

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
6 million 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.

5 ➔Section 5. KRS 79.080 is amended to read as follows:

6 (1) The term "health maintenance organization" for the purposes of this section, means
7 a health maintenance organization as defined in KRS 304.38-030, which has been
8 licensed by the Cabinet for Health and Family Services~~[Kentucky Health Facilities~~
9 ~~and Health Services Certificate of Need and Licensure Board]~~ and issued a
10 certificate of authority by the Department of Insurance as a health maintenance
11 organization and which is qualified under the requirements of the United States
12 Department of Health, Education and Welfare, except as provided in subsection (4)
13 of this section.

14 (2) Cities of all classes, counties, and urban-county governments and the agencies of
15 cities, counties, charter county, and urban-county governments are authorized to
16 establish and operate plans for the payment of retirement, disability, health
17 maintenance organization coverage, or hospitalization benefits to their employees
18 and elected officers, and health maintenance organization coverage or
19 hospitalization benefits to the immediate families of their employees and elected
20 officers. The plan may require employees to pay a percentage of their salaries into a
21 fund from which coverage or benefits are paid, or the city, county, charter county,
22 urban-county government, or agency may pay out of its own funds the entire cost of
23 the coverage or benefits. A plan may include a combination of contributions by
24 employees and elected officers and by the city, county, charter county, urban-county
25 government, or agency into a fund from which coverage or benefits are paid, or it
26 may take any form desired by the city, county, charter county, urban-county
27 government, or agency. Each city, county, charter county, urban-county

1 government, or agency may make rules and regulations and do all other things
2 necessary in the establishment and operation of the plan.

3 (3) Cities of all classes, counties, charter counties, urban-county governments, the
4 agencies of cities, counties, charter counties, and urban-county governments, and all
5 other political subdivisions of the state may provide disability, hospitalization, or
6 other health or medical care coverage to their officers and employees, including
7 their elected officers, through independent or cooperative self-insurance programs
8 and may cooperatively purchase the coverages.

9 (4) Any city, county, charter county, or urban-county government which is a
10 contributing member to any one (1) of the retirement systems administered by the
11 state may participate in the state health insurance coverage program for state
12 employees as defined in KRS 18A.225 to 18A.229. Should any city, county, charter
13 county, or urban-county government opt at any time to participate in the state health
14 insurance coverage program, it shall do so for a minimum of three (3) consecutive
15 years. If after the three (3) year participation period, the city, county, charter county,
16 or urban-county government chooses to terminate participation in the state health
17 insurance coverage program, it will be excluded from further participation for a
18 period of three (3) consecutive years. If a city, county, charter county, or urban-
19 county government, or one (1) of its agencies, terminates participation of its active
20 employees in the state health insurance coverage program and there is a state
21 appropriation for the employer's contribution for active employees' health insurance
22 coverage, neither the unit of government, or its agency, nor the employees shall
23 receive the state-funded contribution after termination from the state employee
24 health insurance program. The three (3) year participation and exclusion cycles shall
25 take effect each time a city, county, charter county, or urban-county government
26 changes its participation status.

27 (5) Any city, county, charter county, urban-county government, or other political

1 subdivision of the state which employs more than twenty-five (25) persons and
2 which provides hospitalization benefits or health maintenance organization
3 coverage to its employees and elected officers, shall annually give its employees an
4 option to elect either standard hospitalization benefits or membership in a qualified
5 health maintenance organization which is engaged in providing basic health
6 services in a health maintenance service area in which at least twenty-five (25) of
7 the employees reside; except that if any city, county, charter county, urban-county
8 government, or agencies of any city, county, charter county, urban-county
9 government, or any other political subdivision of the state which does not have a
10 qualified health maintenance organization engaged in providing basic health
11 services in a health maintenance service area in which at least twenty-five (25) of
12 the employees reside, the city, county, charter county, urban-county government, or
13 agencies of the city, county, charter county, urban-county government, or any other
14 political subdivision of the state may annually give its employees an option to elect
15 either standard hospitalization benefits or membership in a health maintenance
16 organization which has been licensed by the Kentucky Health Facilities and Health
17 Services Certificate of Need and Licensure Board and issued a certificate of
18 authority by the Department of Insurance as a health maintenance organization and
19 which is engaged in providing basic health services in a health maintenance service
20 area in which at least twenty-five (25) of the employees reside. Any premium due
21 for health maintenance organization coverage over the amount contributed by the
22 city, county, charter county, urban-county government, or other political subdivision
23 of the state which employs more than twenty-five (25) persons for any other
24 hospitalization benefit shall be paid by the employee.

25 (6) If an employee moves his place of residence or employment out of the service area
26 of a health maintenance organization, under which he has elected coverage, into
27 either the service area of another health maintenance organization or into an area of

1 the state not within a health maintenance organization service area, the employee
2 shall be given an option, at the time of the move or transfer, to elect coverage either
3 by the health maintenance organization into which service area he moves or is
4 transferred or to elect standard hospitalization coverage offered by the employer.

5 (7) Any plan adopted shall provide that any officer or member of a paid fire or police
6 department who has completed five (5) years or more as a member of the
7 department, but who is unable to perform his duties by reason of heart disease or
8 any disease of the lungs or respiratory tract, is presumed to have contracted his
9 disease while on active duty as a result of strain or the inhalation of noxious fumes,
10 poison or gases, and shall be retired by the pension board under terms of the
11 pension system of which he is a member, if the member passed an entrance physical
12 examination and was found to be in good health as required.

13 (8) The term "agency" as used herein shall include boards appointed to operate
14 waterworks, electric plants, hospitals, airports, housing projects, golf courses, parks,
15 health departments, or any other public project.

16 (9) After August 1, 1988, except as permitted by KRS 65.156, no new retirement plan
17 shall be created pursuant to this section, and cities which were covered by this
18 section on or prior to August 1, 1988, shall participate in the County Employees
19 Retirement System effective August 1, 1988. Any city, county, charter county,
20 urban-county, or agency thereof which provided a retirement plan for its employees,
21 pursuant to this section, on or prior to August 1, 1988, shall place employees hired
22 after August 1, 1988, in the County Employees Retirement System. The city,
23 county, charter county, urban-county, or agency thereof shall offer employees hired
24 on or prior to August 1, 1988, membership in the County Employees Retirement
25 System under the alternate participation plan as described in KRS 78.530(3), but
26 such employees may elect to retain coverage under this section.

27 ➔Section 6. KRS 200.480 is amended to read as follows:

1 The Commission for Children with Special Health Care Needs shall ~~make a biennial~~
2 ~~report to the Governor showing~~ the amount of money received and expended and a
3 detailed statement of its activities upon request to the Governor and the General
4 Assembly~~for such period. A copy of such report shall be furnished each member of the~~
5 ~~General Assembly at its first session following the filing of such report with the~~
6 ~~Governor~~.

7 ➔Section 7. KRS 216.577 is amended to read as follows:

8 Upon a finding that conditions in a long-term care facility constitute a Type A violation,
9 and the licensee fails to correct the violation within the time specified for correction by
10 the cabinet, the secretary shall take at least one (1) of the following actions with respect to
11 the facility in addition to the issuance of a citation, or the assessment of a civil penalty
12 therefor:

- 13 (1) Institute proceedings to obtain an order compelling compliance with the regulations,
14 standards, or requirements as set forth by the Cabinet for Health and Family
15 Services~~Kentucky Health Facilities and Health Services Certificate of Need and~~
16 ~~Licensure Board~~, the provisions of KRS 216.510 to 216.525, or applicable federal
17 laws and regulations governing the certification of a long-term care facility under
18 Title 18 or 19 of the Social Security Act;
- 19 (2) Institute injunctive proceedings in Circuit Court to terminate the operation of the
20 facility; or
- 21 (3) Selectively transfer residents whose care needs are not being adequately met by the
22 long-term care facility.

23 ➔Section 8. KRS 216.935 is amended to read as follows:

24 As used in KRS 216.935 to 216.939, unless the context requires otherwise:

- 25 (1) "Home health aide" means an individual who is hired to perform home health aide
26 services.
- 27 (2) "Home health agency" means a public agency or private organization, or a

1 subdivision of such an agency or organization which is licensed as a home health
2 agency by the *Cabinet for Health and Family Services*~~[Kentucky Health Facilities~~
3 ~~and Health Services Certificate of Need and Licensure Board]~~ and is certified to
4 participate as a home health agency under Title XVIII of the Social Security Act.

- 5 (3) "Home health aide services" means those services provided by a home health aide
6 and supervised by a registered nurse which are directed towards the personal care of
7 the patient. Such services shall include, but not be limited to, the following:
- 8 (a) Helping the patient with bath and care of mouth, skin, and hair;
 - 9 (b) Helping the patient to the bathroom or in using a bedpan;
 - 10 (c) Helping the patient in and out of bed and assisting with ambulation;
 - 11 (d) Helping the patient with prescribed exercises which the patient and home
12 health aide have been taught by appropriate professional personnel;
 - 13 (e) Assisting with medication ordinarily self-administered that has been
14 specifically ordered by a physician or advanced practice registered nurse;
 - 15 (f) Performing incidental household services as are essential to the patient's
16 health care at home, if these services would have been performed if the patient
17 was in a hospital or skilled nursing facility; and
 - 18 (g) Reporting changes in the patient's condition or family situation to the
19 professional nurse supervisor.
- 20 (4) "Nurse aide" means an individual, including a nursing student, medication aide, and
21 a person employed through a nursing pool, who provides nursing or nursing related
22 services to a resident in a nursing facility or home health agency, excluding:
- 23 (a) An individual who is a licensed health professional;
 - 24 (b) A volunteer who provides the nursing or nursing-related services without
25 monetary compensation; and
 - 26 (c) A person who is hired by the resident or family to sit with the resident and
27 who does not perform nursing or nursing-related services.

1 ➔Section 9. KRS 211.670 is amended to read as follows:

- 2 (1) All lists and medical records maintained by hospitals and medical laboratories
3 pursuant to KRS 211.660 shall be confidential. All information collected and
4 analyzed pursuant to KRS 211.660 ~~and 211.665~~ shall be held confidential as to the
5 identity of the individual patient. Staff of the cabinet, the department, or its designee
6 may use the information to notify parents of available medical care and other
7 services available for the child and family. Further disclosure shall be made only
8 pursuant to the written consent of the child's parent or legal guardian.
- 9 (2) Access to information assembled by the Kentucky birth surveillance registry shall
10 be limited to the cabinet, the department, or its designee and to qualified persons or
11 organizations engaged in demographic, epidemiological or other similar studies
12 related to health and health care provision. A written agreement to maintain
13 confidentiality shall be required if access is approved for persons other than
14 representatives of the cabinet.
- 15 (3) The department shall maintain a record of all persons given access to the
16 information in the Kentucky birth surveillance registry. The record shall include: the
17 name of the person authorizing access; name, title, and organizational affiliation of
18 person given access; dates of access; and the specific purpose for which information
19 is to be used. This record of access shall be open to public inspection during normal
20 operating hours of the department.
- 21 (4) Information assembled by the Kentucky birth surveillance registry may be disclosed
22 in summary, statistical, or other form which does not identify particular individuals
23 or individual sources of information.
- 24 (5) Any person who, in violation of a written agreement to maintain confidentiality,
25 discloses any information provided under KRS 211.660 ~~and 211.665~~ may be
26 denied further access to confidential information maintained by the department.

27 ➔Section 10. The following KRS sections are repealed:

- 1 194A.090 Citizen advisory bodies -- Public Health Services Advisory Council --
- 2 Institute for Aging.
- 3 211.665 Advisory committee -- Duties.
- 4 211.674 Perinatal Advisory Committee -- Membership -- Meetings -- Report.