AN ACT relating to insulin assistance 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 315 IS CREATED TO READ AS FOLLOWS:

For the purposes of Sections 1 to 7 of this Act, unless the context otherwise requires:

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

(2) "Program" means the insulin assistance program established in Section 2 of this Act;

(3) "Qualified individual" means an individual who:

(a) Does not have health coverage through the state medical assistance program established in KRS Chapter 205 or a health plan as defined in KRS 304.17A-005; and

(b) Submits a completed statement of financial need form to the board pursuant to Section 3 of this Act; and

(4) "Qualified insulin product" means any prescription product containing insulin for which the board determines the wholesale acquisition cost of the drug, or other relevant measure of drug cost, exceeds the national average for comparable prescription products containing insulin.

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

(1) The board shall implement an insulin assistance program by January 1, 2021. Under the program, the board shall:

(a) To the extent that moneys are available in the insulin assistance fund established in Section 7 of this Act, reimburse participating pharmacies for insulin products and related supplies that are dispensed by the pharmacy to qualified individuals subject to a valid prescription;

(b) Accept statements of financial need, in a form prescribed by the board, from

persons seeking to participate in the program as qualified individuals and maintain a list of qualified individuals on the board's Web site; and

(c) Seek the participation in the program by pharmacies in all areas of the state and maintain a list of participating pharmacies on the board's Web site.

(2) The board shall develop a statement of financial need form and make the form available to individuals and health care professionals on the board's Web site. The form shall:

(a) State that the individual signing the form requires insulin products and related supplies to avoid serious health complications;

(b) State that the individual signing the form has attested, to the physician or other health care professional providing a prescription for insulin products and related supplies, that the individual lacks the financial means to pay for insulin products and related supplies and does not have health coverage through the state medical assistance program established in KRS Chapter 205 or a health plan as defined in KRS 304.17A-005; and

(c) Provide for the signature of both the individual and the physician or other health care professional providing a prescription for insulin products and related supplies.

(3) The board shall promulgate administrative regulations necessary to carry out the provisions of Sections 1 to 7 of this Act.

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

(1) An individual wishing to participate in the insulin assistance program established in Section 2 of this Act shall:

(a) Submit a completed statement of financial need form established by the board pursuant to subsection (2) of Section 2 of this Act. A completed copy of the form shall be signed by the individual and the physician or other

health care provider providing a prescription for insulin products and related supplies; and

(b) Provide a paper or electronic copy of the statement of financial need form to a participating pharmacy when initially filing the prescription.

(2) (a) An individual who has submitted a completed statement of financial need form pursuant to subsection (1) of this section shall be eligible for the program for ninety (90) days beginning on the date on which the form is completed and signed.

(b) An individual may extend or renew his or her eligibility and participation in the program for an additional ninety (90) day period by submitting a new statement of financial need to the board and a participating pharmacy.

(c) There shall be no limit to the number of times an individual may extend his or her eligibility and participation in the program if the individual continues to lack the financial means to pay for insulin products and related supplies and does not have health coverage through the state medical assistance program established in KRS Chapter 205 or a health plan as defined in KRS 304.17A-005.

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

(1) Pharmacy participation in the insulin assistance program established in Section 2 of this Act shall be voluntary.

(2) A pharmacy wishing to participate in the program shall register with the board in a manner prescribed by the board and shall agree to the reimbursement terms established by the board.

(3) (a) A participating pharmacy shall dispense insulin products and related supplies to a qualified individual who presents a valid prescription and who is either on the list of qualified individuals maintained by the board or,

when initially filling a prescription, provides a paper or electronic copy of a completed statement of financial need form signed by the individual and the physician or other health care provider providing a prescription for insulin products and related supplies within the previous ninety (90) days.

(b) When dispensing insulin products and related supplies to a qualified individual, a participating pharmacy shall:

1. Dispense the insulin products and related supplies at no cost to the qualified individual;

2. Provide the qualified individual with information about any relevant drug manufacturer patient discount programs; and

3. Provide the qualified individual with information about applying for the state medical assistance program.

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

A manufacturer who has obtained a permit from the board pursuant to Section 8 of this Act and that holds a Food and Drug Administration approved New Drug Application or approved Abbreviated New Drug Application for any qualified insulin product or a wholesale distributor licensed under Section 9 of this Act who delivers or distributes any qualified insulin product shall pay an insulin product fee as specified in this section.

(1) (a) Beginning on January 1, 2021, and at least quarterly thereafter, the board shall use the data submitted pursuant to Section 6 of this Act to identify qualified insulin products and prepare invoices for each manufacturer and wholesale distributor that is required to pay an insulin product fee for a qualified insulin product.

(b) The invoice for each quarter shall be prepared and sent to manufacturers and wholesale distributors no later than thirty (30) days after the end of

each quarter, except that the first invoice shall be for the last three (3) quarters of calendar year 2020.

(c) Manufacturers and wholesale distributors shall be required to remit payment to the board no later than thirty (30) days after the date of the invoice. If a manufacturer or wholesale distributor fails to remit payment by that date, the board shall charge interest at the rate that manufacturers are charged interest for making late Medicaid rebate payments.

(d) 1. A manufacturer or wholesale distributor may dispute the amount invoiced by the board no later than thirty (30) days after the date of the invoice. However, the manufacturer or wholesale distributor shall still be required to remit payment for the amount invoiced as required by this section. The dispute shall be filed with the board in a manner prescribed by the board and shall be accompanied by data satisfactory to the board that demonstrates that the original amount invoiced was incorrect. The board shall make a decision concerning a dispute not later than sixty (60) days after the manufacturer or wholesale distributor initially files the dispute.

2. If the board determines that the manufacturer or wholesale distributor has satisfactorily demonstrated that the original fee invoiced by the board was incorrect, the board shall apply any excess amount paid by the manufacturer or wholesale distributor toward the insulin product fee invoiced to the manufacturer or wholesale distributor for the next quarter.

3. If the board determines that the manufacturer or wholesale distributor has not satisfactorily demonstrated that the original fee invoiced by the board was incorrect, the manufacturer or wholesale distributor may, within thirty (30) days of the board's decision, file a written

request for an administrative hearing on the invoice. The hearing shall be conducted in compliance with KRS Chapter 13B.

(2) The board shall calculate the fee that is to be paid by a manufacturer or wholesale distributor using a base rate for all qualified insulin products, equal to one dollar and fifty cents ($1.50) per unit, as defined by the board, distributed or dispensed.

(3) The board may work with the Department of Revenue to collect any fees owed under this section or Section 6 of this Act if the board determines that this collaboration is necessary.

(4) All fees collected under this section shall be deposited into the insulin assistance fund established in Section 7 of this Act.

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

(1) Beginning on December 1, 2020, a manufacturer who has obtained a permit from the board pursuant to Section 8 of this Act or a wholesale distributor licensed under Section 9 of this Act shall provide the board, in a manner prescribed by the board, with the following information about each of its products that contains insulin and that is sold within the state:

(a) The trade and generic name of the product;

(b) The strength of the product;

(c) The package size in which the product is sold;

(d) The wholesale acquisition cost of the product; and

(e) The National Drug Code for the product;

A manufacturer or wholesale distributor shall notify the board of any change to this data no later than thirty (30) days after the change is made. The board may require a manufacturer or wholesale distributor to confirm the accuracy of the data on a quarterly basis. If a manufacturer or wholesale distributor fails to

provide information required by this subsection on a timely basis, as defined by the board, the board may assess an administrative penalty of one hundred dollars ($100) per day. This penalty shall not be considered a form of disciplinary action.

(2) Beginning on December 1, 2020, and on a monthly basis thereafter, a manufacturer who has obtained a permit from the board pursuant to Section 8 of this Act or a wholesale distributor licensed under Section 9 of this Act shall report to the board every sale, delivery, or other distribution within or into the state of any prescription product containing insulin that is made to any practitioner, pharmacy, or hospital. Reporting shall be made in a manner prescribed by the board and shall occur by the fifteenth day of each calendar month for all sales, deliveries, and other distributions that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2020. If a manufacturer or wholesale distributor fails to provide the information required by this subsection on a timely basis, as defined by the board, the board may assess an administrative penalty of one hundred dollars ($100) per day. This penalty shall not be considered a form of disciplinary action.

(3) Beginning on December 1, 2020, and on a monthly basis thereafter, an out-of-state pharmacy that has obtained a permit from the board pursuant to KRS 315.0351 shall report the dispensing of any prescription product containing insulin to patients located within the state. Reporting shall be made in a manner prescribed by the board and shall occur by the fifteenth day of each calendar month for dispensing that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2020. If an out-of-state pharmacy fails to provide the information required by this subsection on a timely basis, as defined by the board, the board may assess an administrative penalty of one hundred dollars ($100) per day. This penalty shall

not be considered a form of disciplinary action.

(4) Beginning on December 1, 2020, and on a monthly basis thereafter, a pharmacy that has obtained a permit from the board pursuant to KRS 315.035 shall report the intracompany delivery or distribution, into the state, of any prescription product containing insulin, to the extent that those deliveries and distributions are not reported by a wholesale distributor owned by, under contract to, or otherwise operating on behalf of the pharmacy. Reporting shall be made in a manner prescribed by the board and shall occur by the fifteenth day of each calendar month for deliveries and distributions that occurred during the previous calendar month, except that the first report submitted to the board shall include data retroactive to July 1, 2020. If a pharmacy fails to provide the information required by this subsection on a timely basis, as defined by the board, the board may assess an administrative penalty of one hundred dollars ($100) per day. This penalty shall not be considered a form of disciplinary action.

(5) All fees collected under this section shall be deposited into the insulin assistance fund established in Section 7 of this Act.

➔SECTION 7. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

(1) The insulin assistance fund is hereby created within the State Treasury. The fund shall consist of moneys collected pursuant to Sections 5 and 6 of this Act.

(2) Moneys transferred to the fund are hereby appropriated for the purpose of administering the insulin assistance program as established in Section 2 of this Act.

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

(4) Any interest earnings of the fund shall become part of the fund and shall not lapse.

➔Section 8. KRS 315.036 is amended to read as follows:

(1) Except as provided in subsection (4) of this section, each manufacturer of drugs shall be required to register with and obtain a permit from the board. Such permit shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars ($250) annually or increase more than twenty-five dollars ($25) per year.

(2) Manufacturers shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that manufacturers periodically report to the board all drugs manufactured, received, and sold.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice, compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order.

(5) The board shall not renew a permit for a manufacturer unless the manufacturer has paid the insulin product fee as required by Section 5 of this Act.

➔Section 9. KRS 315.195 is amended to read as follows:

(1) All license, permit, and certificate fees, charges, fines, and other moneys collected by the board under the provisions of this chapter, and the administrative regulations of the board, ***except for moneys collected pursuant to Sections 1 to 7 of this Act,*** shall be deposited into the State Treasury and credited to a trust and agency fund to be used by the board in carrying out the provisions of this chapter, and are hereby appropriated for those purposes.

(2) Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the

fiscal year shall not lapse but shall be carried forward into the succeeding fiscal year.

➔Section 10. KRS 315.402 is amended to read as follows:

(1) A wholesale distributor shall be licensed by the board under this section prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred fifty dollars ($250) annually or increase more than twenty-five dollars ($25) per year.

(2) A wholesale distributor shall be required to maintain accurate records of all drugs handled in accordance with KRS 315.400 to 315.412, and records shall be made available to agents of the board for inspection upon request.

(3) Licensing requirements that exceed the requirements of federal law shall not apply to a manufacturer distributing its own FDA-approved drugs or co-licensed products, unless there is reasonable cause to believe that the manufacturer presents a special risk of distributing counterfeit prescription drugs in the Commonwealth.

(4) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(5) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure in conformity with the guidelines for state licensure of a wholesale prescription drug distributor issued by the FDA.

(6) Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.

(7) The board shall not renew a license for a wholesale distributor unless the wholesale distributor has paid the insulin product fee as required by Section 5 of this Act.