

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2023

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HOUSE BILL 935

Short Title: Reorganize & Fund Rare Disease Adv. Council. (Public)

Sponsors: Representatives Carney and Lambeth (Primary Sponsors).

For a complete list of sponsors, refer to the North Carolina General Assembly web site.

Referred to: Health, if favorable, Appropriations, if favorable, Rules, Calendar, and Operations of the House

May 1, 2024

A BILL TO BE ENTITLED
AN ACT REVISING THE COMPOSITION AND DUTIES OF THE ADVISORY COUNCIL ON RARE DISEASES; TRANSFERRING THE COUNCIL TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND APPROPRIATING FUNDS TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO COVER THE ADMINISTRATIVE COSTS OF THE COUNCIL.

The General Assembly of North Carolina enacts:

SECTION 1. Part 6 of Article 1B of Chapter 130A of the General Statutes reads as rewritten:

"Part 6. Taylor's Law Establishing the Advisory Council on Rare Diseases.

"§ 130A-33.65. Advisory Council on Rare Diseases; membership; terms; compensation; meetings; quorum.

(a) Short Title. – This Part shall be known as Taylor's Law Establishing the Advisory Council on Rare Diseases.

(a1) Establishment of Advisory Council. – There is established the Advisory Council on Rare Diseases within the School of Medicine of the University of North Carolina at Chapel Hill Department of Health and Human Services to advise the Governor, the Secretary, and the General Assembly on research, diagnosis, treatment, and education relating to rare diseases. This Part shall be known as Taylor's Law Establishing the Advisory Council on Rare Diseases. For purposes of this Part, "rare disease" has the same meaning as provided in 21 U.S.C. § 360bb.

(b) Advisory Council Membership. – The advisory council shall consist of 19 members to be appointed as follows:

(1) ~~Upon the recommendation of the Dean of the School of Medicine of the University of North Carolina at Chapel Hill, the~~ The Secretary shall appoint members to the advisory council as follows: ~~the following 15 members:~~

- a. ~~A physician~~ Two physicians licensed and practicing in this State with experience researching, diagnosing, or treating rare diseases.
- b. ~~A medical researcher with experience conducting research concerning rare diseases.~~
- c. ~~A~~ One registered nurse or advanced practice registered nurse licensed and practicing in the State with experience treating rare diseases.
- d. ~~One rare diseases survivor.~~
- e. ~~One member who represents a rare diseases foundation.~~



- 1 f. ~~One representative—researcher from each—an~~ academic research
2 institution in this State that receives any grant funding for rare diseases
3 research.
- 4 g. ~~One parent of a childhood rare disease survivor.~~
- 5 h. One hospital administrator, or the hospital administrator's designee,
6 representing a hospital in the State that provides care to persons
7 diagnosed with a rare disease.
- 8 i. Two persons age 18 or older who have been diagnosed with a rare
9 disease.
- 10 j. Two persons age 18 or older who are, or were previously, caregivers
11 to a person diagnosed with a rare disease.
- 12 k. One representative of a rare disease patient organization that operates
13 in the State.
- 14 l. One pharmacist licensed and practicing in this State with knowledge
15 and experience regarding drugs used to treat rare diseases.
- 16 m. One representative of the life sciences, biotechnology, or
17 biopharmaceutical industry that either focuses on research efforts
18 related to the development of therapeutic products for persons
19 diagnosed with a rare disease or has demonstratable understanding of
20 the path to commercialization of such products.
- 21 n. Two representatives of a health benefit plan or health insurer, at least
22 one of whom is a representative of a North Carolina Medicaid
23 Managed Care health plan.
- 24 o. One genetic counselor with experience providing services to persons
25 diagnosed with a rare disease or caregivers of persons diagnosed with
26 a rare disease.
- 27 (2) ~~The chairs of the Joint Legislative Oversight Committee on Health and Human~~
28 ~~Services, or the chairs' designees, shall serve on the advisory council. A~~
29 ~~member of the advisory council who is designated by the chairs of the Joint~~
30 ~~Legislative Oversight Committee on Health and Human Services may be a~~
31 ~~member of the General Assembly.~~
- 32 (2a) One member appointed by the President Pro Tempore of the Senate.
- 33 (2b) One member appointed by the Speaker of the House of Representatives.
- 34 (2c) One member appointed by the Governor.
- 35 (3) The Secretary, or the Secretary's designee, shall serve as an ex officio,
36 nonvoting member of the advisory council.
- 37 (c) ~~Members—Length of Terms. – All initial members appointed pursuant to subsection~~
38 ~~(b) of this section to the advisory council shall serve for a term of three years, and no member~~
39 ~~initial member, except for the initial physician members and the initial member representing a~~
40 ~~rare disease patient organization, shall serve more than three consecutive terms. The initial~~
41 ~~physician members and the initial member representing a rare disease patient organization may~~
42 ~~serve for up to four consecutive terms. Thereafter, members appointed by the President Pro~~
43 ~~Tempore of the Senate, the Speaker of the House of Representatives, and the Governor shall~~
44 ~~serve for a term of two years and members appointed by the Secretary shall serve for a term of~~
45 ~~two, three, or four years as determined by the chair of the advisory council.~~
- 46 (c1) Vacancies and Removals. – Any appointment to fill a vacancy on the advisory council
47 created by the resignation, dismissal, death, or disability of a member shall be filled by the
48 appointing authority for the balance of the unexpired term. Each appointing authority may
49 remove any member appointed by that appointing authority for misfeasance, malfeasance, or
50 nonfeasance.

(d) Per Diem and Expenses. – Members of the advisory council shall receive per diem and necessary travel and subsistence expenses in accordance with the provisions of G.S. 138-5 or G.S. 138-6 or travel and subsistence expenses in accordance with the provisions of G.S. 120-3.1, as applicable.

(e) Administrative Support. – All administrative support and other services required by the advisory council shall be provided by the ~~School of Medicine of the University of North Carolina at Chapel Hill~~ Department.

(f) ~~Upon the recommendation of the Dean of the School of Medicine of the University of North Carolina at Chapel Hill,~~ Selection of Chair. – The Secretary shall select the chair of the advisory council from among the members of the council. The chair shall serve in this position until the expiration of his or her term.

(g) ~~The chair shall convene the first meeting of the advisory council no later than October 1, 2015.~~ Meetings and Quorum. – A majority of the council members shall constitute a quorum. A majority vote of a quorum shall be required for any official action of the advisory council. Following the first meeting, the advisory council shall meet at least quarterly. The advisory council may meet more frequently upon the call of the chair or upon the request of a majority of council members.

"§ 130A-33.66. Advisory Council on Rare Diseases; powers and duties; reports.

The advisory council shall have the following powers and duties:

- (1) ~~Advise on coordinating the Governor, the Secretary, and the General Assembly on all of the following:~~
 - a. Coordination of statewide efforts for the to study of the incidence of rare diseases within the State and the status of the rare disease community.
 - b. Coordination of statewide efforts to increase public awareness and understanding of rare diseases.
 - c. Identification of policy issues related to rare diseases and the advancement of policy initiatives related to rare diseases at the State and federal levels.
 - d. The appropriation of State funds to facilitate increased public awareness of and improved treatment for rare diseases.
- (2) Report to the Secretary, the Governor, and the Joint Legislative Oversight Committee on Health and Human Services on behalf of the General Assembly not later than January 1, 2016, and annually thereafter, on the activities of the advisory council and its findings and recommendations regarding rare disease research and care in North Carolina, including any recommendations for statutory changes and amendments to the structure, organization, and powers or duties of the advisory council.
- (3) In consultation with accredited medical schools, accredited schools of public health, and hospitals licensed to operate in the State that provide care to persons diagnosed with a rare disease, develop resources or recommendations regarding quality of and access to treatment and services available within the State for persons diagnosed with a rare disease.
- (4) Advise and consult with the Department, the North Carolina Drug Utilization Review Board, and the Medicaid Preferred Drug List Review Panel in developing recommendations, resources, and programs relating to the diagnosis and treatment of rare diseases.
- (5) Identify additional relevant areas for the advisory council to study and evaluate."

SECTION 2. Effective July 1, 2024, there is appropriated from the General Fund to the Department of Health and Human Services the sum of two hundred fifty thousand dollars

1 (\$250,000) in recurring funds for the 2024-2025 fiscal year to be allocated to cover the
2 administrative costs of the Advisory Council on Rare Diseases authorized by Section 1 of this
3 act.

4 **SECTION 3.** Except as otherwise provided, this act is effective when it becomes
5 law.