

1 AN ACT relating to insulin assistance and making an appropriation therefor.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7 The form shall:

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

10 (b) State that the individual signing the form has attested, to the physician or
11 other health care professional providing a prescription for insulin products
12 and related supplies, that the individual lacks the financial means to pay for
13 insulin products and related supplies and does not have health coverage
14 through the state medical assistance program established in KRS Chapter
15 205 or a health plan as defined in KRS 304.17A-005; and

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

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

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

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

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

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

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

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

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

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

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

20 (1) Pharmacy participation in the insulin assistance program established in Section
21 2 of this Act shall be voluntary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20 (b) The strength of the product;

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

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

23 (e) The National Drug Code for the product;

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

- 1 provide information required by this subsection on a timely basis, as defined by
2 the board, the board may assess an administrative penalty of one hundred dollars
3 (\$100) per day. This penalty shall not be considered a form of disciplinary action.
- 4 (2) Beginning on December 1, 2020, and on a monthly basis thereafter, a
5 manufacturer who has obtained a permit from the board pursuant to Section 8 of
6 this Act or a wholesale distributor licensed under Section 9 of this Act shall
7 report to the board every sale, delivery, or other distribution within or into the
8 state of any prescription product containing insulin that is made to any
9 practitioner, pharmacy, or hospital. Reporting shall be made in a manner
10 prescribed by the board and shall occur by the fifteenth day of each calendar
11 month for all sales, deliveries, and other distributions that occurred during the
12 previous calendar month, except that the first report submitted to the board shall
13 include data retroactive to July 1, 2020. If a manufacturer or wholesale
14 distributor fails to provide the information required by this subsection on a timely
15 basis, as defined by the board, the board may assess an administrative penalty of
16 one hundred dollars (\$100) per day. This penalty shall not be considered a form
17 of disciplinary action.
- 18 (3) Beginning on December 1, 2020, and on a monthly basis thereafter, an out-of-
19 state pharmacy that has obtained a permit from the board pursuant to KRS
20 315.0351 shall report the dispensing of any prescription product containing
21 insulin to patients located within the state. Reporting shall be made in a manner
22 prescribed by the board and shall occur by the fifteenth day of each calendar
23 month for dispensing that occurred during the previous calendar month, except
24 that the first report submitted to the board shall include data retroactive to July 1,
25 2020. If an out-of-state pharmacy fails to provide the information required by this
26 subsection on a timely basis, as defined by the board, the board may assess an
27 administrative penalty of one hundred dollars (\$100) per day. This penalty shall

1 not be considered a form of disciplinary action.

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

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

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

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

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

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

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

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

- 2 (1) Except as provided in subsection (4) of this section, each manufacturer of drugs
3 shall be required to register with and obtain a permit from the board. Such permit
4 shall be issued in accordance with policy and procedure prescribed by regulations of
5 the board. Each application shall be accompanied by a reasonable permit fee to be
6 set by administrative regulation of the board, not to exceed two hundred fifty dollars
7 (\$250) annually or increase more than twenty-five dollars (\$25) per year.
- 8 (2) Manufacturers shall be required to maintain accurate records of all drugs
9 manufactured, received and sold, as established by administrative regulation of the
10 board. Such records shall be made available to agents of the board for inspection at
11 reasonable times. The board may require by regulation that manufacturers
12 periodically report to the board all drugs manufactured, received, and sold.
- 13 (3) Failure to report to the board or willful submission of inaccurate information shall
14 be grounds for disciplinary action under the provisions of KRS 315.131.
- 15 (4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in
16 the normal course of professional practice, compounds reasonable quantities of
17 drugs pursuant to or in anticipation of a valid prescription drug order.
- 18 **(5) The board shall not renew a permit for a manufacturer unless the manufacturer**
19 **has paid the insulin product fee as required by Section 5 of this Act.**

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

- 21 (1) All license, permit, and certificate fees, charges, fines, and other moneys collected
22 by the board under the provisions of this chapter, and the administrative regulations
23 of the board, **except for moneys collected pursuant to Sections 1 to 7 of this Act,**
24 shall be deposited into the State Treasury and credited to a trust and agency fund to
25 be used by the board in carrying out the provisions of this chapter, and are hereby
26 appropriated for those purposes.
- 27 (2) Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the

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

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

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

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

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

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

18 (5) The board shall promulgate an administrative regulation pursuant to KRS Chapter
19 13A to specify the criteria for licensure in conformity with the guidelines for state
20 licensure of a wholesale prescription drug distributor issued by the FDA.

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

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