AN ACT relating to the Kentucky Prescription Drug Affordability Board and making an appropriation therefor.

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

➔SECTION 1. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

As used in Sections 1 to 6 of this Act:

(1) "Affordability review" means the review required under Section 5 of this Act; and

(2) "Board" means the Kentucky Prescription Drug Affordability Board established in Section 2 of this Act.

➔SECTION 2. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

(1) There is hereby created and established the Kentucky Prescription Drug Affordability Board, whose duties shall be to:

(a) Collect and review information relating to the cost of prescription drugs sold in this state;

(b) Conduct affordability reviews of prescription drugs; and

(c) Make the legislative recommendations and reports relating to the cost of prescription drugs in this state required under Section 6 of this Act and any other law.

(2) (a) The board shall consist of:

1. Nine (9) members, who:

a. Are residents of this state;

b. Have expertise in:

i. Health care economies and finance; or

ii. Pharmaceutical economies and finance; and

c. Are not employees, board members, or consultants of:

i. A manufacturer that sells, or offers for sale, prescription drugs;

ii. A wholesale distributor that sells, or offers for sale, prescription drugs;

iii. A health insurer;

iv. A pharmacy benefit manager or any other administrator of prescription drug benefits; or

v. Any trade association related to any person referenced under subpart i., ii. iii., or iv. of this subdivision; and

2. Three (3) alternate members who:

a. Meet the requirements of subparagraph 1.a. to c. of this paragraph; and

b. Shall be designated by the chair of the board to participate in any activity or vote of the board for which a member is recused.

(b) At least one (1) of the members of the board shall also have expertise in the 340B Program established under Section 340B of the Public Health Service Act, Pub. L. No. 78-410.

(c) 1. Members of the board shall:

a. Be appointed, and subject to removal by, the Governor for four (4) year terms;

b. Be subject to Senate confirmation in accordance with KRS 11.160;

c. Be eligible to succeed themselves if the member continues to be qualified under paragraph (a) of this subsection; and

d. To the extent practicable and consistent with federal and state law, reflect the racial, ethnic, and gender diversity of the state.

2. In making appointments to the board, the Governor shall consider

conflicts of interests disclosed by prospective members under subsection (2) of Section 3 of this Act shall be considered in making appointments to the board.

3. The Governor may remove a member of the board for malfeasance in office, failure to regularly attend meetings, or any cause that renders the member incapable or unfit to discharge the duties of the member. Removal from the board under this subparagraph shall not be subject to review.

(3) (a) The board:

1. Shall select one (1) of its members as a chairperson and another as a vice chairperson;

2. Shall determine the terms, duties, and powers necessary for the performance of the functions of the offices held under subparagraph 1. of this paragraph;

3. Shall meet at least once every six (6) weeks unless the board does not have a prescription drug to review under Section 5 of this Act; and

4. May meet more frequently than as required under subparagraph 3. of this paragraph upon the call of the chair.

(b) A majority of members shall constitute a quorum.

(4) (a) The board shall be a budgetary unit of the Office of Data Analytics, which shall:

1. Pay all of the board's necessary operating expenses;

2. Furnish all office space, personnel, equipment, supplies, and technical or administrative services required by the board in the performance of the board's functions; and

3. Maintain a webpage on its public website for the board to use for its purposes, including but not limited to publishing disclosures under

subsection (4)(a) of Section 3 of this Act.

(b) Members of the board shall not receive compensation for services, but shall receive actual and necessary travel expenses associated with attending meetings in accordance with state administrative regulations relating to travel reimbursement.

(5) The board:

(a) Shall appoint an executive director with knowledge and demonstrated experience in pharmacoeconomics, pharmacology, health policy, health services research, or a related field or discipline;

(b) May employ consultants, investigators, and other staff for the operation of the board; and

(c) 1. May enter into a contract with a qualified independent third party for any service necessary to carry out the powers and duties of the board.

2. Unless otherwise authorized by the board in writing, a third party that has entered into a contract under subparagraph 1. of this paragraph shall not release, publish, or otherwise use any information to which the third party has access under the contract.

(6) In order to carry out its duties under Sections 1 to 6 of this Act, the board may:

(a) Collect and review publicly available information, including but not limited to data regarding:

1. Prescription drug manufacturers;

2. Prescription drug wholesale distributors;

3. Insurers; and

4. Pharmacy benefit managers and other administrators of pharmacy benefits;

(b) Enter into memorandums of understanding with states that require reporting on the cost of prescription drugs;

(c) Access available prescription drug pricing information from state agencies; and

(d) Subscribe to any one (1) or more prescription drug pricing files.

(7) (a) To the extent there is not sufficient information available under subsection (6) of this section to carry out the board's duties under Sections 1 to 6 of this Act, including conducting affordability reviews, the board may request pricing information for any prescription drug identified under subsection (2) of Section 5 of this section from any prescription drug wholesale distributor, insurer, pharmacy benefit manager, or other administrator of pharmacy benefits.

(b) The failure of a prescription drug manufacturer, prescription drug wholesale distributor, insurer, pharmacy benefit manager, or other administrator of pharmacy benefits to provide pricing information under paragraph (a) of this subsection shall not affect the authority of the board to conduct a review.

(8) The board may promulgate any administrative regulations, in accordance with KRS Chapter 13A, necessary to carry out its duties under Sections 1 to 6 of this Act.

➔SECTION 3. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "Conflict of interest":

1. Means any financial or personal association that has a potential to bias, or have the appearance of biasing, a person's decisions in matters related to the board or its activities;

2. Includes any instance in which a person, the person's immediate family member, including a spouse, parent, child, or other legal

dependent, or any in-law of any of the preceding individuals, has received, or could receive:

a. A direct or indirect financial benefit of any amount deriving from the results or findings of a decision or determination of the board; or

b. A financial benefit from any person that owns or manufactures a prescription drug that is, or could be, reviewed by the board under Section 5 of this Act; and

3. Does not include the ownership of securities if the securities are:

a. Part of a diversified mutual or exchange-traded fund; or

b. In a tax-deferred or tax-exempt retirement account that is administered by an independent trustee;

(b) Except as provided in paragraph (a)3. of this subsection, "financial benefit" includes:

1. Honoraria;

2. Fees;

3. Stock;

4. Increases to the value of existing stock holdings; and

5. Any other compensation; and

(c) "Third-party contractor" means any person who has contracted with the board, or the office on behalf of the board, to provide services or goods.

(2) Prior to any person accepting an appointment, employment, or contractual agreement in connection with the board, the person shall disclose any conflict of interest to the applicable appointing, hiring, or contracting authority.

(3) (a) A board member, staff member of the board, or third-party contractor shall:

1. Disclose, in accordance with paragraph (b) of this subsection, any conflict of interest relating to any board activity or vote; and

2. Recuse himself or herself from any board activity or vote in which the member, staff member, or contractor has a conflict of interest.

(b) A conflict of interest shall be disclosed to the board by the earlier of:

1. Prior to the first meeting after the conflict is identified; or

2. Within five (5) days after the conflict is identified.

(4) (a) Except as provided in paragraph (b) of this subsection, the board shall promptly publish, on the webpage maintained under subsection (4) of Section 2 of this Act, any conflict of interest disclosed to the board under subsection (3)(a) of this section, including the type, nature, and magnitude of the conflict of interest.

(b) A conflict of interest disclosed by a staff member of the board or a third-party contractor relating to a personal association shall remain confidential.

(5) A board member, staff member of the board, or third-party contractor shall not accept any gift, bequeath, or donation of services or property that:

(a) Suggests a conflict of interest; or

(b) Otherwise has the appearance of creating bias in the activities or votes of the board.

➔SECTION 4. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

(1) The Kentucky Prescription Drug Affordability Board fund is hereby created in the State Treasury.

(2) The following shall be deposited into the fund:

(a) Any assessments collected under subsection (6) of this section; and

(b) Any grants received under subsection (5) of this section.

(3) Notwithstanding KRS 45.229, moneys in the fund not expended at the close of a fiscal year shall not lapse but shall be carried forward to the next fiscal year. Any

interest earnings of the fund shall become part of the fund and shall not lapse.

(4) Moneys in the fund are hereby appropriated by the General Assembly, and shall be available to the office to implement Sections 1 to 6 of this Act.

(5) The executive director of the board shall be authorized to seek and accept any grants available to support the activities of the board.

(6) The Office of Data Analytics shall assess and collect an annual fee, in an amount sufficient to cover the costs of implementing Sections 1 to 6 of this Act, on:

(a) Manufacturers or wholesale distributors that offer for sale or sell prescription drugs in this state;

(b) Pharmacy benefit managers licensed in this state;

(c) Health insurers authorized to transact insurance in this state; and

(d) Any other administrator of prescription drug benefits in this state.

(7) The Office of Data Analytics may coordinate collection activities with the Department of Revenue under KRS 131.560 for any fee that is assessed but not collected by the office.

➔SECTION 5. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

(1) As used in this section:

(a) "FDA" means the United States Food and Drug Administration;

(b) "Health utility" means a measure of the degree to which having a particular form of disease or disability, or having a particular functional limitation, negatively impacts the quality of life as compared to a state of perfect health, expressed as a number between zero (0) and one (1); and

(c) "Quality-adjusted life-year" means the product of a health utility multiplied by the extra months or years of life that a patient may gain as a result of treatment.

(2) (a) The board shall review, in accordance with this section, a minimum of ten

(10) prescription drugs per year to determine whether use of each prescription drug consistent with the labeling approved for the drug by the FDA, or with standard medical practice, is unaffordable for Kentucky consumers.

(b) At least one (1) insulin drug shall be reviewed per year under this section.

(c) A drug that is designated by the secretary of the FDA as a drug for a rare disease or condition under 21 U.S.C. sec. 360bb, as amended, shall not be subject to review under this section.

(3) (a) The board shall identify the following prescription drugs for review under subsection (4)(a) of this section:

1. A brand-name drug or biological product that, as adjusted annually for inflation, has:

a. An initial wholesale acquisition cost of thirty thousand dollars ($30,000) or more for:

i. A twelve (12) month supply; or

ii. A course of treatment that is less than twelve (12) months in duration; or

b. An increase in the wholesale acquisition cost of ten percent (10%) or more during the immediately preceding twelve (12) months for:

i. A twelve (12) month supply; or

ii. A course of treatment that is less than twelve (12) months in duration;

2. A biosimilar drug that has an initial wholesale acquisition cost that is not at least fifteen percent (15%) lower than the corresponding biological product; and

3. A generic drug:

a. That, as adjusted annually for inflation, has a wholesale acquisition cost of one hundred dollars ($100) or more for:

i. A thirty (30) day supply or less, based on the recommended dosage approved for labeling by the FDA; or

ii. One (1) dose if the labeling approved by the FDA does not recommend a finite dosage; and

b. For which the wholesale acquisition cost increased by two hundred percent (200%) or more during the immediately preceding twelve (12) months, as determined by comparing the current wholesale acquisition cost to the average wholesale acquisition cost reported during the immediately preceding twelve (12) months.

(b) The board may identify prescription drugs not described in paragraph (a) of this subsection for review under subsection (4)(a) of this section if the prescription drug may impose costs that create a significant affordability challenge for the state health care system or patients.

(4) (a) The board shall determine whether to conduct an affordability review for each prescription drug identified under subsection (3) of this section.

(b) When making the determination required under paragraph (a) of this subsection, the board shall:

1. Evaluate the class of the drug and whether any therapeutically equivalent prescription drugs are available for sale;

2. Evaluate aggregated data;

3. Seek and consider input about the drug from stakeholders:

4. Consider the average patient's out-of-pocket cost for the drug; and

5. Consider any other criteria established by the board in administrative regulation.

(5) (a) In conducting an affordability review of a prescription drug, the board:

1. Shall consider the following, to the extent practicable:

a. The number of residents in this state prescribed the drug;

b. The price of the drug, including:

i. The wholesale acquisition cost; and

ii. Any other relevant prescription drug cost index for the drug;

c. The relevant factors contributing to the price of the drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions;

d. The price and availability of therapeutic alternatives to the drug that are sold in this state;

e. The relevant factors contributing to the price paid for the therapeutic equivalents of the drug, including the wholesale acquisition cost, discounts, rebates, or other price concessions for the therapeutic equivalent;

f. The cost to health insurance contracts, policies, certificates, or plans based on patient use of the drug that is consistent with:

i. The labeling approved by the FDA; and

ii. Recognized standard medical practice;

g. The impact on patient access to the drug based on standard prescription drug benefit designs in health insurance contracts, policies, certificates, and plans offered in this state;

h. The dollar value and accessibility of patient assistance programs offered by the manufacturer of the drug;

i. The relative financial impacts to health, medical, or social services costs as can be quantified and compared to the costs of

existing therapeutic alternatives;

j. The effect of the price of the drug on Kentucky consumers' access to the drug;

k. The average patient copayment or other cost sharing that is associated with the drug and typically required pursuant to health insurance policies, certificates, plans, and contracts issued by insurers in the state;

l. The impact on safety net providers if the drug is available through Section 340B of the Public Health Service Act, Pub. L. No. 78-410;

m. Orphan drug status;

n. Input from:

i. Patients and caregivers affected by the condition or disease that is treated by the prescription drug; and

ii. Individuals who possess scientific and medical training with respect to the condition or disease treated by the prescription drug; and

o. Any other information that a manufacturer, insurer, pharmacy benefit manager, other administrator of pharmacy benefits, or other entity chooses to provide to the board; and

2. May consider:

a. Any documents or information relating to the manufacturer's selection of the initial price, or price increase, of the prescription drug, including documents and information relating to:

i. Life-cycle management;

ii. The average cost of the drug in the state;

iii. Market competition and context;

iv. Projected revenue; and

v. Off-label usage of the drug; and

b. Any additional factors established by the board in administrative regulation.

(b) If the board determines that the cost-effectiveness of a prescription drug shall be considered as an additional factor under paragraph (a)2.b. of this subsection, the board shall:

1. Not use quality-adjusted life years, or similar formulas that consider a patient's age, severity of illness, or disability to identify subpopulations for which a prescription drug would be less cost-effective; and

2. For any drug that extends life, weigh the value of the quality of life equally for all patients, regardless of the patient's age, severity of illness, or disability.

➔SECTION 6. A NEW SECTION OF KRS CHAPTER 194A IS CREATED TO READ AS FOLLOWS:

By September 1 of each year, the board shall submit the following information to the Legislative Research Commission, for referral to the Interim Joint Committees on Health Services and Banking and Insurance:

(1) Price trends for the prescription drugs identified under subsection (3) of Section 5 of this Act.

(2) Prescription drugs for which the board conducted an affordability review and the results of the review; and

(3) Recommendations, if any, for legislative changes necessary to make prescription drugs more affordable in this state.

➔Section 7. KRS 304.2-100 is amended to read as follows:

(1) The commissioner shall personally supervise the operations of the department.

(2) The commissioner shall examine and inquire into violations of this code, shall

enforce the provisions of this code with impartiality and shall execute the duties imposed upon him or her by this code.

(3) The commissioner shall have the powers and authority expressly conferred upon him or her by or reasonably implied from the provisions of this code.

(4) The commissioner may conduct such examinations and investigations of insurance matters, in addition to examinations and investigations expressly authorized, as the commissioner may deem proper upon reasonable and probable cause to determine whether any person has violated any provisions of this code or to secure information useful in the lawful administration of any such provision. The cost of such additional examinations and investigations shall be borne by the state.

(5) The commissioner may establish and maintain such branch offices in this state as may be reasonably required for the efficient administration of this code.

(6) The commissioner shall have such additional powers and duties as may be provided by other laws of this state.

(7) The commissioner shall assist the Office of ~~[Health]~~Data ~~[and]~~Analytics in carrying out**:**

(a) Subtitle 17B of this chapter**;**~~[and]~~

(b) KRS 194A.099***; and***

(c) Sections 1 to 6 of this Act.

➔Section 8. By September 1, 2024, the Kentucky Prescription Drug Affordability Board established under Section 2 of this Act shall submit the following to the Legislative Research Commission, for referral to the Interim Joint Committees on Health Services and Banking and Insurance:

(1) A report on the legality, obstacles, and benefits of setting upper payment limits on purchases and payor reimbursements of prescription drugs in this state;

(2) Recommendations regarding whether the General Assembly should pass legislation to expand the authority of the board to set upper payment limits for purchases

and payor reimbursements of prescription drug in this state; and

(3) A plan for establishing upper payment limits on purchases and payor reimbursements of prescription drugs that are subject to an affordability review under Section 5 of this Act, which shall include:

(a) A methodology for establishing upper payment limits;

(b) An analysis of:

1. The resources needed by the board to implement the plan;

2. How an upper payment limit would be enforced;

3. How an upper payment limit could be implemented with respect to:

a. Prescription drug benefits provided under KRS 18A.225, KRS 18A.2254, and Chapter 205;

b. Health insurance policies, certificates, plans, and contracts; and

c. To the extent permitted by federal law, other forms of insurance that provide prescription drug benefits;

4. Any potential savings or costs associated with implementing the plan with respect to:

a. The state;

b. Insurers;

c. Hospitals; and

d. Consumers.

➔Section 9. (1) The initial appointments to the Kentucky Prescription Drug Affordability Board established under Section 2 of this Act, shall be made within 180 days of the effective date of this Act.

(2) Notwithstanding subsection (2)(c)1. of Section 2 of this Act, the initial appointments to the Kentucky Prescription Drug Affordability Board established in Section 2 of this Act shall be staggered as follows:

(a) Three appointments shall be for a term of two years;

(b) Three appointments shall be for a term of three years; and

(c) Three appointments shall be for a term of four years.

(3) The first meeting of the board shall take place within 30 days of the appointment of all members.