

[First Reprint]

ASSEMBLY, No. 4016

STATE OF NEW JERSEY
219th LEGISLATURE

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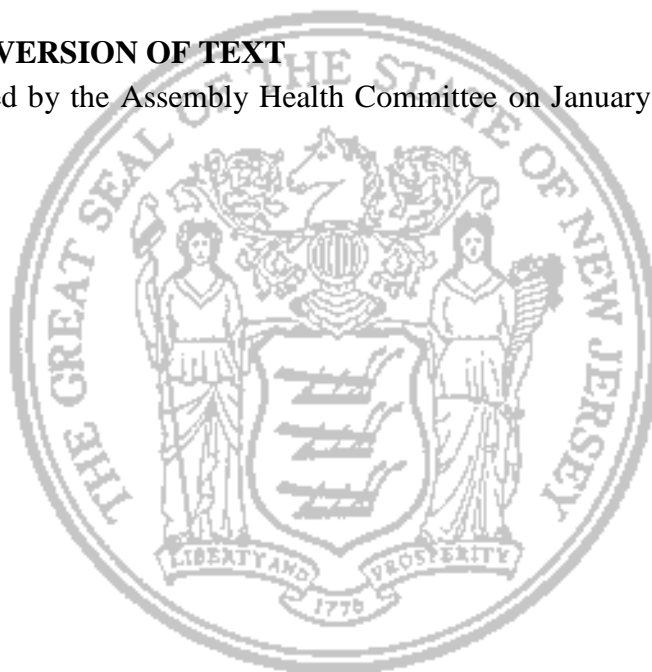
**Assemblymen DePhillips, Giblin, Assemblywomen Vainieri Huttle,
Murphy and Assemblyman Zwicker**

SYNOPSIS

Establishes the New Jersey Rare Disease Advisory Council.

CURRENT VERSION OF TEXT

As reported by the Assembly Health Committee on January 13, 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 ¹**[%]** percent¹ 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:

¹Assembly AHE committee amendments adopted January 13, 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 ¹~~30~~ 20¹ members as
15 follows:

16 (1) the Commissioners of Banking and Insurance, ¹~~Children and~~
17 Families, Environmental Protection,¹ 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) ¹~~20~~ 12¹ public members to be appointed by the Governor,
27 who shall include: ¹~~two physicians~~ one physician¹ licensed to
28 practice in this State who ¹~~have~~ has¹ expertise in treating patients
29 with rare diseases, ¹~~one of whom shall be a pediatrician who provides~~
30 care to children with rare diseases; a registered professional nurse
31 licensed in this State who has expertise in providing care to patients
32 with rare diseases] and is associated with the research department of
33 an academic institution in this State¹; a representative of general
34 hospital or hospital system in this State recommended by the New
35 Jersey Hospital Association; a representative of federally qualified
36 health center in this State recommended by the New Jersey Primary
37 Care Association; a geneticist licensed to practice in this State; a
38 genetic 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; ¹~~a~~
42 pharmacist licensed to practice in this State who has experience with
43 persons with a rare disease;]¹ a representative of the ¹biotechnology
44 industry or¹ pharmaceutical industry who has expertise in rare diseases
45 recommended by ¹~~the HealthCare Institute of New Jersey~~ BIO NJ¹;
46 a ¹~~representative of the biotechnology industry~~ pharmacist licensed

1 in this State¹ who ~~is~~¹ has expertise in rare diseases ~~recommended~~
2 ~~by BIO NJ~~¹; a representative of the medical technology industry who
3 has expertise in rare diseases and is recommended by the HealthCare
4 Institute of New Jersey¹; ~~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~~ one representative¹ of a¹ rare disease patient
9 advocacy ~~organizations~~ organization¹; ~~two persons~~ one
10 person¹, age 18 years or older, who ~~have~~ has¹ a rare disease; and
11 ~~two caregivers~~ one caregiver¹ or care ~~partners~~ partner¹ for a
12 patient or partner with a rare disease¹; ~~one of who shall be a caregiver~~
13 ~~for a child with a rare disease~~¹.

14 b. Public members of the advisory council shall serve for a term
15 of three years, except that of the initial appointments, ~~seven~~ four¹
16 public members shall serve for one year, ~~seven~~ four¹ public
17 members shall serve for two years, and ~~six~~ four¹ public members
18 shall serve for three years. Vacancies in the membership of the council
19 shall be filled in the same manner as the original appointments were
20 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 a majority of¹ its public¹ 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. ~~The Department of Health shall provide staff services to the~~
37 ~~advisory council~~ 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 council¹.

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 ¹[and cost-effectiveness]¹ of ¹[,]¹ and access
11 to¹[,]¹ 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
35 of money from the federal government, private foundations, or
36 other 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.

A4016 [1R] DANCER, BENSON

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1 6. The Commissioner of Health, pursuant to the
2 "Administrative Procedures Act," P.L.1968, c.410 (C.52:14B-1 et
3 seq.) shall adopt rules and regulations necessary to effectuate the
4 purposes of this act.

5

6 7. This act shall take effect immediately.