

[Second Reprint]

SENATE, No. 2682

STATE OF NEW JERSEY
219th LEGISLATURE

INTRODUCED JULY 6, 2020

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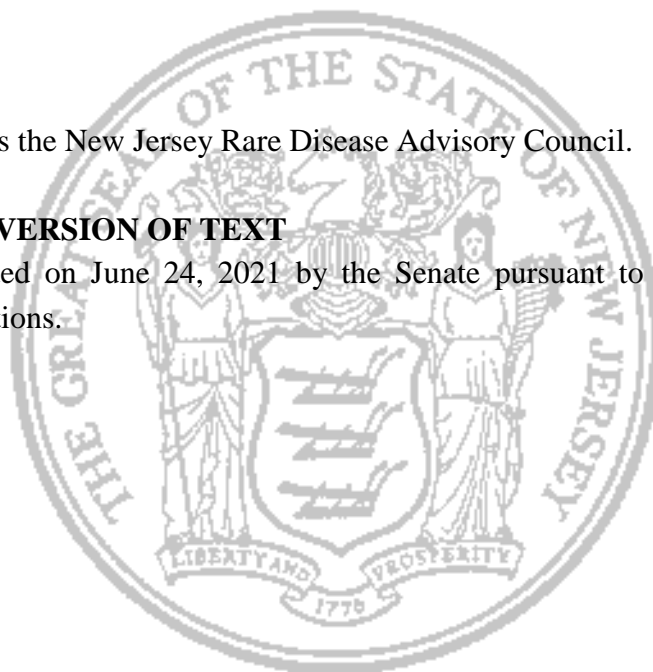
Senators Singer, Pou, Assemblymen DePhillips, Giblin, Assemblywomen Vainieri Huttie, Murphy and Assemblyman Zwicker

SYNOPSIS

Establishes the New Jersey Rare Disease Advisory Council.

CURRENT VERSION OF TEXT

As amended on June 24, 2021 by the Senate pursuant to the Governor's recommendations.



(Sponsorship Updated As Of: 5/20/2021)

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 ¹**[%]** percent¹ of rare diseases are genetic in origin
14 and can be linked to mutations in a single gene or in multiple genes
15 which can 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

EXPLANATION – Matter enclosed in bold-faced brackets **[thus]** in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.

Matter enclosed in superscript numerals has been adopted as follows:

¹Senate SHH committee amendments adopted February 9, 2021.

²Senate amendments adopted in accordance with Governor's recommendations June 24, 2021.

h. It is therefore an appropriate public policy for the State of New Jersey to establish an advisory body, whose membership would be comprised of qualified professionals and persons living with rare diseases, that would be tasked to educate medical professionals, government agencies, and the public about the importance of rare diseases as an important public health issue, and to encourage ²[and fund]² research in the development of new treatments for rare diseases.

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

a. The advisory council shall consist of ¹[30] 20¹ members as follows:

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

(2) two members of the ²[Senate] public², one of whom ²[is] shall be² appointed by the ²Governor upon recommendation of the² President of the Senate, and one of whom ²[is] shall be² appointed by the Minority Leader of the Senate ²which public members shall be any of the following: an epidemiologist, a registered nurse or nurse practitioner licensed to practice in this State with experience in providing care to patients with rare diseases, or a pediatrician or other physician licensed to practice in this State with expertise in providing care to patients with rare diseases²;

(3) two members of the ²[General Assembly] public², one of whom ²[is] shall be² appointed by the ²Governor upon recommendation of the² Speaker of the General Assembly, and one of whom ²[is] shall be² appointed by the Minority Leader of the General Assembly ²which public members shall be any of the following: an epidemiologist, a registered nurse or nurse practitioner licensed to practice in this State with experience in providing care to patients with rare diseases, or a pediatrician or other physician licensed to practice in this State with expertise in providing care to patients with rare diseases²; and

(4) ¹[20] 12¹ public members to be appointed by the Governor, who shall include: ¹[two physicians] one physician¹ licensed to practice in this State who ¹[have] has¹ expertise in treating patients with rare diseases, ¹[one of whom shall be a pediatrician who provides care to children with rare diseases; a registered professional nurse licensed in this State who has expertise in providing care to patients with rare diseases] and is associated with

1 the research department of an academic institution in this State¹; a
 2 representative of general hospital or hospital system in this State
 3 recommended by the New Jersey Hospital Association; a
 4 representative of federally qualified health center in this State
 5 recommended by the New Jersey Primary Care Association; a
 6 geneticist licensed to practice in this State; a genetic counselor who
 7 has experience in providing services to persons diagnosed with a
 8 rare disease, their families, or their caregivers or care partners; a
 9 representative of the health insurance industry recommended by the
 10 New Jersey Association of Health Plans; ¹**【a pharmacist licensed to**
 11 **practice in this State who has experience with persons with a rare**
 12 **disease;】**¹ a representative of the ¹biotechnology industry or¹
 13 pharmaceutical industry who has expertise in rare diseases
 14 recommended by ¹**【the HealthCare Institute of New Jersey】** BIO
 15 NJ¹; a ¹**【representative of the biotechnology industry】** pharmacist
 16 licensed in this State¹ who ¹**【is】**¹ has expertise in rare diseases
 17 ¹**【recommended by BIO NJ】**¹; a representative of the medical
 18 technology industry who has expertise in rare diseases ¹and is
 19 recommended by the HealthCare Institute of New Jersey¹; ¹**【a**
 20 **representative of the Rutgers Biomedical and Health Sciences who**
 21 **is engaged in rare disease research; a representative of the Rowan**
 22 **University Graduate School of Biomedical Sciences who is engaged**
 23 **in rare disease research; two representatives】** one representative¹ of
 24 ¹a¹ rare disease patient advocacy ¹**【organizations】** organization¹;
 25 ¹**【two persons】** one person¹, age 18 years or older, who ¹**【have】**
 26 has¹ a rare disease; and ¹**【two caregivers】** one caregiver¹ or care
 27 ¹**【partners】** partner¹ for a patient or partner with a rare disease¹;
 28 one of who shall be a caregiver for a child with a rare disease¹.

29 b. Public members of the advisory council shall serve for a term
 30 of three years, except that of the initial appointments, ¹**【seven】**
 31 ²**【four¹】** five² public members shall serve for one year, ¹**【seven】**
 32 ²**【four¹】** five² public members shall serve for two years, and ¹**【six】**
 33 ²**【four¹】** six² public members shall serve for three years. Vacancies
 34 in the membership of the council shall be filled in the same manner
 35 as the original appointments were made. The public members of
 36 the council shall serve without compensation but may be
 37 reimbursed for traveling and other miscellaneous expenses
 38 necessary to perform their duties within the limits of funds made
 39 available to the council for its purposes.

40 c. The advisory council shall organize as soon as practicable
 41 after the appointment of ¹a majority of¹ its ¹public¹ members, and
 42 the Governor shall select a chairperson and vice-chairperson from
 43 among its members. The chairperson shall appoint a secretary who
 44 need not be a member of the council.

45 d. The advisory council shall meet a minimum of three times a
 46 year but may meet more often at the call of its chair. The council

1 may hold hearings at the times and in the places it deems
2 appropriate and necessary to fulfill its charge. The council shall be
3 entitled to call to its assistance, and avail itself of the services of the
4 employees of, any State, county, or municipal department, board,
5 bureau, commission, or agency as it may require and as may be
6 available to it for its purposes.

7 e. ¹~~【The Department of Health shall provide staff services to~~
8 ~~the advisory council】~~ The Department of Health shall maintain
9 oversight of the advisory council and may delegate the
10 administration thereof to a State research university or institution
11 with expertise in either the clinical treatment of rare disease
12 patients, research of rare diseases, or health care policy pertaining
13 to rare disease patients. The Department of Health may issue a
14 request, within 180 days after the effective date of this act, for
15 proposals for a location for the advisory council to operate and for
16 staff and resources to support the operations of the council. The
17 Department of Health shall provide staff services to the advisory
18 council if the proposals submitted to the department are not
19 sufficient to meet the needs of the council¹.

20
21 3. The purpose of the advisory council shall be to:

22 a. act as the advisory body on rare diseases to the Legislature
23 and State departments, agencies, commissions, authorities, and
24 private agencies that provide services to, or are charged with the
25 care of, persons with rare diseases;

26 b. conduct a thorough and comprehensive study of all issues
27 relating to the quality ¹~~【and cost-effectiveness】~~¹ of ¹~~【,】~~¹ and access
28 to ¹~~【,】~~¹ treatment and services provided to persons with rare
29 diseases in this State, including the link between rare diseases and
30 the COVID-19 pandemic, and to develop policy recommendations
31 on those issues;

32 c. ²~~【establish and implement a repository of】~~ develop
33 recommendations for² best practice standards ²~~【to share with health~~
34 ~~care providers that will ensure they are adequately informed of】~~
35 encompassing² the most effective strategies for recognizing and
36 treating rare diseases in New Jersey;

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

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

41 f. evaluate and make recommendations to improve:

42 (1) the State's Newborn Screening Program in the Department of
43 Health; and

44 (2) State Medicaid coverage for approved treatments and
45 medications for patients with a rare disease;

1 g. research and make policy recommendations to the
2 Legislature on access to health insurance specialists and other
3 needed services for patients with a rare disease; and

4 h. identify, with assistance from the public, additional research
5 topics on rare disease to inform future studies the council may
6 conduct.

7
8 ²**[4.** The advisory council shall apply for, and accept, any grant
9 of money from the federal government, private foundations, or
10 other sources, which may be available for programs related to rare
11 diseases.]²

12
13 ²**[5.]** 4.² The advisory council shall report to the Governor
14 and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the
15 Legislature, no later than December 31st, on a biennial basis,
16 starting in the second year next following the enactment of this act,
17 on the activities of the advisory council and its findings and
18 recommendations on issues relating to the quality of, and access to,
19 treatment and services for persons with rare diseases in this State.

20
21 ²**[6.]** 5.² The Commissioner of Health, pursuant to the
22 "Administrative Procedures Act," P.L.1968, c.410 (C.52:14B-
23 1 et seq.) ²**[shall]** may² adopt rules and regulations necessary to
24 effectuate the purposes of this act.

25
26 ²**[7.]** 6.² This act shall take effect immediately.