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 217 IS CREATED TO READ AS FOLLOWS:

For the purpose of Sections 1 to 5 of this Act, unless the context otherwise requires:

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

(2) "Manufacturer" means any person or entity which:

(a) Derives, produces, prepares, compounds, mixes, cultivates, grows, or processes any drug or medicine;

(b) Repackages any drug or medicine for the purpose of resale; or

(c) Produces or makes any devices or appliances that are restricted by federal law to sale by or on the order of a physician;

(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 purchases in the Unites States, not including any discounts, rebates, or reductions in price, as reported in wholesale price guides or other publications of drug pricing data.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

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

(a) 1. 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. For the purposes of Sections 1 to 5 of this Act, innovator prescription insulin drugs do not include biosimilars approved under U.S.C. sec. 262(k) or other products approved as lower-cost alternatives to the

reference innovator product; and

(b) A list of prescription drugs described in paragraph (a) of this subsection that have been subject to an increase in the wholesale acquisition cost of a percentage equal to or greater than:

1. 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

2. 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.

(2) On or before February 1 of each year, the cabinet shall post the lists required to be compiled by subsection (1) of this section on the cabinet's Web site.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

On or before April 1 of each year:

(1) The manufacturer of a prescription drug that appears on the most current list compiled by the cabinet pursuant to subsection (1)(b) 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 total profit that the manufacturer has earned from the drug;

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

(c) 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;

(d) The wholesale acquisition cost of the drug;

(e) The aggregate amount of all rebates and, separately, the aggregate amount of all administrative fees that the manufacturer has provided to pharmacy benefit managers for sales of the drug within this state;

(f) A list of all factors that have contributed to the increase in the wholesale acquisition price;

(g) An explanation of the role of each factor in the wholesale acquisition price increase; and

(h) Any additional information required pursuant to administrative regulations promulgated by the cabinet for the purpose of analyzing the cost and cost trends of prescription drugs that appear on the lists compiled pursuant to subsection (1)(b) of Section 2 of this Act; and

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

1. The total amount of all rebates that the pharmacy benefit manager negotiated with the manufacturers of prescription drugs included on the list compiled by the cabinet pursuant to subsection (1)(a) 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 recipients of Medicare or Medicaid;

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 (c) of this subsection.

(b) Except as otherwise provided in paragraph (c) of this paragraph, 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.

(c) A plan described in paragraph (b) of this subsection may, by contract, require a pharmacy benefit manager that manages the coverage of prescription drugs under the plan to comply with the requirements of this subsection.

(3) Any data disclosed, forwarded, or otherwise sent by a managed care organization or subcontractor in compliance with the reporting requirements established in this section, 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 this section shall be exempt from disclosure pursuant to KRS 61.870 to 61.884.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 217 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 the prescription drugs that appear on the most

current lists compiled by the department pursuant to Section 2 of this Act. The report shall, at minimum, include a summary of all information submitted to the cabinet by manufacturers and pharmacy benefit managers Section 3 of this Act;

(3) Submit the report to the Legislative Research Commission; and

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

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO READ AS FOLLOWS:

The cabinet shall promulgate administrative regulations necessary to carry out Sections 1 to 5 of this Act, including but not limited to the form and manner in which manufacturers and pharmacy benefit managers are to provide to the cabinet the information described in Section 3 of this Act.

➔Section 6. KRS 217.990 is amended to read as follows:

(1) Any person who violates any of the provisions of KRS 217.350 shall be fined not more than twenty-five dollars ($25).

(2) Any person who violates any of the provisions of subsection (2) of KRS 217.390 shall be fined not less than ten dollars ($10) nor more than one hundred dollars ($100), or imprisoned for not more than fifty (50) days, or both.

(3) Except as provided in subsections (1) and (2) of this section, any person who violates any of the provisions of KRS 217.280 to 217.390 or who refuses to comply with any lawful order or requirement duly made in writing as provided in KRS 217.380, shall, for the first offense, be fined not less than ten dollars ($10) nor more than one hundred dollars ($100), or imprisoned for not more than thirty (30) days, or both, and for any subsequent offense shall be fined not less than fifty dollars ($50) nor more than two hundred dollars ($200), or imprisoned for not more than ninety (90) days, or both. Each day after the expiration of the time limit for abating unsanitary conditions and completing improvements to abate such conditions, as ordered under KRS 217.380, shall be a separate offense.

(4) Any person who violates any of the provisions of KRS 217.400 shall be fined not less than ten dollars ($10) nor more than one hundred dollars ($100).

(5) Any person who violates any of the provisions of KRS 217.420 to 217.440 shall be fined not less than two hundred dollars ($200) nor more than one thousand dollars ($1,000), or imprisoned in the county jail for not more than one (1) year, or both.

(6) Any person who violates any of the provisions of KRS 217.450 shall be fined one hundred dollars ($100).

(7) Any person who violates any provision of KRS 217.801 shall be fined not less than fifty dollars ($50) nor more than five hundred dollars ($500) or imprisoned for not less than thirty (30) days nor more than six (6) months, or both.

(8) Any person who violates any of the provisions of KRS 217.808 to 217.812, or any rule or regulation adopted thereunder, or who operates a vending machine company or vending machine commissary without a permit as prescribed in KRS 217.808 to 217.812, or who fails to comply with any order of the cabinet or of any local health department issued pursuant thereto shall be fined not less than twenty-five dollars ($25) nor more than one hundred dollars ($100). Each day of violation or noncompliance shall constitute a separate offense.

(9) Willful noncompliance with KRS 217.816 shall constitute a violation and shall subject the violator to a fine of not over fifty dollars ($50) for the first offense and not over two hundred dollars ($200) for a subsequent offense.

(10) Any person who willfully fails to comply with the provisions of KRS 217.816 to 217.826 shall be guilty of a violation and shall be subject to a fine of not less than one hundred dollars ($100) nor more than five hundred dollars ($500) for each violation.

(11) Any person who violates any of the provisions of KRS 217.177 shall be fined not less than twenty-five dollars ($25) nor more than five hundred dollars ($500) or be imprisoned in the county jail for not less than five (5) nor more than thirty (30)

days, or both.

(12) Any manufacturer or distributor who dispenses, sells, or otherwise provides to any other person any legend drug in solid dosage form that fails to comply with the requirements of KRS 217.907 to 217.915 shall be fined not less than one hundred dollars ($100) nor more than five hundred dollars ($500) for each offense.

(13) 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 7. 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 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 discussing any information under subsection (3) of this section; ***or***~~[and]~~

(c) ***Prohibit a pharmacy from selling a less expensive alternative drug***~~[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 pursuant to this section for a prescription drug***; or***

(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.

(5) An insurer issuing or renewing a health benefit plan or pharmacy benefit plan manager shall not impose a penalty on a pharmacy for complying with this section.

➔Section 8. 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 recent list***

of insulin drugs that are essential for treating diabetes 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 9. 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 recent list of drugs that are essential for treating diabetes 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.