

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

7 *(1) "Cabinet" means the Cabinet for Health and Family Services;*

8 *(2) "Consumer price index" means the Consumer Price Index for All Urban*
9 *Consumers, U.S. City Average, All Items, as published by the United States*
10 *Bureau of Labor Statistics;*

11 *(3) "Manufacturer":*

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

15 *(b) Does not include a manufacturer with annual gross revenue of less than*
16 *two million dollars (\$2,000,000) from insulin sales in the state;*

17 *(4) "Pharmacist" has the same meaning as in KRS 315.010;*

18 *(5) "Pharmacy" has the same meaning as in KRS 315.010;*

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

22 *(7) "Urgent-need supply of insulin" means a thirty (30) day supply of an insulin*
23 *product as prescribed by a health care provider; and*

24 *(8) "Wholesale acquisition cost":*

25 *(a) Means a manufacturer's list price for insulin to wholesalers or direct*
26 *purchases in the United States for the most recent month for which the*
27 *information is reported in wholesale price guides or other publication of*

1 drug or biological pricing data; and
 2 (b) Does not include prompt pay or other discounts, rebates, or any other
 3 reduction in price.

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

6 (1) The Urgent-Need Insulin Program and the Continuing Access to Insulin
 7 Program are hereby established. The Urgent-Need Insulin Program shall ensure
 8 affordable access to insulin to eligible individuals who are in urgent need of
 9 insulin, and the Continuing Access to Insulin Program shall ensure affordable
 10 access to insulin to eligible individuals who have an ongoing need for access to
 11 insulin. Both programs shall be administered and overseen by the Cabinet for
 12 Health and Family Services.

13 (2) (a) In order to be eligible to obtain insulin under the Urgent-Need Insulin
 14 Program, an individual shall:

- 15 1. Be a resident of Kentucky;
- 16 2. Not be enrolled in the state's Medical Assistance Program or the
 17 Kentucky Children's Health Insurance Program as established in
 18 KRS Chapter 205;
- 19 3. Not be enrolled in a health benefit plan that limits cost sharing for
 20 prescription insulin drugs pursuant to KRS 304.17A-148(3)(b), except
 21 as permitted under paragraph (b) of this subsection;
- 22 4. Not have received an urgent-need supply of insulin through the
 23 program within the previous twelve (12) months, except as permitted
 24 under paragraph (c) of this subsection; and
- 25 5. Be in urgent need of insulin.

26 (b) Notwithstanding paragraph (a)3. of this subsection, an individual who is
 27 enrolled in a health benefit plan that limits cost sharing for prescription

1 insulin drugs pursuant to KRS 304.17A-148(3)(b) shall be eligible to receive
2 insulin under the Urgent-Need Insulin Program if the health benefit plan in
3 which the individual is enrolled does not provide coverage for the specific
4 prescription insulin drug prescribed to the individual by his or her health
5 care provider and the individual meets all other eligibility requirements
6 established in paragraph (a) of this subsection.

7 (c) Notwithstanding paragraph (a)4. of this subsection, an individual may
8 receive an additional urgent-need supply of insulin during a twelve (12)
9 month period if the individual has applied for the state's Medical Assistance
10 Program or the Kentucky Children's Health Insurance Program as
11 established in KRS Chapter 205 but has not been determined eligible or has
12 been determined eligible but coverage has not become effective and the
13 individual meets all other eligibility requirements established in paragraph
14 (a) of this subsection.

15 (3) (a) In order to be eligible to obtain insulin under the Continuing Access to
16 Insulin Program, an individual shall:

- 17 1. Be a resident of Kentucky;
- 18 2. Not be enrolled in the state's Medical Assistance Program or the
19 Kentucky Children's Health Insurance Program as established in
20 KRS Chapter 205;
- 21 3. Not be eligible to receive health care through a federally funded
22 program or receive prescription drug benefits through the federal
23 Department of Veterans Affairs, except as permitted under paragraph
24 (c) of this subsection; and
- 25 4. Not be enrolled in a health benefit plan that limits cost sharing for
26 prescription insulin drugs pursuant to KRS 304.17A-148(3)(b), except
27 as permitted under paragraph (d) of this subsection.

1 **(b) An individual who is eligible to obtain prescription insulin under the**
2 **Continuing Access to Insulin Program may obtain insulin under that**
3 **program for up to twelve (12) months.**

4 **(c) Notwithstanding paragraph (a)3. of this subsection, an individual who is**
5 **enrolled in Medicare Part D shall be eligible for the Continuing Access to**
6 **Insulin Program if the individual has spent one thousand dollars (\$1,000)**
7 **on prescription drugs in the current calendar year and meets all other**
8 **eligibility requirements established in paragraph (a) of this subsection.**

9 **(d) Notwithstanding paragraph (a)4. of this subsection, an individual who is**
10 **enrolled in a health benefit plan that limits cost sharing for prescription**
11 **insulin drugs pursuant to KRS 304.17A-148(3)(b) shall be eligible for the**
12 **Continuing Access to Insulin Program if the health benefit plan in which**
13 **the individual is enrolled does not provide coverage for the specific**
14 **prescription insulin drug prescribed to the individual by his or her health**
15 **care provider and the individual meets the other eligibility requirements**
16 **established in paragraph (a) of this subsection.**

17 **(4) Notwithstanding any provision of law to the contrary, an individual who is**
18 **enrolled in or covered by a health plan or health insurance policy that provides**
19 **prescription drug benefits that is not subject to the cost-sharing limits established**
20 **in KRS 304.17A-148(3)(b) shall be eligible for:**

21 **(a) The Urgent-Need Insulin Program if he or she:**

22 **1. Is a resident of Kentucky;**

23 **2. Is not enrolled in the state's Medical Assistance Program or the**
24 **Kentucky Children's Health Insurance Program as established in**
25 **KRS Chapter 205; and**

26 **3. Has not received an urgent-need supply of insulin through the**
27 **program within the previous twelve (12) months, except as permitted**

- 1 under subsection (2)(c) of this section; or
- 2 **(b) The Continuing Access to Insulin Program if he or she is:**
- 3 **1. A resident of Kentucky;**
- 4 **2. Not enrolled in the state's Medical Assistance Program or the**
- 5 **Kentucky Children's Health Insurance Program as established in**
- 6 **KRS Chapter 205; and**
- 7 **3. Not eligible to receive health care through a federally funded program**
- 8 **or receive prescription drug benefits through the federal Department**
- 9 **of Veterans Affairs, except as permitted under subsection (3)(d) of this**
- 10 **section.**

11 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO

12 READ AS FOLLOWS:

- 13 **(1) By July 1, 2022, the cabinet shall:**
- 14 **(a) Develop application forms to be used by an individual who is seeking to**
- 15 **obtain insulin under either the Urgent-Need Insulin Program or the**
- 16 **Continuing Access to Insulin Program. The application forms shall require**
- 17 **the individual to show proof that he or she meets the eligibility requirements**
- 18 **for the program under which he or she is seeking to obtain insulin as**
- 19 **established in Section 2 of this Act;**
- 20 **(b) Develop an information sheet on the Urgent-Need Insulin Program and the**
- 21 **Continuing Access to Insulin Program. The information sheet shall**
- 22 **contain:**
- 23 **1. A description of the Urgent-Need Insulin Program, including**
- 24 **eligibility requirements and information on how to access the**
- 25 **program;**
- 26 **2. A description of the Continuing Access to Insulin Program, including**
- 27 **eligibility requirements and information on how to access the**

- 1 program;
- 2 3. Information on providers who participate in prescription drug
- 3 discount programs, including providers who are authorized to
- 4 participate in the 340B program under 42 U.S.C. sec. 256b;
- 5 4. Information about each manufacturer's consumer insulin programs;
- 6 5. Information on accessing prescription drug copayment assistance
- 7 programs; and
- 8 6. A notification that an individual in need of assistance may contact his
- 9 or her local health department for more information or assistance in
- 10 accessing ongoing affordable insulin options;
- 11 (c) Make the application forms and information sheet developed pursuant to
- 12 paragraphs (a) and (b) of this subsection accessible on its Web site and
- 13 make them available to the Department of Insurance, the Board of
- 14 Pharmacy, health care providers, pharmacists, and pharmacies that
- 15 prescribe or dispense insulin, hospital emergency departments, urgent care
- 16 clinics, community health clinics, and local health departments;
- 17 (d) Regularly update the information sheet developed pursuant to paragraph
- 18 (b) of this subsection; and
- 19 (e) Promulgate and implement administrative regulations, in accordance with
- 20 KRS Chapter 13A, necessary to carry out Sections 1 to 7 of this Act.
- 21 (2) The Department of Insurance and the Board of Pharmacy shall make the
- 22 application forms and information sheet made available to them by the cabinet
- 23 accessible on their Web sites.

24 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 211 IS CREATED TO

25 READ AS FOLLOWS:

- 26 (1) An eligible individual seeking to obtain prescription insulin under either the
- 27 Urgent-Need Insulin Program or the Continuing Access to Insulin Program shall

1 submit the following to a pharmacy:

2 (a) A completed, signed, and dated application form developed by the cabinet
3 pursuant to Section 3 of this Act;

4 (b) A valid insulin prescription; and

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

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

15 (a) The pharmacist or pharmacy shall:

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

18 2. Within seventy-two (72) hours, notify the health care practitioner who
19 issued the prescription order that the insulin was dispensed under the
20 Urgent-Need Insulin Program or the Continuing Access to Insulin
21 Program;

22 3. Provide the individual with the information sheet developed by the
23 cabinet pursuant to Section 3 of this Act; and

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

26 (b) The pharmacist and pharmacy are encouraged to:

27 1. Inform the individual that he or she may be eligible for the state's

1 medical assistance program or Children's Health Insurance Program
2 as established in KRS Chapter 205 or an affordable insurance product
3 on the state-based marketplace; and

4 2. Notify the individual of any known manufacturer-sponsored programs
5 that assist individuals who cannot afford their insulin prescriptions;
6 and

7 (c) The pharmacist or pharmacy may:

8 1. Collect from the individual to whom the prescription insulin is
9 dispensed a copayment in an amount not to exceed twenty-five dollars
10 (\$25) to cover the pharmacy's cost of processing and dispensing; and

11 2. Except as provided in subsection (4) of this section, submit to the
12 manufacturer of the dispensed prescription insulin product or to the
13 manufacturer's vendor an electronic claim for payment that is in
14 accordance with the National Council for Prescription Drug
15 Programs standards for electronic claims processing, unless the
16 manufacturer agrees to send to the pharmacy a replacement supply of
17 the same insulin product that was dispensed in the amount that was
18 dispensed.

19 (3) If a pharmacist or pharmacy submits an electronic claim for payment to the
20 manufacturer or the manufacturer's vendor, the manufacturer or vendor shall,
21 within thirty (30) days after receipt of the claim, either:

22 (a) Reimburse the pharmacy in an amount that is equal to the difference
23 between the pharmacy's wholesale acquisition cost for the insulin product
24 that was dispensed and any amount paid for the insulin pursuant to
25 subsection (2)(c)1. of this section; or

26 (b) Send the pharmacy a replacement supply of the same insulin in an amount
27 equal to or greater than the amount that covers the difference between the

1 pharmacy's wholesale acquisition cost for the insulin product that was
2 dispensed and any amount paid for the insulin pursuant to subsection
3 (2)(c)1. of this section.

4 **(4) A pharmacy or pharmacist shall not submit a claim for payment for insulin**
5 dispensed under either the Urgent-Need Insulin Program or the Continuing
6 Access to Insulin Program if the wholesale acquisition cost of the dispensed
7 insulin is less than or equal to eight dollars (\$8) per milliliter, adjusted annually
8 based on the annual percent change in the consumer price index.

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

11 **By July 1, 2022, each manufacturer shall establish:**

12 **(1) A process for a pharmacist or pharmacy to submit an electronic claim for**
13 payment as provided in Section 4 of this Act; and

14 **(2) Any procedures necessary to make insulin available to eligible individuals in**
15 accordance with Sections 1 to 7 of this Act.

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

18 **(1) By July 15, 2023, and annually thereafter, each manufacturer shall submit a**
19 report to the cabinet containing the following information for the preceding
20 calendar year:

21 **(a) The number of Kentucky residents who accessed and received an insulin**
22 product produced by the manufacturer through either the Urgent-Need
23 Insulin Program or the Continuing Access to Insulin Program; and

24 **(b) The value of the insulin provided to residents of Kentucky by the**
25 manufacturer under the Urgent-Need Insulin Program and the Continuing
26 Access to Insulin Program. As used in this paragraph, "value" means the
27 wholesale acquisition cost of the insulin provided.

1 (2) Upon receipt of a request from the Legislative Research Commission, the Interim
 2 Joint Committee on Health, Welfare, and Family Services, or any other
 3 committee of the Kentucky General Assembly, the cabinet shall submit a report
 4 containing the following information:

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

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

9 (c) Any other information on the Urgent-Need Insulin Program and the
 10 Continuing Access to Insulin Program as requested.

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

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

20 ➔Section 8. Whereas there is urgent need to improve affordable access to insulin
 21 for the roughly 500,000 Kentuckians diagnosed with diabetes, an emergency is declared
 22 to exist, and this Act takes effect upon its passage and approval by the Governor or upon
 23 its otherwise becoming a law.