preferences; and

5. Are continually updated through a review of new evidence, research, and newly developed treatments.

(b) In the absence of clinical practice guidelines that meet the requirements of paragraph (a) of this subsection, an insurer, health plan, pharmacy benefit manager, or private review agent may use peer-reviewed publications to establish step therapy protocols.

(c) When establishing clinical review criteria for a step therapy protocol, an insurer, health plan, pharmacy benefit manager, or private review agent shall take into account the needs of atypical patient populations and diagnoses.

(d) 1. An insurer, health plan, pharmacy benefit manager, or private review agent shall, upon written request, provide all specific written clinical review criteria relating to a particular condition or disease, including clinical review criteria relating to a step therapy exception determination.

2. The clinical review criteria and other clinical information shall be made available:

a. On the insurer's, health plan's, pharmacy benefit manager's, or private review agent's ***website***~~[Web site]~~; and

b. To a health care professional on behalf of an insured upon written request.

(e) Nothing in this subsection shall be construed to require an insurer, health plan, pharmacy benefit manager, or private review agent to establish a new entity to develop clinical review criteria used for step therapy protocols.

(3) (a) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by an insurer, health plan, private review agent, or a pharmacy benefit manager by a step therapy protocol, the insured and prescribing provider shall have access to a clear, readily accessible, and

convenient process to request a step therapy exception.

(b) An insurer, health plan, private review agent, or pharmacy benefit manager:

1. May use its existing medical exceptions process to satisfy the requirements of paragraph (a) of this subsection;
2. Shall make the step therapy protocol easily accessible on its ***website*** ~~[Web site]~~; and
3. Shall, upon request, disclose all rules and criteria related to the step therapy protocol to all prescribing providers, including the specific information and documentation that must be submitted by a prescribing provider or insured to be considered a complete request for a step therapy exception.

(4) (a) A step therapy exception request, or an internal appeal under KRS 304.17A-617 of a step therapy exception request denial, shall be granted by the insurer, health plan, private review agent, or the pharmacy benefit manager within forty-eight (48) hours if:

1. All necessary information to perform the step therapy exception review, or make the appeal determination, has been provided; and
2. One (1) of the following apply:
   a. The required prescription drug is:
      i. Contraindicated or will likely cause an adverse reaction by physical or mental harm to the insured; or
      ii. Expected to be ineffective based on the known clinical characteristics of the insured and the prescription drug regimen;
   b. Based on clinical appropriateness, the required prescription drug is not in the best interest of the insured because the insured's use of the required prescription drug is expected to:

i. Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

ii. Worsen a comorbid condition of the insured; or

iii. Decrease the insured's ability to achieve or maintain reasonable functional ability in performing daily activities;

c. The insured has tried the required prescription drug while under the insured's current or a previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; or

d. The insured is stable on the prescription drug selected by the insured's health care provider for the medical condition under consideration while under a current or previous health plan.

(b) If a request for a step therapy exception, or an internal appeal under KRS 304.17A-617 of a step therapy exception request denial, is incomplete or additional clinically relevant information is required, the insurer, health plan, pharmacy benefit manager, or private review agent shall notify the prescribing provider within forty-eight (48) hours of submission of the request or appeal:

1. That the request or appeal is incomplete; and

2. What additional or clinically relevant information is required in order to approve or deny the step therapy exception.

(5) If a step therapy exception request determination, notification under subsection (4)(b) of this section, or internal appeal determination under KRS 304.17A-617 of a step therapy exception request denial by an insurer, health plan, pharmacy benefit manager, or private review agent is not received by the prescribing provider within the time period specified in subsection (4) of this section, the step therapy exception

request or internal appeal shall be deemed granted.

(6) An insured or a provider may:

(a) Initiate an internal appeal under KRS 304.17A-617 upon the denial of a step therapy exception request under this section; and

(b) Request an external review under KRS 304.17A-623 upon the denial of an internal appeal under paragraph (a) of this subsection.

(7) An insurer, health plan, pharmacy benefit manager, or private review agent shall:

(a) Upon the granting of a step therapy exception request, internal appeal, or external review, authorize coverage for the prescription drug selected by the insured's health care provider; or

(b) Upon the denial of a step therapy exception request or internal appeal, inform the insured of the internal appeal or external review process, as applicable.

(8) (a) Except as provided in paragraph (b) of this subsection, the duration of any step therapy protocol shall not be longer than a period of thirty (30) days if the treatment is deemed and documented as clinically ineffective by the prescribing provider.

(b) When the prescribing provider can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than thirty (30) days to provide any relief or an amelioration to the insured, the step therapy protocol may be extended up to seven (7) additional days.

(9) Nothing in this section shall be construed to prevent:

(a) An insurer, health plan, pharmacy benefit manager, or private review agent from requiring:

1. An insured to try an AB-rated generic equivalent~~[or]~~ interchangeable biological product, as defined in 42 U.S.C. sec. 262(i)(3), ***or biosimilar biological product, as defined 42 U.S.C. sec. 262(i)(2),*** prior to providing coverage for the equivalent branded prescription drug, unless

the requirement meets any of the criteria set forth in subsection (4)(a)2. of this section pursuant to a step therapy exception request submitted under subsection (4) of this section; or

2. A pharmacist to effect substitutions of prescription drugs consistent with KRS 217.814 to 217.896 and 304.17A-535; or

(b) A health care provider from prescribing a prescription drug that is determined to be medically appropriate.

➔Section 2. KRS 217.814 is amended to read as follows:

The following words and phrases, as used in KRS 217.815 to 217.826, shall have the following meanings, unless the context requires otherwise:

(1) "Biological product" has the same meaning as in 42 U.S.C. sec. 262;

(2) ***"Biosimilar biological product" has the same meaning as in 42 U.S.C. sec. 262(i)(2);***

(3) "Board" means the Kentucky Board of Pharmacy;

(4) ~~[(3)]~~ "Brand name" means the name that a manufacturer of a drug or pharmaceutical places on the container thereof at the time of packaging;

(5) ~~[(4)]~~ "Dosage formulation" shall include but not be limited to those specific dosage forms which, by the nature of their physical manufacture, are deemed to be nonequivalent to other similar formulations such as controlled-release tablets, aerosol-nebulizer drug delivery systems, and enteric-coated oral dosage forms;

(6) ~~[(5)]~~ "Equivalent drug product" means a product with the same generic name, active ingredients, strength, quantity, and dosage form as the drug product identified in a prescription;

(7) ~~[(6)]~~ "Generic name" means the chemical or established name of a drug or pharmaceutical;

(8) ~~[(7)]~~ "Interchangeable biological product" means:

(a) A biological product that the United States Food and Drug Administration has

licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. sec. 262(k)(4); or

(b) A biological product that the United States Food and Drug Administration has determined is therapeutically equivalent as set forth in the latest edition or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(9) ~~[(8)]~~ "Nonequivalent drug product formulary" means a formulary of drugs, drug products, and dosage formulations for which there are no equivalent drugs, drug products, or dosage formulations and which have been determined to be noninterchangeable or to have actual or potential bioequivalency problems by the United States Food and Drug Administration and are contained in a drug bioequivalence problems list as published in the United States Food and Drug Administration publication entitled "Approved prescription drug products with therapeutic equivalence evaluations" with supplements;

(10) ~~[(9)]~~ "Pharmacist" has the same meaning as in KRS 315.010; and

(11) ~~[(10)]~~ "Practitioner" has the same meaning as in KRS 217.015.

➔Section 3. KRS 217.822 is amended to read as follows:

(1) When a pharmacist receives a prescription for a brand name drug which is not listed by generic name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall select a lower-priced therapeutically equivalent drug which the pharmacist has in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's practitioner. If a lower-priced selection is made, the label on the container of the drug shall show the name of the drug dispensed.

(2) When a pharmacist receives a prescription for a brand name biological product which is not listed by name in the nonequivalent drug product formulary prepared by the board, the pharmacist shall dispense a lower-priced interchangeable

biological product ***or biosimilar biological product***, if there is one in stock, unless otherwise instructed by the patient at the point of purchase or by the patient's prescribing practitioner. If an interchangeable ***or biosimilar biological*** product is selected, the label on the container shall show the name of the biological product dispensed.

(3) When an equivalent drug product**,**~~[or]~~ interchangeable biological product***, or biosimilar biological product*** is dispensed in lieu of a brand name drug prescribed, the price of the equivalent drug**,**~~[or]~~ interchangeable biological product***, or biosimilar biological product*** dispensed shall be lower in price to the purchaser than the drug product prescribed.

(4) If, in the opinion of a practitioner, it is to the best interest of the practitioner's patient that an equivalent drug**,**~~[or]~~ interchangeable biological product***, or biosimilar biological product*** should not be dispensed, the practitioner may indicate in the manner of his or her choice on the prescription "Do Not Substitute," except that the indication shall not be preprinted on a prescription.

(5) The selection of any drug**,**~~[or]~~ interchangeable biological product***, or biosimilar biological product*** by a pharmacist under the provisions of this section shall not constitute the practice of medicine.

(6) A pharmacist who selects an equivalent drug product**,**~~[or]~~ interchangeable biological product***, or biosimilar biological product*** pursuant to KRS 217.815 to 217.826 assumes no greater liability for selecting the dispensed drug product than would be incurred in dispensing a prescription for a drug product or biological product prescribed by its generic, nonbrand, or proper name.

(7) When a pharmacist receives a generically written prescription for a multiple source drug product, he or she shall dispense an equivalent drug product in accordance with the provisions of KRS 217.815 to 217.826.

(8) When a pharmacist receives a prescription for a biological product written by

nonbrand or proper name, he or she shall dispense an interchangeable biological product ***or biosimilar biological product*** in accordance with the provisions of KRS 217.814 to 217.826, provided that the~~[interchangeable]~~ product has been deemed by the United States Food and Drug Administration to be interchangeable ***or biosimilar*** with that specific reference product as identified by the nonbrand or proper name.

(9) A pharmacist shall not substitute a biological product for a prescribed biological product unless the substituted product is an interchangeable ***or biosimilar*** biological product for the prescribed biological product.

(10) (a) Within five (5) business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner the specific product provided to the patient, including the name of the product and the manufacturer.

(b) Communication shall be conveyed by making an entry that is electronically accessible to the prescribing practitioner through:

1. An interoperable electronic medical records system;
2. An electronic prescribing technology;
3. A pharmacy benefit management system; or
4. A pharmacy record.

(c) Communication entries into an electronic records system as described in this subsection are presumed to provide notice to the prescribing practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescribing practitioner using facsimile, telephone, electronic transmission, or other prevailing means. Communication to the prescribing practitioner, or the prescribing practitioner's office personnel, using facsimile, telephone, electronic transmission, or other prevailing means shall be presumed to provide notice to the prescribing practitioner.

(d) Communication shall not be required where:

1. There is no United States Food and Drug Administration-approved interchangeable ***or biosimilar*** biological product for the product prescribed;
2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription; or
3. The prescribing practitioner indicates "Do Not Substitute" on the prescription.

(e) Communication received by the prescribing practitioner from the dispensing pharmacist or the pharmacist's designee shall be treated in accordance with the standards of acceptable and prevailing practice of the prescribing practitioner within the Commonwealth of Kentucky and the following as they relate to patient records:

1. The principles of ethics of the American Medical Association;
2. The code of ethics of the American Osteopathic Association;
3. The principles of ethics and code of professional conduct of the American Dental Association;
4. The code of ethics of the American Chiropractic Association;
5. The principles of veterinary medical ethics of the American Veterinary Medical Association;
6. The code of ethics of the American Optometric Association; or
7. The code of ethics for nurses of the American Nurses Association.

➔Section 4. The General Assembly finds that increased access to biosimilar medicines has the potential to significantly reduce prescription drug costs. Biosimilar medicines are approved according to the same United States Food and Drug Administration standards of pharmaceutical quality, safety, and efficacy as their reference medications. Therefore, it is the intent of this Act to eliminate barriers impeding access to

biosimilar medicines and the savings they can provide.