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:

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

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

2. a. There shall be established within the department a rare disease advisory council to identify best practices, raise awareness regarding rare diseases, evaluate barriers to access to care, and to make recommendations to the legislature and the governor.

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

3. a. The council shall consist of at least fifteen members, including the commissioner or such commissioner's designee, the superintendent of financial services or such superintendent's designee, and nine members to be appointed by the governor. Two members shall be appointed by the speaker of the assembly, two members shall be appointed by the temporary president of the senate. Membership of such council shall consist of residents of the state of New York and include, but not be limited to, individuals with expertise in rare diseases, including physicians, nurses and other health care professionals with experience researching, diagnosing or treating rare diseases; members of the scientific community engaged in rare disease research; representatives from the health 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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uals who have a rare disease and caregivers of a person with a rare disease; and representatives of rare disease patient organizations.

b. The council shall prioritize the representation of patient and caregiver voices while ensuring no single disease state is disproportionately represented.

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

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

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

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

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

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

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

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

a. identifying best practices that could improve the awareness of rare diseases and referral of people with potential rare diseases to specialists;

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

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

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

e. providing testimony and comments on pending legislation and regulations before the legislature and other state agencies that impact New York's rare disease community;

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

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

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

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

b. This report shall be submitted to the governor, the speaker of the assembly, the minority leader of the assembly, the temporary president of the senate, the minority leader of the senate, the senate chair of the committee on health, and the chair of the assembly committee on health, one year following the effective date of this section and by each January thirtieth thereafter and shall be posted on the department's website.

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

8. The council may identify public, private, and other available funding sources and may accept and utilize funds from such sources to implement the provisions of this section, including, but not limited to, state funds appropriated for rare disease research, treatment, education, programming, and related activities.

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