

**CHAPTER 32****( SB 16 )**

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

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

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

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

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

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

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

NOW, THEREFORE,

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

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

- (1) *The Kentucky Rare Disease Advisory Council is hereby established to advise the General Assembly and state departments, agencies, commissions, authorities, and private institutions that provide services for individuals diagnosed with a rare disease.*
- (2) *In order to reduce the administrative burden on state agencies, the council authorized under Sections 1 to 3 of this Act shall be administered by an existing eligible entity operating within the state defined in subsection (3) of this section.*
- (3) *An eligible entity shall be a non-profit organization as defined by 26 U.S.C. sec. 501 that operates within Kentucky and has experience working in the field of rare diseases.*
- (4) *The Governor or his or her designee shall appoint a chair and vice chair to the advisory council to serve for an initial term of two (2) years.*
- (5) *Upon their initial appointment, the chair and vice chair of the council shall appoint other members of the council.*
- (6) *Upon their initial appointment, the chair and vice chair of the council shall develop and submit to the Governor and the General Assembly a written description of the intended mission of the council, including any state agencies and legislative committees it intends to advise.*
- (7) *After the initial appointments, the Kentucky Rare Disease Advisory Council shall determine its procedures governing membership and participation with the following exceptions:*
  - (a) *The total council membership shall not exceed twenty (20) members;*
  - (b) *All future appointed members to the council shall be approved by a majority vote of existing members;*
  - (c) *All existing and future members of the council, including the chair and vice chair, shall serve terms of two (2) years, beginning on the day of the Governor's appointment, shall be eligible to succeed themselves, and shall serve until their successors are appointed; and*

- (d) *Members of the council shall serve until replaced. A majority of the council members shall constitute a quorum for the purposes of conducting business.*
- (8) *After members are appointed to the council, the council shall apply for, and accept, any grant of money from the federal government, private foundations, or other sources that may be available for programs related to rare diseases.*

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

*The Kentucky Rare Disease Advisory Council shall:*

- (1) *Act as the advisory body on rare diseases to the General Assembly, the Governor, and to all relevant state and private agencies that provide services to, or are charged with the care of, individuals with rare diseases;*
- (2) *Coordinate its duties with those community-based organizations and private-sector institutions within the state for the purpose of ensuring greater cooperation regarding the research, diagnosis, and treatment of rare diseases. The coordination shall require, when appropriate:*
  - (a) *Disseminating the outcomes of the Advisory Council's research, identified best practices, and policy recommendations; and*
  - (b) *Utilizing common research collection and dissemination procedures;*
- (3) *Research and determine the most appropriate methods to collect thorough and complete information on rare diseases in Kentucky and other information as the council deems necessary and appropriate to collect;*
- (4) *Research and identify priorities relating to the quality, cost-effectiveness, and access to treatment and services provided to persons with rare diseases, and develop related policy recommendations;*
- (5) *Identify best practices for rare disease care from other states and at the national level that may improve rare disease care in Kentucky;*
- (6) *Develop effective strategies to raise public awareness of rare diseases in Kentucky;*
- (7) *Ensure that the duties of the council are carried out in a manner that is coordinated and compatible with similar research being conducted at the state and federal levels;*
- (8) *In conjunction with the state's medical schools, the state's schools of public health, and hospitals in the state that provide care to persons diagnosed with a rare disease, develop a list of existing, publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases;*
- (9) *Report biennially on its activities, findings, and recommendations relating to the quality, cost-effectiveness, and access to treatment and services for persons with rare diseases in Kentucky to the Governor, the Cabinet for Health and Family Services, and the General Assembly;*
- (10) *Upon receipt of the council's biennial report, the Governor and Cabinet for Health and Family Services shall within ninety (90) days issue a written response to the council detailing its efforts to improve state policies pertaining to the identification, treatment, and care of rare diseases; and*
- (11) *Upon receipt of the council's biennial report, the Interim Joint Committee on Health and Welfare and Family Services shall within one hundred and twenty (120) days convene a hearing on issues pertaining to the identification, treatment, and care of rare diseases identified by the council in its report.*

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

- (1) *The Kentucky Rare Disease Council shall cease to exist on December 1, 2028, unless otherwise reestablished by the General Assembly.*
- (2) *If the General Assembly does not reestablish the Kentucky Rare Disease Council, any outstanding funds collected by the council as described in subsection (8) of Section 1 of this Act shall be donated for the purposes of improving the treatment and care of rare diseases, including for conducting research on specific rare diseases.*

Signed by Governor March 19, 2019.