

## CHAPTER 135

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

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

C.26:2AA-7 Findings, declarations relative to orphan disease.

1. The Legislature finds and declares:

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

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

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

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

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

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

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

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 research in the development of new treatments for rare diseases.

C.26:2AA-8 New Jersey Rare Disease Advisory Council, established.

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 20 members as follows:

(1) the Commissioners of Banking and Insurance, 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 public, one of whom shall be appointed by the Governor upon recommendation of the President of the Senate, and one of whom shall be appointed by the Minority Leader of the Senate which 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 diseases;

(3) two members of the public, one of whom shall be appointed by the Governor upon recommendation of the Speaker of the General Assembly, and one of whom shall be appointed by the Minority Leader of the General Assembly which 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 diseases; and

(4) 12 public members to be appointed by the Governor, who shall include: one physician licensed to practice in this State who has expertise in treating patients with rare diseases, and is associated with the research department of an academic institution in this State; a representative of general hospital or hospital system in this State recommended by the New Jersey Hospital Association; a representative of federally qualified health center in this State recommended by the New Jersey Primary Care Association; a geneticist licensed to practice in this State; a genetic counselor who has experience in providing services to persons diagnosed with a rare disease, their families, or their caregivers or care partners; a representative of the health insurance industry recommended by the New Jersey Association of Health Plans; a representative of the biotechnology industry or pharmaceutical industry who has expertise in rare diseases recommended by BIO NJ; a pharmacist licensed in this State who has expertise in rare diseases; a representative of the medical technology industry who has expertise in rare diseases and is recommended by the HealthCare Institute of New Jersey; one representative of a rare disease patient advocacy organization; one person, age 18 years or older, who has a rare disease; and one caregiver or care partner for a patient or partner with a rare disease.

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

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

d. The advisory council shall meet a minimum of three times a year but may meet more often at the call of its chair. The council may hold hearings at the times and in the places it deems appropriate and necessary to fulfill its charge. The council shall be entitled to call to

its assistance, and avail itself of the services of the employees of, any State, county, or municipal department, board, bureau, commission, or agency as it may require and as may be available to it for its purposes.

e. The Department of Health shall maintain oversight of the advisory council and may delegate the administration thereof to a State research university or institution with expertise in either the clinical treatment of rare disease patients, research of rare diseases, or health care policy pertaining to rare disease patients. The Department of Health may issue a request, within 180 days after the effective date of this act, for proposals for a location for the advisory council to operate and for staff and resources to support the operations of the council. The Department of Health shall provide staff services to the advisory council if the proposals submitted to the department are not sufficient to meet the needs of the council.

C.26:2AA-9 Purpose of council.

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

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

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

c. develop recommendations for best practice standards encompassing the most effective strategies for recognizing and treating rare diseases in New Jersey;

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

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

f. evaluate and make recommendations to improve:

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

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

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

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

C.26:2AA-10 Report to Governor, Legislature.

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

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

6. This act shall take effect immediately.

Approved June 30, 2021.