AN ACT relating to the cost of insulin.

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

➔SECTION 1. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section and Section 2 of this Act:

(a) "Certified insulin" means insulin that has been certified under Section 2 of this Act;

(b) "Covered person" means an individual entitled to receive benefits or services under a health plan;

(c) "Health plan" means any policy, contract, or plan that offers or provides coverage in this state for pharmacy or pharmacist services, whether that coverage is by direct payment, reimbursement, or otherwise;

(d) "Insulin" means any insulin product approved by the Food and Drug Administration to improve glycemic control in patients with diabetes mellitus;

(e) "Insurer" means any of the following persons or entities that offer or issue a health plan:

1. An insurance company;

2. A health maintenance organization;

3. A limited health service organization;

4. A self-insurer, including a governmental plan, church plan, or multiple employer welfare arrangement, not exempt by federal law from regulation under the insurance laws of this state;

5. A provider-sponsored integrated health delivery network;

6. A self-insured employer-organized association;

7. A nonprofit hospital, medical-surgical, dental, and health service corporation; or

8. Any other third-party payor that is:

a. Authorized to transact health insurance business in this state; or

b. Not exempt by federal law from regulation under the insurance laws of this state;

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

(g) "Pharmacy or pharmacist services" means any health care procedures, treatments within the scope of practice of a pharmacist, or services provided by a pharmacy or a pharmacist, including the provision of:

1. Prescription drugs, as defined in KRS 315.010; and

2. Home medical equipment, as defined in KRS 309.402; and

(h) "Rebate" means:

1. Any discount, price concession, or fee, the terms of which are fixed at the time of sale and disclosed, but which is not received at the time of sale; and

2. Does not include the fee described in subsection (3) of this section.

(2) For health plans issued or renewed on or after the effective date of this Act, an insurer or pharmacy benefit manager shall not:

(a) Except as provided in subsection (3) of this section, directly or indirectly receive any of the following from a manufacturer for the provision of certified insulin to covered persons:

1. A rebate;

2. A reduction in price; or

3. Any other remuneration;

(b) Restrict or disadvantage certified insulin from the formulary applicable to any health plan or coverage, relative to any other insulin or similar formulation;

(c) Impose a higher cost-sharing on a covered person with respect to certified

insulin than the cost-sharing that applied with respect to insulin in the year in which the insulin was certified under Section 2 of this Act;

(d) Apply any deductible requirements for coverage of certified insulin under the health plan or coverage;

(e) Impose any prior authorization requirements for coverage of certified insulin that were not applied during the year in which the insulin was certified under Section 2 of this Act; and

(f) Establish a step therapy requirement for certified insulin that was not applied during the year in which the insulin was certified under Section 2 of this Act.

(3) The requirements of subsection (2)(a) of this section shall not apply to any:

(a) Reduction of price that is reflected at the point of sale to the covered person; or

(b) Remuneration that is a flat fee-based service in which a manufacturer of certified insulin pays a pharmacy benefit manager for services rendered to the manufacturer that relate to arrangements by the pharmacy benefit manager to provide pharmacy benefit management services to a health plan or insurer, if conditions established by the commissioner are met, including that the fees are transparent to the insurer.

(4) The provisions of this section shall be subject to all applicable federal law and regulations. To the extent that any provision of this section conflicts with an applicable federal law or regulation, the applicable federal law or regulation shall control.

➔SECTION 2. A NEW SECTION OF SUBTITLE 17A OF KRS CHAPTER 304 IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "List price" means, with respect to a drug or biological, the manufacturer's

list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or 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 or biological pricing data; and

(b) "Authorized generic drug" has the same meaning as in 21 U.S.C. sec. 355(t)(3).

(2) A manufacturer of insulin may apply to have an insulin product determined a certified insulin by submitting the following, certified by the manufacturer to be accurate, to the commissioner:

(a) Data on the list price of the insulin product manufactured by the manufacturer during the period beginning on January 1, 2000, or the first date in which the manufacturer began manufacturing the insulin product, through the list price applicable at the time of the submission, except for an insulin product that:

1. The manufacturer did not manufacture on or prior to July 1, 2006; or

2. Is classified as an authorized generic drug; and

(b) A certification that the manufacturer has reduced its list price for the insulin product to an amount that is no greater than the list price for the same insulin that applied as of July 1, 2006, except:

1. If a manufacturer did not manufacture the insulin product on or prior to the July 1, 2006, the manufacturer shall submit a certification that the list price for the insulin product is no greater than the weighted average list price, in 2006, for one (1) of the following categories of insulin, as applicable:

a. All short-acting insulins;

b. All rapid-acting insulins;

c. All long-acting insulins; or

d. Any other categories of insulin as the commissioner determines appropriate; or

2. If a manufacturer is certifying an insulin product that is classified as an authorized generic drug then the manufacturer shall submit one (1) of the following:

a. If the listed drug insulin product upon which the authorized generic was based was first manufactured on or prior to July 1, 2006, a certification that the list price of the generic drug insulin product is no greater than the list price of the listed drug insulin product upon which the authorized generic was based as of July 1, 2006; or

b. If the listed drug insulin product upon which the authorized generic was based was first manufactured after July 1, 2006, a certification that the list price for the generic insulin product is no greater than the weighted average list price, in 2006, for one (1) of the following categories of insulin, as applicable:

i. All short-acting insulins;

ii. All rapid-acting insulins;

iii. All long-acting insulins; or

iv. Any other categories of insulin as the commissioner determines appropriate.

(3) For any certified insulin product that is classified as an authorized generic drug, any certification under this section shall be limited to the authorized generic drug insulin, and shall not apply with respect to the applicable listed drug insulin upon which the authorized generic drug was based.

(4) (a) A manufacturer who has had an insulin product determined certified

insulin under this section may renew the certification pursuant to paragraph (b) of this subsection.

(b) A manufacturer seeking certified insulin renewal shall submit a certification to the commissioner that the manufacturer has not increased the list price for the insulin product for which a renewal is being sought by more than the rate by which the medical care component of the consumer price index for all urban consumers, U.S. city average, increased since the initial certification under this section.

(5) (a) The commissioner shall approve an insulin product as certified insulin if the commissioner finds that the requirements of this section have been met.

(b) Within sixty (60) days of the date a manufacturer submits information under subsections (2) or (4) of this section, the commissioner shall notify the manufacturer of approval or disapproval of the insulin product as a certified insulin.

(c) Any approval of an insulin product as a certified insulin shall be valid for one (1) year after the date the approval was issued.

(d) The commissioner may cause the financial records and other relevant records of any manufacturer submitting data under subsections (2) or (4) of this section to be audited.

(e) Any manufacturer, or an officer, director, agent, or managing employee of a manufacturer, that knowingly submits false or incomplete data shall be subject to a civil penalty for each insulin for which false or incomplete data is submitted in an amount:

1. Equal to two (2) times the total amount of rebates paid by the manufacturer to Medicaid plans in this state for the insulin for rebate periods occurring in calendar year 2018 under 42 U.S.C. sec. 1396r-8; or

2. An amount to be determined by the commissioner, but not to exceed the amount provided under subparagraph 1. of this paragraph.

➔Section 3. This Act may be cited as the "Insulin Price Reduction Act."