

1 AN ACT relating to the establishment of emergency insulin programs and declaring
2 an emergency.

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

4 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
5 READ AS FOLLOWS:

6 *For the purposes of this Act, unless context otherwise requires:*

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

8 *(2) "Cost sharing" means the same as in KRS 304.17A-164;*

9 *(3) "Manufacturer":*

10 *(a) Means an entity engaged in the manufacturing of insulin that is self-*
11 *administered on an outpatient basis and that is made available for sale or*
12 *distribution in the state; and*

13 *(b) Shall not include a manufacturer with annual gross revenue of two million*
14 *dollars (\$2,000,000) or less from insulin sales in the state;*

15 *(4) "Pharmacist" means the same as in KRS 315.010;*

16 *(5) "Pharmacy" means the same as in KRS 315.010;*

17 *(6) "Urgent need of insulin" means having readily available for use less than a*
18 *seven (7) day supply of insulin and in need of insulin in order to avoid the*
19 *likelihood of negative health consequences; and*

20 *(7) "Urgent-need supply of insulin" means a thirty (30) day supply of an insulin*
21 *product as prescribed by a health care provider.*

22 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
23 READ AS FOLLOWS:

24 *(1) The urgent-need insulin program and the continuing access to insulin program*
25 *are hereby established. The urgent-need insulin program shall ensure affordable*
26 *access to insulin to eligible individuals who are in urgent need of insulin. The*
27 *continuing access to insulin program shall ensure affordable access to insulin to*

1 eligible individuals who have an ongoing need for access to insulin. Both
2 programs shall be administered and overseen by the Kentucky Board of
3 Pharmacy.

4 (2) (a) In order to be eligible to receive insulin under the urgent-need insulin
5 program, an individual shall:

6 1. Be a resident of Kentucky;

7 2. Not be enrolled in the state's medical assistance program or children's
8 health insurance program as established in KRS Chapter 205;

9 3. Not be enrolled in or entitled to any prescription drug coverage that
10 limits the total amount of cost-sharing that the enrollee is required to
11 pay for a thirty (30) day supply of insulin to seventy-five dollars (\$75)
12 or less, regardless of the type or amount of insulin prescribed;

13 4. Not have received an urgent-need supply of insulin through the
14 program within the previous twelve (12) months, except as permitted
15 under paragraph (b) of this subsection; and

16 5. Be in urgent need of insulin.

17 (b) Notwithstanding paragraph (a)4. of this subsection, an individual may
18 receive an additional urgent-need supply of insulin during a twelve (12)
19 month period if:

20 1. a. The individual has applied for the state's medical assistance
21 program or children's health insurance program as established
22 in KRS Chapter 205 but has not been determined eligible or has
23 been determined eligible but coverage has not become effective;
24 or

25 b. The individual has been determined ineligible for a
26 manufacturer's patient assistance program by the manufacturer
27 and the individual has requested a review pursuant to subsection

1 (4) of Section 4 of this Act but the panel has not rendered a
2 decision; and

3 2. The individual meets all other eligibility requirements established in
4 paragraph (a) of this subsection.

5 (3) (a) In order to be eligible for the continuing access to insulin program, an
6 individual shall:

7 1. Be a resident of Kentucky;

8 2. Have a family income that is equal to or less than four hundred (400)
9 percent of the federal poverty guidelines;

10 3. Not be enrolled in the state's medical assistance program or children's
11 health insurance program as established in KRS Chapter 205;

12 4. Not be eligible to receive health care through a federally funded
13 program or receive prescription drug benefits through the federal
14 Department of Veterans Affairs, except as permitted under paragraph
15 (b) of this subsection; and

16 5. Not be enrolled in or entitled to any prescription drug coverage that
17 limits the total amount of cost-sharing that the enrollee is required to
18 pay for a thirty (30) day supply of insulin to seventy-five dollars (\$75)
19 or less, regardless of the type or amount of insulin prescribed.

20 (b) Notwithstanding paragraph (a)4. of this subsection, an individual who is
21 enrolled in Medicare Part D shall be eligible for the continuing access to
22 insulin program if the individual has spent one thousand dollars (\$1,000)
23 on prescription drugs in the current calendar year and meets the other
24 eligibility requirements established in paragraph (a) of this subsection.

25 (4) By July 1, 2021, each manufacturer shall establish procedures to make insulin
26 available in accordance with Sections 1 to 8 of this Act to eligible individuals who
27 are in urgent need of insulin or who are in need of continuing access to an

1 affordable insulin supply.

2 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
3 READ AS FOLLOWS:

4 (1) An eligible individual seeking an urgent supply of insulin through the urgent-
5 need insulin program shall submit the following to a pharmacy:

6 (a) A completed, signed, and dated application form developed by the board
7 pursuant to Section 5 of this Act;

8 (b) A valid insulin prescription; and

9 (c) Proof of residency, or if the person in urgent need of insulin is under
10 eighteen (18) years of age, the individual's parent or legal guardian shall
11 provide proof of residency. Proof of residency shall include but not be
12 limited to a valid Kentucky identification card, driver's license, or driver's
13 permit, a utility agreement or bill, a rental housing agreement, or a signed
14 letter from a homeless shelter, health care facility, or social service agency
15 that is currently providing the individual with treatment or services attesting
16 that the applicant is a resident of Kentucky.

17 (2) Upon receipt of the documents identified in subsection (1) of this section:

18 (a) The pharmacist or pharmacy shall:

19 1. Dispense to the individual the prescribed insulin in an amount that
20 will provide the individual with a thirty (30) day supply;

21 2. Within seventy-two (72) hours, notify the health care practitioner who
22 issued the prescription order that the insulin was dispensed under the
23 urgent-need insulin program;

24 3. Provide the individual with the information sheet developed by the
25 board pursuant to Section 5 of this Act; and

26 4. Retain a copy of the application form and proof of residency submitted
27 by the individual to the pharmacy for reporting and auditing purposes;

1 and

2 **(b) The pharmacist or pharmacy may:**

- 3 **1. Submit to the manufacturer of the dispensed insulin product or to the**
4 **manufacturer's vendor a claim for payment that is in accordance with**
5 **the National Council for Prescription Drug Program standards for**
6 **electronic claims processing, unless the manufacturer agrees to send**
7 **to the pharmacy a replacement supply of the same insulin product that**
8 **was dispensed in the amount that was dispensed. If the pharmacy**
9 **submits an electronic claim to the manufacturer or the**
10 **manufacturer's vendor, the manufacturer or vendor shall reimburse**
11 **the pharmacy in an amount that is equal to the pharmacy's**
12 **acquisition cost for the insulin product that was dispensed no later**
13 **than sixty (60) days after receipt of the claim; and**
- 14 **2. Collect an insulin copayment from the individual to whom the urgent**
15 **supply of insulin is dispensed to cover the pharmacy's cost of**
16 **processing and dispensing in an amount not to exceed twenty-five**
17 **dollars (\$25).**

18 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
19 READ AS FOLLOWS:

- 20 **(1) By July 1, 2021, each manufacturer shall establish a patient assistance program**
21 **which shall be made available to any individual who meets the eligibility**
22 **requirements for the continuing access to insulin program established in Section**
23 **2 of this Act. Each manufacturer's patient assistance program shall comply with**
24 **the requirements of this section, and each manufacturer shall provide the board**
25 **with information regarding its patient assistance program, including information**
26 **on the application process and contact information for individuals to call for**
27 **assistance in accessing or applying for the patient assistance program. Each**

1 manufacturer shall also make the information provided to the board publicly
2 available on its Web site.

3 (2) (a) Upon receipt of a patient assistance program application, the manufacturer
4 shall process the application, determine eligibility, and notify the applicant
5 of the determination within ten (10) business days of receipt of the
6 applicant. If necessary, the manufacturer may request additional
7 information from the application. If additional information is needed, the
8 manufacturer shall notify the applicant within five (5) business days of
9 receipt of the application as to what additional information is being
10 requested. Within three (3) business days of receipt of the requested
11 additional information, the manufacturer shall determine eligibility and
12 notify the applicant of the determination.

13 (b) If the individual is determined to be ineligible, the manufacturer shall
14 include reasons for denying eligibility in the notification. The individual
15 may seek an appeal of the determination in accordance with subsection (4)
16 of this section.

17 (c) Except as provided in paragraph (d) of this subsection, if the individual is
18 determined to be eligible, the manufacturer shall provide the individual with
19 an eligibility statement or other indication that the individual has been
20 determined eligible for the manufacturer's patient assistance program. An
21 individual's eligibility shall be valid for twelve (12) months and is renewable
22 upon a redetermination of eligibility.

23 (d) If an eligible individual has prescription drug coverage through an
24 individual or group health plan, the manufacturer may determine that the
25 individual's insulin needs are better addressed through the use of the
26 manufacturer's copayment assistance program, in which case, the
27 manufacturer shall inform the individual and provide the individual with

1 the necessary coupons to submit to a pharmacy. However, in no instance
2 shall an individual who is eligible for a manufacturer's patient assistance
3 program be required to pay more than the copayment amount specified in
4 subsection (3)(e) of this section.

5 (3) (a) An eligible individual seeking to obtain insulin through the continuing
6 access to insulin program shall submit to a pharmacy the statement of
7 eligibility provided by the manufacturer pursuant to subsection (2) of this
8 section.

9 (b) Upon receipt of an individual's eligibility statement, the pharmacy shall
10 submit an order containing the name of the insulin product and the daily
11 dosage amount as contained in a valid prescription to the product's
12 manufacturer. The order shall contain the following information:

13 1. The pharmacy's name and shipping address;

14 2. A telephone number, fax number, electronic mail address, and a
15 contact name; and

16 3. Any specific days or times when deliveries are not accepted by the
17 pharmacy.

18 (c) Upon receipt of an order from a pharmacy, the manufacturer shall send to
19 the pharmacy a ninety (90) day supply of insulin as ordered, unless a lesser
20 amount is requested in the order, at no charge to the individual or
21 pharmacy, or if the manufacturer provides a mail order service option, the
22 manufacturer may send the insulin as ordered directly to the individual.

23 (d) Upon receipt of the insulin from the manufacturer, the pharmacy shall,
24 except as provided in paragraph (e) of this subsection, provide the insulin to
25 the individual at no charge. The pharmacy shall not provide the insulin
26 received from the manufacturer to anyone other than they individual
27 associated with the specific order, and the pharmacy shall not seek

1 reimbursement for the insulin from the manufacturer or from any third-
2 party payer.

3 (e) The pharmacy may collect a copayment from the individual to cover the
4 pharmacy's costs in processing and dispensing in an amount not to exceed
5 fifty dollars (\$50) for each ninety (90) day supply if the insulin is delivered
6 to the pharmacy.

7 (f) The pharmacy may submit to a manufacturer a reorder for an individual if
8 the individual's eligibility statement has not expired. Upon receipt of a
9 reorder from a pharmacy, the manufacturer shall send to the pharmacy, or
10 directly to the individual, an additional ninety (90) day supply of the
11 product, unless a lesser amount is requested, at no charge to the individual
12 or pharmacy.

13 (4) If an individual disagrees with a manufacturer's determination of eligibility
14 under subsection (2) of this section, the individual may contact the board to
15 request the use of a three (3) person panel to review eligibility. The panel shall be
16 composed of three (3) members of the board. The individual requesting the review
17 shall submit to the board, with the request for a review, all documents submitted
18 by the individual to the manufacturer, and the board shall provide the panel with
19 the documents submitted by the individual. The panel shall render a decision
20 within ten (10) business days of receipt of all the necessary documents from the
21 individual. If the panel determines that the individual is eligible, the board shall
22 notify the manufacturer of its decision and request that the manufacturer provide
23 the individual with an eligibility statement within five (5) business days. The
24 decision of the panel shall be final.

25 ➔SECTION 5. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
26 READ AS FOLLOWS:

27 By July 1, 2021, the board shall:

- 1 (1) Develop an application form to be used by an individual who is in urgent need of
2 insulin which shall require the individual to attest to the eligibility requirements
3 for the urgent-need insulin program as establish in Section 2(2) of this Act;
- 4 (2) Develop an information sheet on the urgent-need and the continuing access to
5 insulin programs. The information sheet shall contain the following:
- 6 (a) A description of the urgent-need insulin program, including how to access
7 the program;
- 8 (b) A description of each manufacturer's patient assistance program and cost-
9 sharing assistance program, including contact information on accessing the
10 assistance programs for each manufacturer;
- 11 (c) Information on how to contact the board if a manufacturer determines that
12 an individual is not eligible for the manufacturer's patient assistance
13 program;
- 14 (d) Information on providers who participate in prescription drug discount
15 programs, including providers who are authorized to participate in the 340B
16 program under 42 U.S.C. sec. 256b;
- 17 (e) Information on accessing prescription drug copayment assistance
18 programs; and
- 19 (f) A notification that an individual in need of assistance may contact their
20 local health department for more information or assistance in accessing
21 ongoing affordable insulin options;
- 22 (3) Make the application and information sheet developed pursuant to subsections
23 (1) and (2) of this section accessible on the its Web site and shall make them
24 available to health care providers, pharmacists, and pharmacies that prescribe or
25 dispense insulin, hospital emergency departments, urgent care clinics,
26 community health clinics, and local health departments;
- 27 (4) Regularly update the information sheet developed pursuant to subsection (2) of

1 this section; and

2 (5) Promulgate and implement administrative regulations necessary to carry out
3 Sections 1 to 8 of this Act.

4 ➔SECTION 6. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
5 READ AS FOLLOWS:

6 A manufacturer shall maintain the privacy of all data received from any individual
7 applying for the manufacturer's patient assistance program and is prohibited from
8 selling, sharing, or disseminating data received under Sections 2, 3, and 4 of this Act.

9 ➔SECTION 7. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
10 READ AS FOLLOWS:

11 (1) By July 15, 2022, and annually thereafter, each manufacturer shall submit a
12 report to the board containing the following information for the preceding
13 calendar year:

14 (a) The number of Kentucky residents who accessed and received an insulin
15 product produced by the manufacturer through the urgent-need insulin
16 program;

17 (b) The number of Kentucky residents who applied for the manufacturer's
18 patient assistance program and the number of applicants who were
19 determined by the manufacturer to be eligible and ineligible;

20 (c) The number of Kentucky residents who were determined to be eligible for
21 the manufacturer's patient assistance program by the board pursuant to
22 Section 4(4) of this Act; and

23 (d) The value of the insulin provided to residents of Kentucky by the
24 manufacturer under the urgent-need insulin program and the continuing
25 access to insulin program. As used in this paragraph "value" means the
26 wholesale acquisition cost of the insulin provided.

27 (2) Upon receipt of a request from the Legislative Research Commission, the Interim

1 Joint Committee on Health, Welfare, and Family Services, or any other
2 committee of the Kentucky General Assembly, the board shall submit a report
3 containing the following information:

4 (a) The information reported under subsection (1) of this section; and

5 (b) Any administrative penalties assessed pursuant to Section 8 of this Act,
6 including the name of the manufacturer and the amount of the penalty
7 assessed.

8 ➔SECTION 8. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO
9 READ AS FOLLOWS:

10 If a manufacturer fails to comply with Sections 1 to 7 of this Act, the board may assess
11 an administrative penalty of not more than two hundred thousand dollars (\$200,000)
12 per month of noncompliance, with the penalty increasing to not more than four
13 hundred thousand dollars (\$400,000) per month if the manufacturer continues to be in
14 noncompliance for more than six (6) months, and increasing to not more than six
15 hundred thousand dollars (\$600,000) per month if the manufacturer continues to be in
16 noncompliance after one (1) year.

17 ➔Section 9. Whereas there is urgent need to improve affordable access to insulin
18 for the roughly 500,000 Kentuckians diagnosed with diabetes, an emergency is declared
19 to exist, and this Act takes effect upon its passage and approval by the Governor or upon
20 its otherwise becoming a law.