

ASSEMBLY, No. 4016

STATE OF NEW JERSEY

219th LEGISLATURE

INTRODUCED MAY 4, 2020

Sponsored by:

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District 15 (Hunterdon and Mercer)

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Assemblyman DePhillips

SYNOPSIS

Establishes the New Jersey Rare Disease Advisory Council.

CURRENT VERSION OF TEXT

As introduced.



(Sponsorship Updated As Of: 10/19/2020)

1 AN ACT establishing the New Jersey Rare Disease Advisory
2 Council and supplementing Title 26 of the Revised Statutes.

3
4 **BE IT ENACTED** *by the Senate and General Assembly of the State*
5 *of New Jersey:*

6
7 1. The Legislature finds and declares:

8 a. A rare disease is defined as a disease that affects fewer than
9 20,000 people. Rare diseases are sometimes called orphan diseases.
10 There are 7,000 rare diseases affecting approximately 25 to 30
11 million Americans;

12 b. The exact cause for many rare diseases remains unknown.
13 However, 80% of rare diseases are genetic in origin and can be
14 linked to mutations in a single gene or in multiple genes which can
15 be passed down from generation to generation;

16 c. A person suffering with a rare disease faces a wide range of
17 challenges, including delays in obtaining a diagnosis; being
18 misdiagnosed; shortages of medical specialists who can provide
19 treatment for rare diseases; and the lack of therapies and medication
20 that are used by doctors to treat rare diseases;

21 d. There is a significant link between rare disease and the
22 coronavirus 2019 (COVID-19) pandemic which heightens the
23 importance of the establishment of an advisory council to examine
24 the issues that affect persons with rare diseases in the State. Many
25 people who live with rare diseases are immunosuppressed and have
26 respiratory and neurologic issues that make the consequences of the
27 virus much more severe for them;

28 e. Additionally, those with rare diseases rely on the health care
29 system much more than those who do not have chronic and rare
30 conditions. In as much as they go to their physicians' offices,
31 medical testing sites, and hospitals more often than most, their risk
32 of exposure to the COVID-19 virus is much greater;

33 f. People who live with rare diseases are impacted by potential
34 shortages of life-saving medications and supplies due to changes in
35 supply chain resulting from the COVID-19 pandemic. People with
36 rare diseases also rely on the support of their families and home
37 health aides, and because of the social distancing and quarantining,
38 the pandemic puts them at risk of not having the support they need
39 in accessing services and treatment;

40 g. Researchers have made considerable progress in developing
41 diagnostic tools and treatment protocols for rare diseases and
42 discovering methods of prevention. However, much more remains
43 to be done in the search for new therapeutics and in understanding
44 the link between rare disease and pandemics, and

45 h. It is therefore an appropriate public policy for the State of
46 New Jersey to establish an advisory body, whose membership
47 would be comprised of qualified professionals and persons living
48 with rare diseases, that would be tasked to educate medical

1 professionals, government agencies, and the public about the
2 importance of rare diseases as an important public health issue, and
3 to encourage and fund research in the development of new
4 treatments for rare diseases.

5
6 2. There is established the New Jersey Rare Disease Advisory
7 Council in the Department of Health which shall advise the
8 Legislature, State departments, agencies, commissions, and
9 authorities, and private agencies providing services for persons
10 diagnosed with a rare disease.

11 a. The advisory council shall consist of 30 members as follows:

12 (1) the Commissioners of Banking and Insurance, Children and
13 Families, Environmental Protection, Health, Human Services, and
14 the Executive Director of the New Jersey Office on Minority and
15 Multicultural Health, or their designees, as ex officio members;

16 (2) two members of the Senate, one of whom is appointed by the
17 President of the Senate, and one of whom is appointed by the
18 Minority Leader of the Senate;

19 (3) two members of the General Assembly, one of whom is
20 appointed by the Speaker of the General Assembly, and one of
21 whom is appointed by the Minority Leader of the General
22 Assembly; and

23 (4) 20 public members to be appointed by the Governor, who
24 shall include: two physicians licensed to practice in this State who
25 have expertise in treating patients with rare diseases, one of whom
26 shall be a pediatrician who provides care to children with rare
27 diseases; a registered professional nurse licensed in this State who
28 has expertise in providing care to patients with rare diseases; a
29 representative of general hospital or hospital system in this State
30 recommended by the New Jersey Hospital Association; a
31 representative of federally qualified health center in this State
32 recommended by the New Jersey Primary Care Association; a
33 geneticist licensed to practice in this State; a genetic counselor who
34 has experience in providing services to persons diagnosed with a
35 rare disease, their families, or their caregivers or care partners; a
36 representative of the health insurance industry recommended by the
37 New Jersey Association of Health Plans; a pharmacist licensed to
38 practice in this State who has experience with persons with a rare
39 disease; a representative of the pharmaceutical industry who has
40 expertise in rare diseases recommended by the HealthCare Institute
41 of New Jersey; a representative of the biotechnology industry who
42 is has expertise in rare diseases recommended by BIO NJ; a
43 representative of the medical technology industry who has expertise
44 in rare diseases; a representative of the Rutgers Biomedical and
45 Health Sciences who is engaged in rare disease research; a
46 representative of the Rowan University Graduate School of
47 Biomedical Sciences who is engaged in rare disease research; two
48 representatives of rare disease patient advocacy organizations; two

1 persons, age 18 years or older, who have a rare disease; and two
2 caregivers or care partners for a patient or partner with a rare
3 disease; one of who shall be a caregiver for a child with a rare
4 disease.

5 b. Public members of the advisory council shall serve for a
6 term of three years, except that of the initial appointments, seven
7 public members shall serve for one year, seven public members
8 shall serve for two years, and six public members shall serve for
9 three years. Vacancies in the membership of the council shall be
10 filled in the same manner as the original appointments were made.
11 The public members of the council shall serve without
12 compensation but may be reimbursed for traveling and other
13 miscellaneous expenses necessary to perform their duties within the
14 limits of funds made available to the council for its purposes.

15 c. The advisory council shall organize as soon as practicable
16 after the appointment of its members, and the Governor shall select
17 a chairperson and vice-chairperson from among its members. The
18 chairperson shall appoint a secretary who need not be a member of
19 the council.

20 d. The advisory council shall meet a minimum of three times a
21 year but may meet more often at the call of its chair. The council
22 may hold hearings at the times and in the places it deems
23 appropriate and necessary to fulfill its charge. The council shall be
24 entitled to call to its assistance, and avail itself of the services of the
25 employees of, any State, county, or municipal department, board,
26 bureau, commission, or agency as it may require and as may be
27 available to it for its purposes.

28 e. The Department of Health shall provide staff services to the
29 advisory council.

30

31 3. The purpose of the advisory council shall be to:

32 a. act as the advisory body on rare diseases to the Legislature
33 and State departments, agencies, commissions, authorities, and
34 private agencies that provide services to, or are charged with the
35 care of, persons with rare diseases;

36 b. conduct a thorough and comprehensive study of all issues
37 relating to the quality and cost-effectiveness of, and access to,
38 treatment and services provided to persons with rare diseases in this
39 State, including the link between rare diseases and the COVID-19
40 pandemic, and to develop policy recommendations on those issues;

41 c. establish and implement a repository of best practice
42 standards to share with health care providers that will ensure they
43 are adequately informed of the most effective strategies for
44 recognizing and treating rare diseases in New Jersey;

45 d. identify effective research-based strategies that have been
46 developed to help diagnose, treat, and prevent rare diseases;

47 e. develop effective strategies to raise public awareness of rare
48 diseases in this State;

- 1 f. evaluate and make recommendations to improve:
2 (1) the State's Newborn Screening Program in the Department
3 of Health; and
4 (2) State Medicaid coverage for approved treatments and
5 medications for patients with a rare disease;
6 g. research and make policy recommendations to the
7 Legislature on access to health insurance specialists and other
8 needed services for patients with a rare disease; and
9 h. identify, with assistance from the public, additional research
10 topics on rare disease to inform future studies the council may
11 conduct.
12
13 4. The advisory council shall apply for, and accept, any grant
14 of money from the federal government, private foundations, or
15 other sources, which may be available for programs related to rare
16 diseases.
17
18 5. The advisory council shall report to the Governor and,
19 pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the
20 Legislature, no later than December 31st, on a biennial basis,
21 starting in the second year next following the enactment of this act,
22 on the activities of the advisory council and its findings and
23 recommendations on issues relating to the quality of, and access to,
24 treatment and services for persons with rare diseases in this State.
25
26 6. The Commissioner of Health, pursuant to the
27 "Administrative Procedures Act," P.L.1968, c.410 (C.52:14B-1 et
28 seq.) shall adopt rules and regulations necessary to effectuate the
29 purposes of this act.
30
31 7. This act shall take effect immediately.
32
33

34 STATEMENT
35

36 There is a significant link between rare disease and the
37 coronavirus 2019 (COVID-19) pandemic. Many people who live
38 with rare diseases are immunosuppressed and have respiratory and
39 neurologic issues that make the consequences of the virus much
40 more severe for them. This link heightens the importance of the
41 establishment of an advisory council to examine the issues that
42 affect persons with rare diseases in the State.
43 Therefore, this bill establishes the 30-member New Jersey Rare
44 Disease Advisory Council in the Department of Health to advise the
45 Legislature, State departments, agencies, commissions, and
46 authorities, and private agencies providing services for persons
47 diagnosed with a rare disease.

1 The membership of the advisory council will consist of: the
2 Commissioners of Banking and Insurance, Children and Families,
3 Environmental Protection, Health, Human Services, and the
4 Executive Director of the New Jersey Office on Minority and
5 Multicultural Health or their designees, as ex officio members; two
6 members of the Senate, one appointed by the President of the
7 Senate, and one appointed by the Minority Leader of the Senate;
8 two members of the General Assembly, one appointed by the
9 Speaker of the General Assembly, and one appointed by the
10 Minority Leader of the General Assembly; and 20 public members
11 appointed by the Governor, including two physicians licensed to
12 practice in this State who have expertise in treating patients with
13 rare diseases, one who would be a pediatrician who provides care to
14 children with rare diseases; a registered professional nurse licensed
15 in this State who has expertise in providing care to patients with
16 rare diseases; a representative of general hospital or hospital system
17 in this State recommended by the New Jersey Hospital Association;
18 a representative of federally qualified health center in this State
19 recommended by the New Jersey Primary Care Association; a
20 geneticist licensed to practice in this State; a genetic counselor who
21 has experience in providing services to persons diagnosed with a
22 rare disease, their families, or their caregivers or care partners; a
23 representative of the health insurance industry recommended by the
24 New Jersey Association of Health Plans; a pharmacist licensed to
25 practice in this State who has experience with persons with a rare
26 disease; a representative of the pharmaceutical industry who has
27 expertise in rare diseases recommended by the HealthCare Institute
28 of New Jersey; a representative of the biotechnology industry who
29 has expertise in rare diseases recommended by BIO NJ; a
30 representative of the medical technology industry who has expertise
31 in rare diseases; a representative of the Rutgers Biomedical and
32 Health Sciences who is engaged in rare disease research; a
33 representative of the Rowan University Graduate School of
34 Biomedical Sciences who is engaged in rare disease research; two
35 representatives of rare disease patient advocacy organizations; two
36 persons, age 18 years or older, who have a rare disease; and two
37 caregivers or care partners for a patient or partner with a rare
38 disease; one who would be a caregiver for a child with a rare
39 disease.

40 The purpose of the advisory council will be to: act as the
41 advisory body on rare diseases to the Legislature and State
42 departments, agencies, commissions, authorities, and private
43 agencies that provide services to, or are charged with the care of,
44 persons with rare diseases; conduct a thorough and comprehensive
45 study of all issues relating to the quality of, and access to, treatment
46 and services provided to persons with rare diseases in this State,
47 including the link between rare diseases and the COVID-19
48 pandemic, and to develop policy recommendations on those issues;

1 establish and implement a repository of best practice to share with
2 health care providers that will ensure they are adequately informed
3 of the most effective strategies for recognizing and treating rare
4 diseases in New Jersey; identify effective research-based strategies
5 that have been developed to help diagnose, treat, and prevent rare
6 diseases; develop effective strategies to raise public awareness of
7 rare diseases in this State; evaluate and make recommendations to
8 improve the State's Newborn Screening Program in the Department
9 of Health and State Medicaid coverage for approved treatments and
10 medications for patients with a rare disease; research and make
11 policy recommendations to the Legislature on access to health
12 insurance specialists and other needed services for patients with a
13 rare disease; and identify, with assistance from the public,
14 additional research topics on rare disease to inform future studies
15 the council may conduct.

16 Finally, the bill requires the advisory council to report biennially,
17 to the Governor and the Legislature on its findings and
18 recommendations on issues relating to the quality of, and access to,
19 treatment and services provided to persons with rare diseases in this
20 State.

21 This bill is similar to H-7094, the "Rare Disease Community
22 Support, Resource Coordination and Quality of Life Act of 2014,"
23 that was adopted by the state of Rhode Island earlier this year.