AN ACT relating to prescription drugs.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

For the purpose of Sections 1 to 6 and Section 7 of this Act, unless context otherwise requires:

(1) "Cabinet" means the Cabinet for Health and Family Services;

(2) "Innovator prescription insulin drugs" do not include biosimilars approved under 42 U.S.C. sec. 262(k) or other products approved as lower-cost alternatives to the reference innovator product;

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

(4) "Wholesale acquisition cost" means the manufacturer's list price for a prescription drug to wholesalers or direct purchasers in the United States, not including any discounts, rebates, or other reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug pricing data.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

On or before February 1 of each year, the cabinet shall:

(1) Compile a list of innovator prescription insulin drugs that are sold or otherwise made available in the Commonwealth that the cabinet determines to be essential for treating diabetes and the wholesale acquisition cost of each drug on the list;

(2) Compile a list of innovator prescription insulin drugs included in the list described in subsection (1) of this section that have been subject to an increase in the wholesale acquisition cost equal to or greater than:

(a) The percentage increase in the Consumer Price Index for All Urban Consumers: U.S. City Average, Medical Care during the immediately

preceding calendar year; or

(b) Twice the percentage increase in the Consumer Price Index for All Urban Consumers: U.S. City Average, Medical Care during the immediately preceding two (2) calendar years; and

(3) Post the lists required to be compiled pursuant to subsection (1) of this section to the cabinet's Web site.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

On or before April 1 of each year:

(1) The manufacturer of an innovator prescription insulin drug that appears on the most current list compiled by the cabinet pursuant to subsection (2) of Section 2 of this Act shall prepare and submit to the cabinet, in the form prescribed by the cabinet, a report which includes:

(a) The cost of producing the drug;

(b) The wholesale acquisition cost of the drug;

(c) The total administrative expenditures relating to the drug, including marketing and advertising costs;

(d) The total profit that the manufacturer has earned from the drug and the percentage of the manufacturer's total profit for the period during which the manufacturer has marketed the drug for sale that is attributable to the drug;

(e) The total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program for the drug and the total amount of financial assistance that the manufacturer has provided through any patient prescription assistance program for all drugs;

(f) The total cost associated with coupons provided directly to consumers and for programs to assist consumers in paying copayments, and the cost to the

manufacturer attributable to the redemption of those coupons and the use of those programs;

(g) A history of any increases in the wholesale acquisition cost of the drug over the five (5) years immediately preceding the date on which the report is submitted, including:

1. The amount of each such increase expressed as a percentage of the total wholesale acquisition cost of the drug;

2. The month and year in which each increase became effective; and

3. Any explanation for each increase;

(h) The aggregate amount of all rebates that the manufacturer has provided to pharmacy benefit managers for sales of the drug within the Commonwealth;

(i) A list of all factors that have contributed to the increase in the wholesale acquisition cost of the drug, the percentage of the total increase attributable to each factor, and an explanation of the role of each factor in the increase; and

(j) Any additional information required pursuant to administrative regulations promulgated by the cabinet for the purpose of analyzing the cost and cost trends of innovator prescription insulin drugs that appear on the list compiled by the cabinet pursuant to subsection (2) of Section 2 of this Act.

(2) (a) Except as otherwise provided in paragraph (b) of this subsection, a pharmacy benefit manager shall submit to the cabinet, in a form prescribed by the cabinet, a report which includes:

1. The total amount of all rebates that the pharmacy benefit manager negotiated with each manufacturer of a prescription drug included on the list compiled by the cabinet pursuant to subsection (1) of Section 2 of this Act during the immediately preceding calendar year;

2. The total amount of all rebates described in subparagraph 1. of this paragraph that were retained by the pharmacy benefit manager; and

3. The total amount of all rebates described in subparagraph 1. of this paragraph that were negotiated for purchases of prescription drugs for use by:

a. Recipients of Medicare;

b. Recipients of Medicaid;

c. Persons who are covered by third parties that are governmental entities, but who are not described in subdivisions a. and b. of this subparagraph;

d. Persons who are covered by third parties that are not governmental entities; and

e. Persons who are covered by a plan described in paragraph (b) of this subsection to the extent required by a contract entered into pursuant to paragraph (b) of this subsection.

(b) The requirements of this subsection shall not apply to the coverage of prescription drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or any information relating to that coverage, unless a plan contract requires a pharmacy benefit manager who manages the coverage of prescription drugs under the plan to comply with the requirements of this subsection.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

Any data disclosed, forwarded, or otherwise provided to the cabinet by a managed care organization or subcontractor in compliance with the reporting requirements established in Section 3 of this Act, and any report, draft report, data analysis, or other work product generated by any Kentucky government agency relating to data received

from a managed care organization, subcontractor, government agency, or other entity relating to the requirements of Section 3 of this Act shall be exempt from disclosure pursuant to KRS 61.870 to 61.884.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

On or before August 1 of each year, the cabinet shall:

(1) Analyze the information submitted pursuant to Section 3 of this Act;

(2) Compile a report on the price of innovator prescription insulin drugs that appear on the most recent current list compiled by the cabinet pursuant to subsection (2) of Section 2 of this Act. The report shall, at a minimum, include a summary of all information submitted to the cabinet by manufacturers and pharmacy benefit managers pursuant to Section 3 of this Act;

(3) Submit the report described in subsection (2) of this section to the Legislative Research Commission and the Attorney General; and

(4) Post the report on the cabinet's Web site.

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

The cabinet shall promulgate administrative regulations necessary to carry out Sections 2, 3, 4, and 5 of this Act, including but not limited to the form and manner in which manufacturers and pharmacy benefit managers are to provide the information described in Section 3 of this Act to the cabinet.

➔Section 7. KRS 315.990 is amended to read as follows:

(1) Except for the provisions of KRS 315.320 ***and Sections 1 to 6 of this Act***, any person violating any provision of KRS Chapter 315 shall be fined for each offense not less than one hundred dollars ($100) nor more than one thousand dollars ($1,000) or imprisoned in the county jail for not more than six (6) months, or both. Each week that any provision of KRS 315.020, 315.030, or 315.035 is violated shall

also constitute a separate offense.

(2) Any person convicted of willfully resisting, preventing, impeding, obstructing, threatening, or interfering with the officers, agents, or inspectors of the board in the administration of the provisions of this chapter shall be guilty of a Class A misdemeanor.

(3) The board may levy an administrative fine not to exceed five thousand dollars ($5,000) for each offense, for any violation of KRS 315.121. All such fines shall be deposited to the credit of the licensing board to be used by the board in carrying out the provisions of this chapter.

(4) The board may refuse to issue or renew a permit, or may suspend, temporarily suspend, revoke, fine, or reasonably restrict any permit holder for any violation of KRS 315.0351. Any administrative fine levied by the board shall not exceed five thousand dollars ($5,000) for any violation of KRS 315.0351. All such fines shall be deposited to the credit of the licensing board to be used by the Board of Pharmacy in carrying out the provisions of this chapter.

(5) For a violation of KRS 315.320, the Board of Pharmacy may, in addition to any other civil or criminal penalty, levy an administrative fine not exceeding one hundred thousand dollars ($100,000). All such fines shall be deposited to the credit of the Board of Pharmacy in carrying out the provisions of this chapter.

(6) Any manufacturer or pharmacy benefit manager as defined in Section 1 of this Act who fails to comply with the reporting requirements established in Section 3 of this Act shall be fined twenty-five thousand dollars ($25,000) for each day of the failure.

➔Section 8. KRS 304.17A-164 is amended to read as follows:

(1) As used in this section:

(a) "Cost sharing" means the cost to an individual insured under a health benefit plan according to any coverage limit, copayment, coinsurance, deductible, or

other out-of-pocket expense requirements imposed by the plan;

(b) "Insurer" includes:

1. An insurer offering a health benefit plan providing coverage for pharmacy benefits; or

2. Any other administrator of pharmacy benefits under a health benefit plan;

(c) "Pharmacy" includes:

1. A pharmacy, as defined in KRS Chapter 315;

2. A pharmacist, as defined in KRS Chapter 315; or

3. Any employee of a pharmacy or pharmacist; and

(d) "Pharmacy benefit manager" has the same meaning as in KRS 304.17A-161.

(2) An insurer issuing or renewing a health benefit plan on or after ***the effective date of this section***~~[January 1, 2019]~~, or pharmacy benefit manager**,** shall not:

(a) Require an insured purchasing a prescription drug to pay a cost-sharing amount greater than***:***

1. The amount the insured would pay for the drug if he or she were to purchase the drug without coverage under a health benefit plan; ***or***

2. The total amount paid to a pharmacy that is in the network of providers under contract with the insurer, if the insurer provides prescription drug coverage through a network plan;

(b) ***Prohibit a pharmacy from selling a less-expensive alternative drug;***

(c) Prohibit a pharmacy from discussing any information under subsection (3) of this section; and

(d)~~[(c)]~~ Impose a penalty on a pharmacy for complying with this section.

(3) A pharmacist shall have the right to provide an insured information regarding***:***

(a) The applicable limitations on his or her ***cost sharing***~~[cost-sharing]~~ pursuant to this section for a prescription drug***; and***

(b) The clinical efficacy of a less-expensive alternative drug.

(4) Any amount paid by an insured under subsection (2)(a) of this section shall be attributable toward any annual out-of-pocket maximums under the insured's health benefit plan.

➔Section 9. KRS 304.17A-505 is amended to read as follows:

An insurer shall disclose in writing to a covered person and an insured or enrollee, in a manner consistent with the provisions of KRS 304.14-420 to 304.14-450, the terms and conditions of its health benefit plan and shall promptly provide the covered person and enrollee with written notification of any change in the terms and conditions prior to the effective date of the change. The insurer shall provide the required information at the time of enrollment and upon request thereafter.

(1) The information required to be disclosed under this section shall include a description of:

(a) Covered services and benefits to which the enrollee or other covered person is entitled;

(b) Restrictions or limitations on covered services and benefits;

(c) Financial responsibility of the covered person, including copayments and deductibles;

(d) Prior authorization and any other review requirements with respect to accessing covered services;

(e) Where and in what manner covered services may be obtained;

(f) Changes in covered services or benefits, including any addition, reduction, or elimination of specific services or benefits;

(g) The covered person's right to the following:

1. A utilization review and the procedure for initiating a utilization review, if an insurer elects to provide utilization review;

2. An internal appeal of a utilization review made by or on behalf of the

insurer with respect to the denial, reduction, or termination of a health care benefit or the denial of payment for a health care service, and the procedure to initiate an internal appeal; and

3. An external review and the procedure to initiate the external review process;

(h) Measures in place to ensure the confidentiality of the relationship between an enrollee and a health care provider;

(i) Other information as the commissioner shall require by administrative regulation;

(j) A summary of the drug formulary, including, but not limited to, a listing of the most commonly used drugs, ***drugs that are included on the most current list compiled by the Cabinet for Health and Family Services pursuant to subsection (1) of Section 2 of this Act, drugs that have been or will be removed from the formulary during the current plan year or the next plan year,*** drugs requiring prior authorization, any restrictions, limitations, and procedures for authorization to obtain drugs not on the formulary and, upon request of an insured or enrollee, a complete drug formulary; and

(k) A statement informing the insured or enrollee that if the provider meets the insurer's enrollment criteria and is willing to meet the terms and conditions for participation, the provider has the right to become a provider for the insurer.

(2) The insurer shall file the information required under this section with the department.

➔Section 10. KRS 304.17C-030 is amended to read as follows:

(1) An insurer shall disclose in writing to a covered person and an insured or enrollee, in a manner consistent with the provisions of KRS 304.14-420 to 304.14-450, the terms and conditions of its limited health service benefit plan and shall promptly provide the covered person and enrollee with written notification of any change in

the terms and conditions prior to the effective date of the change. The insurer shall provide the required information at the time of enrollment and upon request thereafter.

(2) The information required to be disclosed under this section shall include a description of:

(a) Covered services and benefits to which the enrollee or other covered person is entitled;

(b) Restrictions or limitations on covered services and benefits;

(c) Financial responsibility of the covered person, including copayments and deductibles;

(d) Prior authorization and any other review requirements with respect to accessing covered services;

(e) Where and in what manner covered services may be obtained;

(f) Changes in covered services or benefits, including any addition, reduction, or elimination of specific services or benefits;

(g) The covered person's right to the following:

1. A utilization review and the procedure for initiating a utilization review, if an insurer elects to provide utilization review; and

2. An internal appeal of a utilization review decision made by or on behalf of the insurer with respect to the denial, reduction, or termination of a limited health service benefit plan or the denial of payment for a health care service, and the procedure to initiate an internal appeal;

(h) Measures in place to ensure the confidentiality of the relationship between an enrollee and a health care provider;

(i) Other information as the commissioner shall require by administrative regulation;

(j) A summary of the drug formulary, including but not limited to a listing of the

most commonly used drugs, ***drugs that are included on the most current list compiled by the Cabinet for Health and Family Services pursuant to subsection (1) of Section 2 of this Act, drugs that have been or will be removed from the formulary during the current plan year or the next plan year,*** drugs requiring prior authorization, any restrictions, limitations, and procedures for authorization to obtain drugs not on the formulary, and, upon request of an insured or enrollee, a complete drug formulary; and

(k) A statement informing the insured or enrollee that if the provider meets the insurer's enrollment criteria and is willing to meet the terms and conditions for participation, the provider has the right to become a provider for the insurer.

(3) The insurer shall file the information required under this section with the department.

➔SECTION 11. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

For the purpose of Sections 11 to 13 of this Act, unless context otherwise requires:

(1) (a) "Essential off-patent or generic drug" means any prescription drug that meets all of the following criteria:

1. All exclusive marketing rights for the drug, if any, granted pursuant to the federal Food, Drug, and Cosmetics Act, Section 351 of the federal Public Health Service Act, or federal patent law have expired;

2. The drug appears on the model list of essential medicines most recently adopted by the World Health Organization or has been designated by the secretary as an essential medicine due to its efficacy in treating a life-threatening health condition or a chronic health condition that substantially impairs an individual's ability to engage in activities of daily living;

3. The drug is actively manufactured and marketed for sale in the United

States by three (3) or fewer manufacturers; and

4. The drug is made available for sale in the Commonwealth.

(b) "Essential off-patent or generic drug" includes any drug-device combination product used for the delivery of a drug for which all exclusive marketing rights, if any, granted pursuant to the federal Food, Drug, and Cosmetics Act, Section 351 of the federal Public Health Service Act, or federal patent law have expired;

(2) "Manufacturer" has the same meaning as in KRS 315.010;

(3) "Medical assistance program" means the state medical assistance program established in KRS Chapter 205;

(4) "Secretary" means the secretary of the Cabinet for Health and Family Services;

(5) "Wholesale acquisition cost" has the same meaning as in Section 1 of this Act; and

(6) "Wholesaler" has the same meaning as in KRS 315.010.

➔SECTION 12. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

(1) A manufacturer or wholesaler of an essential off-patent or generic drug is prohibited from engaging in unfair and unconscionable price increases in the sale of the drug.

(2) It shall not be a violation of subsection (1) of this section for a wholesaler to increase the price of an essential off-patent or generic drug if the price increase is directly attributable to additional costs for the drug imposed on the wholesaler by the manufacturer of the drug.

➔SECTION 13. A NEW SECTION OF KRS CHAPTER 367 IS CREATED TO READ AS FOLLOWS:

(1) The secretary shall notify the Attorney General of any increase in the price of an essential off-patent or generic drug if the price increase, by itself or in

combination with other price increases:

(a) 1. Would result in an increase of fifty percent (50%) or more in the wholesale acquisition cost of the drug within the preceding one (1) year period; or

2. Would result in an increase of fifty percent (50%) or more in the price paid by the medical assistance program for the drug within the preceding one (1) year period; and

(b) Meets at least one (1) of the following criteria:

1. A thirty (30) day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost;

2. A full course of treatment with the drug, according to the label for the drug approved under the federal Food, Drug, and Cosmetic Act, would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost; or

3. If the drug is made available to consumers only in quantities that do not correspond to a thirty (30) day supply, a full course of treatment, or a single dose, it would cost more than eighty dollars ($80) at the drug's wholesale acquisition cost to obtain a thirty (30) day supply or a full course of treatment.

(2) The Attorney General's receipt of notification pursuant to subsection (1) of this section shall constitute notice of a potential violation of Section 2 of this Act and KRS 367.170.

(3) Any investigative demand issued by the Attorney General to a manufacturer or wholesaler shall include a request for all of the following:

(a) An itemization of the components of the cost of producing the drug;

(b) An identification of the circumstances and timing of any increase in materials or manufacturing costs that cause any increase in the price of the drug within the one (1) year period immediately preceding the date of the price increase;

(c) 1. An identification of the circumstances and timing of any expenditures made by the manufacturer or wholesaler to expand access to the drug; and

2. An explanation of any improvement in the public health associated with those expenditures; and

(d) Any other information that the manufacturer or wholesaler believes to be relevant to a determination of whether a violation of Section 2 of this Act or KRS 367.170 has occurred.

(4) If a court determines that a violation of Section 2 of this Act or KRS 367.170 has occurred, in addition to the remedies provided for in KRS 367.110 to 367.360, a court may:

(a) Issue an order requiring a manufacturer or wholesaler that has engaged in unrestrained price increases in the sale of an essential off-patent or generic drug to make the drug available to residents of the Commonwealth for a period of up to one (1) year at the price at which the drug was made available to residents of the Commonwealth immediately prior to the manufacturer's violation of Section 2 of this Act or KRS 367.170; and

(b) Impose a civil penalty of up to ten thousand dollars ($10,000) for each violation of Section 2 of this Act and KRS 367.170.

(5) The Attorney General shall not bring an action for a remedy pursuant to this section unless the Attorney General has provided the manufacturer or wholesaler with an opportunity to meet with the Attorney General or his or her staff to offer justification for the increase in the price of the essential off-patent or generic

drug.

(6) Any information provided by a manufacturer or wholesaler to the Attorney General pursuant to this section shall be considered confidential commercial information not subject to disclosure pursuant to KRS 61.870 to 61.884.

(7) In any action brought by the Attorney General pursuant to this section, a person who is alleged to have violated Section 2 of this Act or KRS 367.170 shall not assert as a defense that the person did not deal directly with a consumer residing in the Commonwealth.

➔Section 14. Sections 8, 9, and 10 of this Act take effect January 1, 2021.