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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2025

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A N A C T

RELATING TO HEALTH AND SAFETY -- RARE DISEASE ADVISORY COUNCIL

Introduced By: Representatives Kennedy, Spears, Diaz, Donovan, Cotter, Carson,
Azzinaro, Kazarian, Edwards, and Serpa

Date Introduced: January 10, 2025

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~~ 10,000 known rare diseases affecting approximately ~~25-30~~
6 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~~ **A COUNCIL TO**
8 **BE CALLED THE** "rare disease advisory
9 council."

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

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

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

18 (2) Provide testimony and comments on pending legislation and regulations **AFFECTING**
19 **RHODE ISLAND'S RARE DISEASE COMMUNITY AND RECOMMEND**
20 **SOLUTIONS TO** before the
21 legislature and other state agencies **AND ISSUERS ON THE** that impact Rhode Island's rare disease
22 community. **IMPACT OF ORPHAN DRUG PRICING, PRIOR AUTHORIZATION, COST-**
23 **SHARING, AND OTHER TREATMENT BARRIERS.**

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

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

30 (5) (3) Establish best practices and protocols to include in-state planning related to natural
31 disasters, public health emergencies or other emergency declarations to enable continuity of care
32 for rare disease patients and ensure safeguards against discrimination for rare disease patients are
33 in place.

34 (6) Evaluate and make recommendations to implement improvements to newborn infant
35 screening programs.

36 (7) Evaluate and make recommendations to improve Medicaid coverage of drugs for rare
37 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. For purposes of this~~
3 ~~chapter, "rare disease" or "orphan disease" means a disease that affects fewer than two hundred~~
4 ~~thousand (200,000) people in the United States.~~

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

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

9 ~~(11) (4) Research and identify best practices to reduce health disparities and achieve health~~
10 ~~equity in the research, diagnosis and treatment of rare diseases~~ **IN RHODE ISLAND, INCLUDING**
STRATEGIES TO IMPROVE CONTINUITY OF CARE DURING TRANSITIONS FROM
CHILD/YOUTH TO ADULT SERVICES.

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

13 **(5) IDENTIFY, DEVELOP, AND DISTRIBUTE EDUCATIONAL RESOURCES FOR**
HEALTHCARE PROVIDERS TO FOSTER RECOGNITION, OPITMIZE TREATMENT,
AND IMPROVE CARE FOR RARE DISEASE PATIETNS. MAINTAIN A PUBLICLY
ACCESSIBLE LIST OF RESOURCES ON RESEARCH, DIAGNOSIS, TREATMENT, AND
EDUCATION RELATD TO REARE DISEASES IN RHODE ISLAND ON THE COUNCIL'S
WEBISTE.

14 **23-87.1-3. Membership of council.**

15 **(a) THE COUNCIL'S APPOINTMENT PROCESS SHALL BE CONDUCTED IN A**
TRANSPARENT MANNER TO PROVIDE INTERESTED INDIVIDUALS AN
OPPORTUNITY TO APPLY FOR MEMBERSHIP ON THE COUNCIL. All members of
the council shall be full-time residents of Rhode Island and membership

16 shall include a diverse set of stakeholders.

17 ~~(b) The governor shall appoint all members and shall designate a chair of the council within~~
18 ~~thirty (30) days of enactment. The chair shall not hold any position within the government of Rhode~~
19 ~~Island and shall serve for a term of three (3) years.~~

20 **(e) (B) THE COUNCIL SHALL INCLUDE REPRESENTATIVES FROM THE**
FOLLOWING GROUPS, WITH INDIVIDUALS PROTENTIAALLY FULTILLING
MULTIPLE ROLES IF THEY MEET QUALIFICATIONS FOR MORE THAN ONE
CATEGORY: The governor shall appoint the following members:

21 ~~(1) One representative from academic research institutions in the state that receives any~~
22 ~~grant funding for rare disease research~~ **APPOINTED BY THE GOVERNOR;**

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

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

26 ~~(4) One representative from the Rhode Island department of business regulation insurance~~
27 ~~Division~~ **OFFICE OF THE HEALTH INSURANCE COMMISSION;**

28 ~~(5) One registered nurse or advanced practice registered nurse licensed and practicing in~~

29 Rhode Island with experience treating rare diseases **APPOINTED BY THE GOVERNOR;**

30 (6) One physician practicing in Rhode Island with experience treating rare diseases
APPOINTED BY THE GOVERNOR;

31 (7) One hospital administrator, or designee, from a hospital in Rhode Island that provides
32 care to persons diagnosed with a rare disease **APPOINTED BY THE GOVERNOR;**

33 (8) At least two (2) patients who have a rare disease **AT LEAST ONE TO BE APPOINTED**
BY THE SPEAKER OF THE HOUSE AND ONE APPOINTED BY THE PRESIDENT
OF THE SENATE;

34 (9) At least one caregiver of a person with a rare disease **APPOINTED BY THE SPEAKER**
OF THE HOUSE;

35 (10) One representative of a rare disease patient organization that operates in Rhode Island
APPOINTED BY THE PRESIDENT OF THE SENATE;

1 (11) A pharmacist with experience dispensing drugs used to treat rare diseases **APPOINTED**
2 **BY THE PRESIDENT OF THE SENATE;**

3 (12) A representative of the biopharma industry **APPOINTED BY THE GOVERNOR;**

4 (13) A representative of a health plan company **APPOINTED BY THE SPEAKER OF**
5 **THE HOUSE; and**

6 (14) A member of the scientific community who is engaged in rare disease research,
7 including, but not limited to, a medical researcher with experience conducting research on rare
8 diseases **APPOINTED BY THE PRESIDENT OF THE SENATE.**

9 **(15) A LICENSED MENTAL HEALTH PROVIDER, SUCH AS A PSYCHOLOGIST,**
10 **PSYCHIATRIST OR CLINICAL SOCIAL WORKER, PRACTICING IN RHODE ISLAND**
11 **WITH EXPERIENCE SUPPORTING INDIVIDUALS DIAGNOSED WITH RARE DISEASES**
12 **AND THEIR FAMILIES APPOINTED BY THE GOVERNOR.**

13 **23-87.1-4. Terms and vacancies for council members.**

14 (a) Term of members. Council members shall serve no longer than three (3) years, except
15 that, to facilitate a staggered rotation of members to retain continuity and knowledge transfer,
16 during the initial five (5) years after the establishment of the council, members may serve up to a
17 four (4) year term. **THE COUNCIL SHALL DEVELOP ITS OWN BYLAWS TO ADDRESS THE**
18 **REAPPOINTMENT OF MEMBERS.**

19 **(1) MEMBERS MAY CONTINUE TO SERVE UNTIL THEIR SUCCESSOR IS**
20 **DULY APPOINTED.**

21 **(B) THE CHAIR OF THE COUNCIL SHALL BE DETERMINED BY A MAJORITY VOTE**
22 **OF THE MEMBERS OF THE COUNCIL DURING ITS INAUGURAL MEETING. THE**
23 **CHAIR SHALL NOT HOLD ANY POSITION WITHIN THE GOVERNMENT OF RHODE**
24 **ISLAND.**

25 **(1) AT THE END OF THE CHAIR'S INITIAL (3) YEAR TERM, BY A MAJORITY**
26 **VOTE, A NEW CHAIR WILL BE ELECTED. THE COUNCIL SHALL DEVELOP ITS OWN**
27 **INTERNAL BYLAWS TO ADDRESS THE POSSIBILITY OF A CHAIR BEING ELECTED**
28 **MORE THAN ONCE.**

29 (b) Vacancy. If a vacancy occurs, the vacancy shall be filled in a like manner as required
30 pursuant to this section.

31 **23-87.1-5. Reporting requirements.**

32 (a) The council shall submit a report to the governor, the speaker of the house and the
33 president of the senate, and the chairs of the house and senate health and finance committees
34 **INCLUDING THE JOINT COMMITTEE OF HEALTHCARE OVERSIGHT ESTABLISHED**
35 **PURSUANT TO R.I. GEN. LAWS §40-8.4-14 AND THE ADVISORY COMMISSION ON HEALTH**
36 **CARE ESTABLISHED PURSUANT TO R.I. GEN. LAWS §40-8.4-15** within

37 one year of enactment of the council and annually thereafter. Prior to submission, a draft of the
38 annual report shall be made available for public comment and discussed at an open public meeting.

39 (b) Annual reports shall:

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

41 **(2) INCLUDE AN ASSESSMENT OF THE COUNCIL'S PROGRESS IN MEETING**
42 **ITS GOALS, INCLUDING MEASUREABLE OUTCOMES, IDENTIFIED**
43 **BARRIERS, AND RECOMMENDATIONS FOR IMPROVEMENT;**

44 ~~(2)~~ (3) Provide an update on the status of funding of the council; and

27 ~~(3)~~ (4) Provide recommendations to the governor and legislature on ways to address the needs
28 of people living with rare diseases in the state.

29 **23-87.1-6. Funding for council.**

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

31 (b) The council shall establish a restricted receipt account and all funds designated or raised
32 by or for the advisory council shall be placed in the restricted receipt account to support the
33 activities of the council necessary to carry out the provisions of this chapter.

34 (c) The council shall report funding sources in the annual reports outlined in § 23-87.1-

30 5(b).

31
32 **(D) THE COUNCIL IS AUTHORIZED TO ACCEPT STATE GRANTS AND**
APPROPRIATIONS, AND PROVIDE MONIES FOR ITS OPERATIONAL
PURPOSES.

33 **23-87.1-7. Meeting requirements.**

34 (a) Frequency.

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

1 (2) During the first twelve (12) months after the initial meeting, the council shall meet each
2 **Month IN PERSON OR VIA ONLINE MEETING PLATFORM. TO MAXIMIZE**
3 **PARTICIPATION BY THE GENRAL PUBLIC, MEETINGS MAY BE HELD IN A HYBRID**
4 **IN PERSON AND REMOTE FORMAT.**

3 (3) Thereafter, the council shall meet once per quarter in person or via online meeting
4 platform as determined by the chair.

5 (b) Notice.

6 (1) The council shall, in compliance with chapter 46 of title 42 ("open meetings"):

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

8 and

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

11 **(III) THE RHODE ISLAND DEPARTMENT OF HEALTH SHALL MAINTAIN A PUBLICLY**
12 **ACCESSIBLE WEBPAGE ON ITS OFFICIAL WEBSITE DEDICATED TO THE RARE**
DISEASE ADVISORY COUNCIL. THE WEBPAGE SHALL INCLUDE INFORMATION
ABOUT RDAC MEETINGS, INCLUDING SCHEDULES, AGENDAS, MINUTES AND
DETAILS ON HOW THE PUBLIC CAN PARTICIPATE.

12 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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