

1 AN ACT establishing the Kentucky Rare Disease Advisory Council and making an
2 appropriation therefor.

3 WHEREAS, a rare disease, sometimes called an orphan disease, is defined as a
4 disease that affects fewer than 200,000 people; and

5 WHEREAS, there are 7,000 known rare diseases affecting approximately 30 million
6 men, women, and children in the United States; and

7 WHEREAS, while the exact cause for many rare diseases remains unknown, 80
8 percent of rare diseases are genetic in origin and can be linked to mutations in a single
9 gene or in multiple genes which can be passed down from generation to generation; and

10 WHEREAS, challenges to a person who has a rare disease include delays in
11 obtaining a diagnosis, misdiagnosis, shortages of medical specialists who can provide
12 treatment, and lack of access to therapies and medication used to treat rare diseases but
13 not approved by the Federal Food and Drug Administration for that purpose; and

14 WHEREAS, researchers have made considerable progress in developing diagnostic
15 tools and treatment protocols and in discovering methods of prevention, but much more
16 remains to be accomplished in the search and development of new therapeutics; and

17 WHEREAS, an advisory council composed of qualified professionals and persons
18 living with rare diseases could educate medical professionals, government agencies, and
19 the public about rare diseases as an important public health issue and encourage and
20 secure funding for research for the development of new treatments for rare diseases;

21 NOW, THEREFORE,

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

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

25 ***(1) The Kentucky Rare Disease Advisory Council is established to advise the General***
26 ***Assembly and state departments, agencies, commissions, authorities, and private***
27 ***agencies that provide services for individuals diagnosed with a rare disease.***

- 1 (2) The Kentucky Rare Disease Advisory Council shall be composed of the following
2 members appointed by the Governor:
- 3 (a) Two (2) physicians licensed to practice in Kentucky who have expertise in
4 treating patients with rare diseases, one (1) of whom shall be a pediatrician;
- 5 (b) One (1) advanced practice registered nurse licensed to practice in Kentucky
6 who has expertise in providing care to patients with rare diseases;
- 7 (c) Two (2) representatives of hospitals in Kentucky;
- 8 (d) One (1) representative of the health care insurance industry in Kentucky;
- 9 (e) One (1) representative of the biopharmaceutical industry;
- 10 (f) One (1) representative of the scientific community who is engaged in rare
11 disease research;
- 12 (g) Two (2) parents whose child or children have been diagnosed with a rare
13 disease;
- 14 (h) Two (2) persons with a rare disease;
- 15 (i) Two (2) representatives of Kentucky patient advocacy organizations;
- 16 (j) The commissioner of the Department for Public Health; and
- 17 (k) Any additional at-large appointments that may be necessary to carry out the
18 council's duties and may be appointed on an ad hoc basis.
- 19 (3) After the initial appointments, members of the Kentucky Rare Disease Advisory
20 Council shall serve terms of four (4) years, beginning on the day of the
21 Governor's appointment. Members shall be eligible to succeed themselves and
22 shall serve until their successors are appointed.
- 23 (4) Members of the Kentucky Rare Disease Advisory Council shall not be paid for
24 their service as council members, and shall not be reimbursed for any expenses
25 involved in attending council meetings.
- 26 (5) The Kentucky Rare Disease Advisory Council shall elect a chair and a vice chair
27 from its members who shall serve in those capacities until replaced. A majority of

1 the council members shall constitute a quorum for the purposes of conducting
2 business. The council shall be subject to the provisions of the Kentucky Open
3 Records Act, KRS 61.870 to 61.884.

4 (6) The Kentucky Rare Disease Advisory Council shall meet at least three (3) times
5 annually, when any special-called meeting by the chair occurs, and at the request
6 of the secretary of the Cabinet for Health and Family Services. The council shall
7 receive assistance in carrying out its administrative functions from the Cabinet
8 for Health and Family Services and shall be attached to the Cabinet for Health
9 and Family Services for administrative purposes.

10 (7) Prior to the appointment of members to the council, the Cabinet for Health and
11 Family Services shall research and report to the General Assembly on existing
12 sources of funding that may be used to finance the formation and operation of
13 the council.

14 (8) After members are appointed to the council, the council shall apply for, and
15 accept, any grant of money from the federal government, private foundations, or
16 other sources that may be available for programs related to rare diseases.

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

19 The Kentucky Rare Disease Advisory Council shall:

20 (1) Research and determine the most appropriate methods to collect thorough and
21 complete information on rare diseases in Kentucky and other information as the
22 council deems necessary and appropriate to collect;

23 (2) Research and identify priorities relating to the quality, cost-effectiveness, and
24 access to treatment and services provided to persons with rare diseases and
25 develop related policy recommendations;

26 (3) Identify best practices for rare disease care from other states and at the national
27 level that may improve rare disease care in Kentucky;

1 (4) Develop effective strategies to raise public awareness of rare diseases in
2 Kentucky;

3 (5) Ensure that the duties of the council are carried out in a manner that is
4 coordinated and compatible with similar research being conducted at the state
5 and federal levels; and

6 (6) Report biennially on its activities, findings, and recommendations relating to the
7 quality, cost-effectiveness, and access to treatment and services for persons with
8 rare diseases in Kentucky to the Cabinet for Health and Family Services and the
9 General Assembly.

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

12 (1) There is created a rare disease trust fund, administered by the Cabinet for Health
13 and Family Services.

14 (2) The rare disease trust fund may receive appropriations, federal funds,
15 contributions, gifts, and donations.

16 (3) The purpose of the rare disease trust fund shall be to finance the operation of the
17 council and to support rare disease research and treatment for Kentucky patients.

18 (4) Notwithstanding KRS 45.229, moneys remaining in the fund at the close of a
19 fiscal year shall not lapse but shall carry forward into the succeeding fiscal year.
20 Interest earned on any moneys in the fund shall accrue to the fund. Amounts
21 from the fund shall be disbursed and expended in accordance with this section.

22 (5) The Cabinet for Health and Family Services shall submit on an annual basis a
23 report detailing all expenditures under this section to the Rare Disease Advisory
24 Council and the General Assembly.

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

27 (1) The Kentucky Rare Disease Council shall cease to exist on December 1, 2028,

- 1 unless otherwise reestablished by the General Assembly.
- 2 (2) If the General Assembly does not reestablish the Kentucky Rare Disease Council,
- 3 any moneys remaining in the trust fund established in Section 3 of this Act on
- 4 December 1, 2028, shall be deposited in the general fund.