

STATE OF NEW YORK

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IN ASSEMBLY

January 9, 2025

Introduced by M. of A. PAULIN, SAYEGH, LUCAS, DeSTEFANO, McDONALD, OTIS, WEPRIN, PIROZZOLO, NORBER, NOVAKHOV, CHANG, ALVAREZ, DINOWITZ, DILAN, ROSENTHAL, WIEDER, MANKTELOW, MORINELLO, ANGELINO, KASSAY, COLTON, LEMONDES, GRIFFIN, SEMPOLINSKI -- read once and referred to the Committee on Health -- committee discharged, bill amended, ordered reprinted as amended and recommitted to said committee -- ordered to a third reading, amended and ordered reprinted, retaining its place on the order of third reading

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 seventeen members, includ-
13 ing the commissioner or such commissioner's designee, the superintendent
14 of financial services or such superintendent's designee, and nine
15 members to be appointed by the governor. Two members shall be appointed
16 by the speaker of the assembly, two members shall be appointed by the
17 temporary president of the senate, one member shall be appointed by the
18 assembly minority leader, and one member shall be appointed by the
19 senate minority leader. Membership of such council shall consist of

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

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1 residents of the state of New York and include, but not be limited to,
2 individuals with expertise in rare diseases, including physicians, nurs-
3 es and other health care professionals with experience researching,
4 diagnosing or treating rare diseases; members of the scientific communi-
5 ty engaged in rare disease research; representatives from the health
6 insurance industry; a representative of the biopharma industry; individ-
7 uals who have a rare disease and caregivers of a person with a rare
8 disease; and representatives of rare disease patient organizations.

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

12 c. The members of the rare disease advisory council shall receive no
13 compensation for their role on the council, but shall be allowed their
14 actual and necessary expenses incurred in the performance of their
15 duties as council members.

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

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

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

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

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

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

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

37 a. identifying best practices that could improve the awareness of rare
38 diseases and referral of people with potential rare diseases to special-
39 ists;

40 b. evaluating barriers to treatment, including financial barriers on
41 access to care;

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

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

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

54 f. consulting with experts on rare diseases to develop policy recom-
55 mendations to improve patient access to, and quality of, rare disease

1 specialists, affordable and comprehensive health care coverage, relevant
2 diagnostics, timely treatment, and other needed services;

3 g. advising the Medicaid drug utilization review board in their review
4 of products or medications for the treatment of rare and orphan
5 diseases, and drugs or biological products within the emerging fields of
6 personalized medicine and non-inheritable gene editing therapeutics.
7 All advisory council recommendations shall be presented in writing to
8 members of such board and explained to members of such board by repre-
9 sentatives of the advisory council during their public meetings. The
10 advisory council has no authority on any matter relating to Medicaid,
11 nor may it require such board to follow its recommendations; and

12 h. any other priorities as identified by the department or a majority
13 of the council.

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

19 b. This report shall be submitted to the governor, the speaker of the
20 assembly, the minority leader of the assembly, the temporary president
21 of the senate, the minority leader of the senate, the senate chair of
22 the committee on health, and the chair of the assembly committee on
23 health, one year following the effective date of this section and by
24 each January thirtieth thereafter and shall be posted on the depart-
25 ment's website.

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

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

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