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LC004516

STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2024

A N A C T

RELATING TO HEALTH AND SAFETY -- RARE DISEASE ADVISORY COUNCIL

Introduced By: Representatives Kennedy, Spears, Donovan, Serpa, Bennett, Edwards,
Diaz, O'Brien, Cotter, and Ackerman

Date Introduced: January 31, 2024

Referred To: House Health & Human Services

It is enacted by the General Assembly as follows:

1 SECTION 1. Legislative findings.

2 The general assembly hereby finds and declares:

3 (1) A rare disease, sometimes called an orphan disease, is defined as a disease that affects
4 fewer than 200,000 people in the United States.

5 (2) There are more than 7,000 known rare diseases affecting approximately 25-30 million
6 Americans, more than half of which are children.

7 (3) More than 90% of rare diseases do not have a Food and Drug Administration (FDA)
8 approved treatment.

9 (4) While the exact cause for many rare diseases remains unknown, many rare diseases are
10 genetic in origin and can be linked to mutations in a single gene or in multiple genes, which can be
11 passed down from generation to generation.

12 (5) People with rare diseases face many challenges, including delays in obtaining an
13 accurate diagnosis, finding a health care provider with expertise in their condition, and a lack of
14 affordable access to therapies and medication used to treat rare diseases.

15 (6) A state-based advisory council composed of qualified professionals and persons living
16 with rare diseases and their caregivers could educate medical professionals, government agencies,
17 legislators, and the public about rare diseases as an important public health issue and encourage
18 research into the development of new ways to diagnose and treat rare diseases.

19 SECTION 2. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby

1 amended by adding thereto the following chapter:

2 CHAPTER 87.1

3 RARE DISEASE ADVISORY COUNCIL

4 **23-87.1-1. Short title.**

5 This chapter shall be known and may be cited as the "Rare Disease Advisory Council."

6 **23-87.1-2. Establishment.**

7 (a) There is established in the department of health the office of rare disease advisory
8 council.

9 (b) The purpose of the council is to provide guidance and recommendations to educate the
10 public, legislature, as well as other government agencies, on the needs of individuals with rare
11 diseases living in Rhode Island.

12 (c) The council shall conduct the following activities to benefit those impacted by rare
13 diseases in Rhode Island. The duties of the council shall include:

14 (1) Convene public hearings, make inquiries, and solicit comments from the general public
15 in Rhode Island to assist the council with a first-year landscape or survey of the needs of rare
16 disease patients, caregivers, and providers in the state.

17 (2) Provide testimony and comments on pending legislation and regulations before the
18 legislature and other state agencies that impact Rhode Island's rare disease community.

19 (3) Consult with experts on rare diseases to develop policy recommendations to improve
20 patient access to, and quality of, rare disease specialists, affordable and comprehensive health care
21 coverage, relevant diagnostics, timely treatment and other needed services.

22 (4) Research and make recommendations to state agencies and insurers that provide
23 services to persons with a rare disease on the impact of prior authorization, cost-sharing, tiering, or
24 other utilization management procedures on the provision of treatment and care for patients.

25 (5) Establish best practices and protocols to include in-state planning related to natural
26 disasters, public health emergencies or other emergency declarations to enable continuity of care
27 for rare disease patients and ensure safeguards against discrimination for rare disease patients are
28 in place.

29 (6) Evaluate and make recommendations to implement improvements to newborn
30 screening program.

31 (7) Evaluate and make recommendations to improve Medicaid coverage of drugs for rare
32 disease patients, including engagement with the drug utilization review board, to improve coverage
33 of diagnostics, and facilitate access to necessary healthcare providers with expertise in the treatment
34 of rare diseases.

1 (8) Publish a list of existing, publicly accessible resources on research, diagnosis,
2 treatment, and education relating to the rare diseases on the council's website.

3 (9) Identify areas of unmet need for research and opportunities for collaboration across
4 stakeholders that can inform future studies and reports by the council.

5 (10) Identify and distribute educational resources for health care providers to foster
6 recognition and optimize treatment of rare diseases.

7 (11) Research and identify best practices to reduce health disparities and achieve health
8 equity in the research, diagnosis and treatment of rare diseases.

9 (12) Research and identify best practices to ensure continuity of care for rare disease
10 patients transitioning from child/youth services to adult care.

11 **23-87.1-3. Membership of council.**

12 (a) The council's appointment process shall be conducted in a transparent manner to
13 provide interested individuals an opportunity to apply for membership on the council. All members
14 of the council shall be full-time residents of Rhode Island and membership shall include a diverse
15 set of stakeholders.

16 (b) Governor-appointed positions: The governor shall appoint the chair of the council
17 within thirty (30) days of enactment. The chair shall not hold any position within the government
18 of Rhode Island.

19 (c) Chair-appointed positions: The chair shall appoint the following members:

20 (1) One representative from academic research institutions in the state that receives any
21 grant funding for rare disease research;

22 (2) One representative from the Rhode Island department of health's office of minority
23 health;

24 (3) One representative from the Rhode Island Medicaid agency;

25 (4) One representative from the Rhode Island department of business regulation insurance
26 division;

27 (5) One registered nurse or advanced practice registered nurse licensed and practicing in
28 Rhode Island with experience treating rare diseases;

29 (6) One physician practicing in Rhode Island with experience treating rare diseases;

30 (7) One hospital administrator, or designee, from a hospital in Rhode Island that provides
31 care to persons diagnosed with a rare disease;

32 (8) At least two (2) patients who have a rare disease;

33 (9) At least one caregiver of a person with a rare disease;

34 (10) One representative of a rare disease patient organization that operates in Rhode Island;

- 1 (11) A pharmacist with experience dispensing drugs used to treat rare diseases;
2 (12) A representative of the biopharma industry;
3 (13) A representative of a health plan company; and
4 (14) A member of the scientific community who is engaged in rare disease research,
5 including, but not limited to, a medical researcher with experience conducting research on rare
6 diseases.

7 **23-87.1-4. Reporting requirements.**

8 (a) The council shall submit a report to the governor and the chair and ranking members of
9 the relevant health, budget and finance committees within one year of enactment of the council and
10 annually thereafter. Prior to submission, a draft of the annual report shall be made available for
11 public comment and discussed at an open public meeting.

12 (b) Annual reports shall:

13 (1) Describe the activities and progress of the council under this section;

14 (2) Provide an update on the status of funding of the council (what grants were sought out,
15 accepted, used, and remaining balances); and

16 (3) Provide recommendations to the governor and legislature on ways to address the needs
17 of people living with rare diseases in the state.

18 **23-87.1-5. Funding for council.**

19 (a) The council members may solicit funds on behalf of the council.

20 (b) The council shall set up a method to securely hold and distribute funds to support the
21 functioning of the council, including fulfillment of the duties set forth in subsection (c) of this
22 section.

23 (c) The council shall report funding sources in annual report outlined in § 23-87.1-4(b).

24 **23-87.1-6. Meeting requirements.**

25 (a) Frequency.

26 (1) The initial meeting of the council shall occur within the first ninety (90) days after
27 enactment.

28 (2) During the first twelve (12) months after enactment, the council shall meet no less than
29 one time per month for a time period determined by the chair in person or via online meeting
30 platform.

31 (3) Thereafter, the council shall meet no less than one time per quarter in person or via
32 online meeting platform as determined by the chair.

33 (b) Notice.

34 (1) The council shall:

1 (i) Provide opportunities for the public to hear updates and provide input into their work;
2 and

3 (ii) Create and maintain a public website where meeting minutes, notices of upcoming
4 meetings, and public comments can be submitted.

5 **23-87.1-7. Terms and vacancies for council members.**

6 (a) Term and election of chair.

7 (1) The governor shall appoint the chair for an initial term of three (3) years.

8 (2) At the end of the chair's initial three (3) year term, and every two (2) years thereafter,
9 members of the council shall appoint, by a majority vote, a new chair.

10 (b) Term of members. Council members shall serve no longer than three (3) years, except
11 that, to facilitate a staggered rotation of members to retain continuity and knowledge transfer,
12 during the initial five (5) years after the establishment of the council, members may serve up to a
13 four (4) year term.

14 (c) Vacancy. If a vacancy occurs, the council, by a majority vote, shall fill such vacancy in
15 a timely manner and in compliance with requirements set forth in this subsection.

16 SECTION 3. This act shall take effect upon passage.

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EXPLANATION
BY THE LEGISLATIVE COUNCIL
OF
A N A C T
RELATING TO HEALTH AND SAFETY -- RARE DISEASE ADVISORY COUNCIL

- 1 This act would establish a rare disease advisory council within the department of health.
- 2 The council would provide guidance and recommendations to educate health care providers and
- 3 the citizens of the state.
- 4 This act would take effect upon passage.

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