

# STATE OF NEW YORK

1296--A

2025-2026 Regular Sessions

## IN ASSEMBLY

January 9, 2025

Introduced by M. of A. PAULIN, SAYEGH, LUCAS, DeSTEFANO -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee

AN ACT to amend the public health law, in relation to establishing the rare disease advisory council

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

1 Section 1. Title 2-F of article 2 of the public health law is amended  
2 by adding a new section 245 to read as follows:

3 § 245. Rare disease advisory council. 1. For the purposes of this  
4 section, "rare disease" means any disease or condition which affects  
5 less than two hundred thousand persons in the United States.

6 2. a. There shall be established within the department a rare disease  
7 advisory council to identify best practices, raise awareness regarding  
8 rare diseases, evaluate barriers to access to care, and to make recom-  
9 mendations to the legislature and the governor.

10 b. An existing body or previously convened body, whether dissolved or  
11 not, may be repurposed to meet the requirements of this section.

12 3. a. The council shall consist of at least fifteen members, including  
13 the commissioner or such commissioner's designee, the superintendent of  
14 financial services or such superintendent's designee, and nine members  
15 to be appointed by the governor. Two members shall be appointed by the  
16 speaker of the assembly, two members shall be appointed by the temporary  
17 president of the senate. Membership of such council shall consist of  
18 residents of the state of New York and include, but not be limited to,  
19 individuals with expertise in rare diseases, including physicians, nurs-  
20 es and other health care professionals with experience researching,  
21 diagnosing or treating rare diseases; members of the scientific communi-  
22 ty engaged in rare disease research; representatives from the health  
23 insurance industry; a representative of the biopharma industry; individ-

EXPLANATION--Matter in italics (underscored) is new; matter in brackets  
[-] is old law to be omitted.

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1 uals who have a rare disease and caregivers of a person with a rare  
2 disease; and representatives of rare disease patient organizations.

3 b. The council shall prioritize the representation of patient and  
4 caregiver voices while ensuring no single disease state is dispropor-  
5 tionately represented.

6 c. The members of the rare disease advisory council shall receive no  
7 compensation for their role on the council, but shall be allowed their  
8 actual and necessary expenses incurred in the performance of their  
9 duties as council members.

10 d. Time served on a previously convened body shall not count towards  
11 the term of office for membership on the rare disease advisory council.

12 4. a. Council members shall serve up to two four year terms commencing  
13 from the date of their appointment. Members may serve beyond their term  
14 expiration at the pleasure of the appointing authority.

15 b. If a vacancy occurs for an unexpired term, the council, by a major-  
16 ity vote, shall fill such vacancy in a timely manner and in compliance  
17 with the requirements set forth in subdivisions two and three of this  
18 section.

19 c. The council shall annually elect a chair from amongst its members.  
20 A chair is eligible for reelection.

21 5. a. The initial meeting of the council shall occur within the first  
22 one hundred eighty days after the effective date of this section. The  
23 council shall meet at least once per quarter in person or via an online  
24 meeting platform as determined by the chair. Such meetings shall comply  
25 with article seven of the public officers law.

26 b. The council shall provide opportunities for the public to hear  
27 updates and provide public comment and create and maintain a public  
28 website or utilize an existing website where meeting minutes, notices of  
29 upcoming meetings, and public comments can be submitted.

30 6. The council's focus shall include, but not be limited to:

31 a. identifying best practices that could improve the awareness of rare  
32 diseases and referral of people with potential rare diseases to special-  
33 ists;

34 b. evaluating barriers to treatment, including financial barriers on  
35 access to care;

36 c. establishing best practices and protocols to include in state plan-  
37 ning related to natural disasters, public health emergencies or other  
38 emergency declarations to enable the continuity of care for rare disease  
39 patients and ensure safeguards against discrimination for rare disease  
40 patients are in place;

41 d. convening public hearings, making inquiries, and soliciting  
42 comments from the general public in the state to assist the council with  
43 a first-year landscape or survey of the needs of rare disease patients,  
44 caregivers, and providers in the state;

45 e. providing testimony and comments on pending legislation and regu-  
46 lations before the legislature and other state agencies that impact New  
47 York's rare disease community;

48 f. consulting with experts on rare diseases to develop policy recom-  
49 mendations to improve patient access to, and quality of, rare disease  
50 specialists, affordable and comprehensive health care coverage, relevant  
51 diagnostics, timely treatment, and other needed services;

52 g. advising the Medicaid drug utilization review board in their review  
53 of products or medications for the treatment of rare and orphan  
54 diseases, and drugs or biological products within the emerging fields of  
55 personalized medicine and non-inheritable gene editing therapeutics.  
56 All advisory council recommendations shall be presented in writing to

1 members of such board and explained to members of such board by repre-  
2 sentatives of the advisory council during their public meetings. The  
3 advisory council has no authority on any matter relating to Medicaid,  
4 nor may it require such board to follow its recommendations; and

5 h. any other priorities as identified by the department or a majority  
6 of the council.

7 7. a. The council, in consultation with the department shall prepare a  
8 written report summarizing its findings and recommendations from the  
9 council which shall include a list of existing, publicly accessible  
10 resources on research, diagnosis, treatment, coverage options and educa-  
11 tion relating to rare diseases.

12 b. This report shall be submitted to the governor, the speaker of the  
13 assembly, the minority leader of the assembly, the temporary president  
14 of the senate, the minority leader of the senate, the senate chair of  
15 the committee on health, and the chair of the assembly committee on  
16 health, one year following the effective date of this section and by  
17 each January thirtieth thereafter and shall be posted on the depart-  
18 ment's website.

19 c. Any recommendations of the council shall be posted on the depart-  
20 ment's website and incorporated into any future "Prevention Agenda: New  
21 York State's Health Improvement Plan". The recommendation shall also be  
22 shared at a public meeting of the New York state health equity council  
23 for their consideration.

24 8. The council may identify public, private, and other available fund-  
25 ing sources and may accept and utilize funds from such sources to imple-  
26 ment the provisions of this section, including, but not limited to,  
27 state funds appropriated for rare disease research, treatment, educa-  
28 tion, programming, and related activities.

29 § 2. This act shall take effect on the thirtieth day after it shall  
30 have become a law. Effective immediately, the addition, amendment and/or  
31 repeal of any rule or regulation necessary for the implementation of  
32 this act on its effective date are authorized to be made and completed  
33 on or before such effective date.