

[First Reprint]

**SENATE, No. 2682**

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**STATE OF NEW JERSEY**  
**219th LEGISLATURE**

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INTRODUCED JULY 6, 2020

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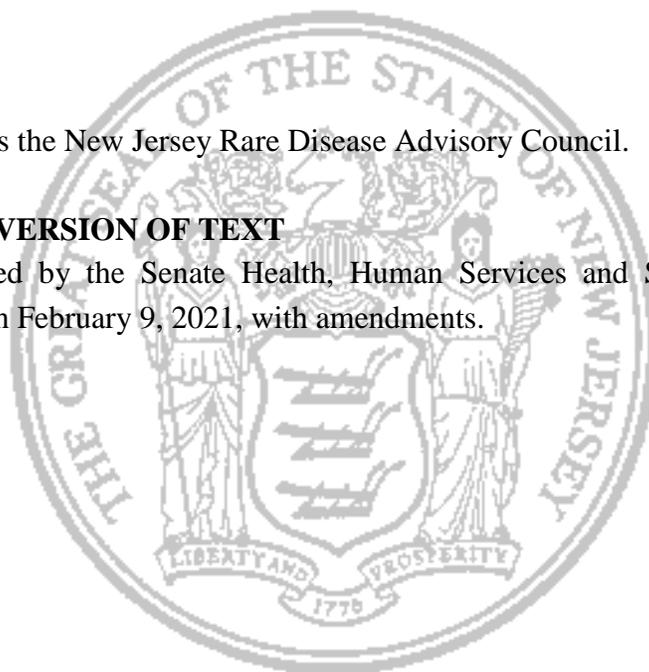
**Senators Singer, Pou, Assemblymen DePhillips, Giblin, Assemblywomen Vainieri Huttle, Murphy and Assemblyman Zwicker**

**SYNOPSIS**

Establishes the New Jersey Rare Disease Advisory Council.

**CURRENT VERSION OF TEXT**

As reported by the Senate Health, Human Services and Senior Citizens Committee on February 9, 2021, with amendments.



**(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 million  
11 Americans;

12 b. The exact cause for many rare diseases remains unknown.  
13 However, 80 <sup>1</sup>**[%]** percent<sup>1</sup> of rare diseases are genetic in origin and  
14 can be linked to mutations in a single gene or in multiple genes which  
15 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 the  
24 issues that affect persons with rare diseases in the State. Many people  
25 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, medical  
31 testing sites, and hospitals more often than most, their risk of exposure  
32 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 health  
37 aides, and because of the social distancing and quarantining, the  
38 pandemic puts them at risk of not having the support they need in  
39 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 to  
43 be done in the search for new therapeutics and in understanding the  
44 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:

<sup>1</sup>Senate SHH committee amendments adopted February 9, 2021.

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

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

14 a. The advisory council shall consist of <sup>1</sup>~~30~~ 20<sup>1</sup> members as  
15 follows:

16 (1) the Commissioners of Banking and Insurance, <sup>1</sup>~~Children and~~  
17 Families, Environmental Protection,<sup>1</sup> Health, Human Services, and  
18 the Executive Director of the New Jersey Office on Minority and  
19 Multicultural Health, or their designees, as ex officio members;

20 (2) two members of the Senate, one of whom is appointed by the  
21 President of the Senate, and one of whom is appointed by the Minority  
22 Leader of the Senate;

23 (3) two members of the General Assembly, one of whom is  
24 appointed by the Speaker of the General Assembly, and one of whom  
25 is appointed by the Minority Leader of the General Assembly; and

26 (4) <sup>1</sup>~~20~~ 12<sup>1</sup> public members to be appointed by the Governor, who  
27 shall include: <sup>1</sup>~~two physicians~~ one physician<sup>1</sup> licensed to practice in  
28 this State who <sup>1</sup>~~have~~ has<sup>1</sup> expertise in treating patients with rare  
29 diseases, <sup>1</sup>~~one of whom shall be a pediatrician who provides care to~~  
30 children with rare diseases; a registered professional nurse licensed in  
31 this State who has expertise in providing care to patients with rare  
32 diseases] and is associated with the research department of an  
33 academic institution in this State<sup>1</sup>; a representative of general hospital  
34 or hospital system in this State recommended by the New Jersey  
35 Hospital Association; a representative of federally qualified health  
36 center in this State recommended by the New Jersey Primary Care  
37 Association; a geneticist licensed to practice in this State; a genetic  
38 counselor who has experience in providing services to persons  
39 diagnosed with a rare disease, their families, or their caregivers or care  
40 partners; a representative of the health insurance industry  
41 recommended by the New Jersey Association of Health Plans; <sup>1</sup>~~a~~  
42 pharmacist licensed to practice in this State who has experience with  
43 persons with a rare disease;]<sup>1</sup> a representative of the <sup>1</sup>biotechnology  
44 industry or<sup>1</sup> pharmaceutical industry who has expertise in rare diseases  
45 recommended by <sup>1</sup>~~the HealthCare Institute of New Jersey~~ BIO NJ<sup>1</sup>;  
46 a <sup>1</sup>~~representative of the biotechnology industry~~ pharmacist licensed

1 in this State<sup>1</sup> who <sup>1</sup>**is**<sup>1</sup> has expertise in rare diseases <sup>1</sup>**recommended**  
2 **by BIO NJ**<sup>1</sup>; a representative of the medical technology industry who  
3 has expertise in rare diseases <sup>1</sup>and is recommended by the HealthCare  
4 Institute of New Jersey<sup>1</sup>; <sup>1</sup>**a representative of the Rutgers Biomedical**  
5 **and Health Sciences who is engaged in rare disease research; a**  
6 **representative of the Rowan University Graduate School of**  
7 **Biomedical Sciences who is engaged in rare disease research; two**  
8 **representatives** <sup>1</sup>one representative<sup>1</sup> of <sup>1</sup>a<sup>1</sup> rare disease patient  
9 advocacy <sup>1</sup>**organizations** <sup>1</sup>organization<sup>1</sup>; <sup>1</sup>**two persons** <sup>1</sup>one  
10 person<sup>1</sup>, age 18 years or older, who <sup>1</sup>**have** <sup>1</sup>has<sup>1</sup> a rare disease; and  
11 <sup>1</sup>**two caregivers** <sup>1</sup>one caregiver<sup>1</sup> or care <sup>1</sup>**partners** <sup>1</sup>partner<sup>1</sup> for a  
12 patient or partner with a rare disease<sup>1</sup>; <sup>1</sup>one of who shall be a caregiver  
13 for a child with a rare disease<sup>1</sup>.

14 b. Public members of the advisory council shall serve for a term  
15 of three years, except that of the initial appointments, <sup>1</sup>**seven** <sup>1</sup>four<sup>1</sup>  
16 public members shall serve for one year, <sup>1</sup>**seven** <sup>1</sup>four<sup>1</sup> public  
17 members shall serve for two years, and <sup>1</sup>**six** <sup>1</sup>four<sup>1</sup> public members  
18 shall serve for three years. Vacancies in the membership of the  
19 council shall be filled in the same manner as the original appointments  
20 were made. The public members of the council shall serve without  
21 compensation but may be reimbursed for traveling and other  
22 miscellaneous expenses necessary to perform their duties within the  
23 limits of funds made available to the council for its purposes.

24 c. The advisory council shall organize as soon as practicable after  
25 the appointment of <sup>1</sup>a majority of<sup>1</sup> its <sup>1</sup>public<sup>1</sup> members, and the  
26 Governor shall select a chairperson and vice-chairperson from among  
27 its members. The chairperson shall appoint a secretary who need not  
28 be a member of the council.

29 d. The advisory council shall meet a minimum of three times a  
30 year but may meet more often at the call of its chair. The council may  
31 hold hearings at the times and in the places it deems appropriate and  
32 necessary to fulfill its charge. The council shall be entitled to call to  
33 its assistance, and avail itself of the services of the employees of, any  
34 State, county, or municipal department, board, bureau, commission, or  
35 agency as it may require and as may be available to it for its purposes.

36 e. <sup>1</sup>**The Department of Health shall provide staff services to the**  
37 **advisory council** <sup>1</sup>The Department of Health shall maintain  
38 oversight of the advisory council and may delegate the  
39 administration thereof to a State research university or institution  
40 with expertise in either the clinical treatment of rare disease  
41 patients, research of rare diseases, or health care policy pertaining  
42 to rare disease patients. The Department of Health may issue a  
43 request, within 180 days after the effective date of this act, for  
44 proposals for a location for the advisory council to operate and for  
45 staff and resources to support the operations of the council. The  
46 Department of Health shall provide staff services to the advisory

1 council if the proposals submitted to the department are not  
2 sufficient to meet the needs of the council<sup>1</sup>.

3

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

5 a. act as the advisory body on rare diseases to the Legislature and  
6 State departments, agencies, commissions, authorities, and private  
7 agencies that provide services to, or are charged with the care of,  
8 persons with rare diseases;

9 b. conduct a thorough and comprehensive study of all issues  
10 relating to the quality <sup>1</sup>[and cost-effectiveness]<sup>1</sup> of <sup>1</sup>[,]<sup>1</sup> and access  
11 to<sup>1</sup>[,]<sup>1</sup> treatment and services provided to persons with rare diseases  
12 in this State, including the link between rare diseases and the COVID-  
13 19 pandemic, and to develop policy recommendations on those issues;

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

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

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

22 f. evaluate and make recommendations to improve:

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

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

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

30 h. identify, with assistance from the public, additional research  
31 topics on rare disease to inform future studies the council may  
32 conduct.

33

34 4. The advisory council shall apply for, and accept, any grant of  
35 money from the federal government, private foundations, or other  
36 sources, which may be available for programs related to rare  
37 diseases.

38

39 5. The advisory council shall report to the Governor and,  
40 pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the  
41 Legislature, no later than December 31st, on a biennial basis,  
42 starting in the second year next following the enactment of this act,  
43 on the activities of the advisory council and its findings and  
44 recommendations on issues relating to the quality of, and access to,  
45 treatment and services for persons with rare diseases in this State.

46

47 6. The Commissioner of Health, pursuant to the "Administrative  
48 Procedures Act," P.L.1968, c.410 (C.52:14B-1 et seq.) shall adopt

1 rules and regulations necessary to effectuate the purposes of this  
2 act.

3

4 7. This act shall take effect immediately.