

Title 26.
Chapter 2AA.
(Rename)
Reflex
Sympathetic
Dystrophy
Syndrome
and Rare Diseases
§§1-4
C.26:2AA-7 to
26:2AA-10
§5
Note

P.L. 2021, CHAPTER 135, *approved June 30, 2021*
Senate, No. 2682 (*Second Reprint*)

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;

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.

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

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

13 g. Researchers have made considerable progress in developing
14 diagnostic tools and treatment protocols for rare diseases and
15 discovering methods of prevention. However, much more remains
16 to be done in the search for new therapeutics and in understanding
17 the link between rare disease and pandemics, and

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

26

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

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

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

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

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

11 (4) ¹**[20]** ¹² public members to be appointed by the Governor,
 12 who shall include: ¹**[two physicians]** one physician¹ licensed to
 13 practice in this State who ¹**[have]** has¹ expertise in treating patients
 14 with rare diseases, ¹**[one of whom shall be a pediatrician who**
 15 **provides care to children with rare diseases; a registered**
 16 **professional nurse licensed in this State who has expertise in**
 17 **providing care to patients with rare diseases]** and is associated with
 18 the research department of an academic institution in this State¹; a
 19 representative of general hospital or hospital system in this State
 20 recommended by the New Jersey Hospital Association; a
 21 representative of federally qualified health center in this State
 22 recommended by the New Jersey Primary Care Association; a
 23 geneticist licensed to practice in this State; a genetic counselor who
 24 has experience in providing services to persons diagnosed with a
 25 rare disease, their families, or their caregivers or care partners; a
 26 representative of the health insurance industry recommended by the
 27 New Jersey Association of Health Plans; ¹**[a pharmacist licensed to**
 28 **practice in this State who has experience with persons with a rare**
 29 **disease;]** ¹ a representative of the ¹biotechnology industry or¹
 30 pharmaceutical industry who has expertise in rare diseases
 31 recommended by ¹**[the HealthCare Institute of New Jersey]** BIO
 32 NJ¹; a ¹**[representative of the biotechnology industry]** pharmacist
 33 licensed in this State¹ who ¹**[is]**¹ has expertise in rare diseases
 34 ¹**[recommended by BIO NJ]**¹; a representative of the medical
 35 technology industry who has expertise in rare diseases ¹and is
 36 recommended by the HealthCare Institute of New Jersey¹; ¹**[a**
 37 **representative of the Rutgers Biomedical and Health Sciences who**
 38 **is engaged in rare disease research; a representative of the Rowan**
 39 **University Graduate School of Biomedical Sciences who is engaged**
 40 **in rare disease research; two representatives]** one representative¹ of
 41 ¹a¹ rare disease patient advocacy ¹**[organizations]** organization¹;
 42 ¹**[two persons]** one person¹, age 18 years or older, who ¹**[have]**
 43 has¹ a rare disease; and ¹**[two caregivers]** one caregiver¹ or care
 44 ¹**[partners]** partner¹ for a patient or partner with a rare disease¹;
 45 one of who shall be a caregiver for a child with a rare disease¹.

1 b. Public members of the advisory council shall serve for a term
2 of three years, except that of the initial appointments, ¹~~【seven】~~
3 ²~~【four¹】~~ five² public members shall serve for one year, ¹~~【seven】~~
4 ²~~【four¹】~~ five² public members shall serve for two years, and ¹~~【six】~~
5 ²~~【four¹】~~ six² public members shall serve for three years. Vacancies
6 in the membership of the council shall be filled in the same manner
7 as the original appointments were made. The public members of
8 the council shall serve without compensation but may be
9 reimbursed for traveling and other miscellaneous expenses
10 necessary to perform their duties within the limits of funds made
11 available to the council for its purposes.

12 c. The advisory council shall organize as soon as practicable
13 after the appointment of ¹a majority of¹ its ¹public¹ members, and
14 the Governor shall select a chairperson and vice-chairperson from
15 among its members. The chairperson shall appoint a secretary who
16 need not be a member of the council.

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

25 e. ¹~~【The Department of Health shall provide staff services to~~
26 ~~the advisory council】~~ The Department of Health shall maintain
27 oversight of the advisory council and may delegate the
28 administration thereof to a State research university or institution
29 with expertise in either the clinical treatment of rare disease
30 patients, research of rare diseases, or health care policy pertaining
31 to rare disease patients. The Department of Health may issue a
32 request, within 180 days after the effective date of this act, for
33 proposals for a location for the advisory council to operate and for
34 staff and resources to support the operations of the council. The
35 Department of Health shall provide staff services to the advisory
36 council if the proposals submitted to the department are not
37 sufficient to meet the needs of the council¹.
38

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

40 a. act as the advisory body on rare diseases to the Legislature
41 and State departments, agencies, commissions, authorities, and
42 private agencies that provide services to, or are charged with the
43 care of, persons with rare diseases;

44 b. conduct a thorough and comprehensive study of all issues
45 relating to the quality ¹~~【and cost-effectiveness】~~¹ of ¹~~【,】~~¹ and access
46 to ¹~~【,】~~¹ treatment and services provided to persons with rare
47 diseases in this State, including the link between rare diseases and

1 the COVID-19 pandemic, and to develop policy recommendations
2 on those issues;

3 c. ²~~establish and implement a repository of~~ develop
4 recommendations for² best practice standards ²~~to share with health~~
5 care providers that will ensure they are adequately informed of]
6 encompassing² the most effective strategies for recognizing and
7 treating rare diseases in New Jersey;

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

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

12 f. evaluate and make recommendations to improve:

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

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

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

20 h. identify, with assistance from the public, additional research
21 topics on rare disease to inform future studies the council may
22 conduct.

23

24 ²~~4.~~ The advisory council shall apply for, and accept, any grant
25 of money from the federal government, private foundations, or
26 other sources, which may be available for programs related to rare
27 diseases.]²

28

29 ²~~5.] 4.~~² The advisory council shall report to the Governor
30 and, pursuant to section 2 of P.L.1991, c.164 (C.52:14-19.1), to the
31 Legislature, no later than December 31st, on a biennial basis,
32 starting in the second year next following the enactment of this act,
33 on the activities of the advisory council and its findings and
34 recommendations on issues relating to the quality of, and access to,
35 treatment and services for persons with rare diseases in this State.

36

37 ²~~6.] 5.~~² The Commissioner of Health, pursuant to the
38 "Administrative Procedures Act," P.L.1968, c.410 (C.52:14B-
39 1 et seq.) ²~~shall~~ may² adopt rules and regulations necessary to
40 effectuate the purposes of this act.

41

42 ²~~7.] 6.~~² This act shall take effect immediately.

43

44

45

46

47 Establishes the New Jersey Rare Disease Advisory Council.