



HOUSE BILL 823: Establish Advisory Council on Rare Diseases

2015-2016 General Assembly

Committee:	House Health	Date:	April 27, 2015
Introduced by:	Reps. Carney, Avila, Earle, Bishop	Prepared by:	Theresa Matula
Analysis of:	First Edition		Kristen Harris Committee Counsel

SUMMARY: *House Bill 823 establishes the Advisory Council on Rare Diseases within the Department of Health and Human Resources.*

CURRENT LAW: 21 U.S.C. § 360bb – defines "rare disease or condition" to mean any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug.

BILL ANALYSIS: House Bill 823 establishes the Advisory Council on Rare Diseases within the Department of Health and Human Services (DHHS) to advise the Secretary on research, diagnosis, treatment, and education relating to rare diseases. For purposes of this section, "rare disease" has the same meaning as provided in 21 U.S.C. § 360bb, as amended.

Members - The Advisory Council membership is provided below and members are appointed by the Secretary:

- Up to five physicians licensed and practicing in the State with experience researching, diagnosing, or treating rare diseases.
- A medical researcher with experience conducting research concerning rare diseases.
- A registered nurse or advanced practice registered nurse licensed and practicing in the State with experience treating rare diseases.
- One hospital administrator from each hospital in the State that provides care to persons diagnosed with a rare disease, or a designee of the hospital administrator.
- Two rare disease survivors over the age of 18.
- A caregiver of a pediatric rare disease survivor.
- A representative of the North Carolina Board of Education.
- A representative in the field of biostatistics.
- A representative in the field of public health.
- Up to three representatives of patient based organizations operating within the State.

The members above can serve for a term of three years, and no member shall serve more than two consecutive terms.

Additional Members

- The chairpersons of the Joint Legislative Oversight Committee on Health and Human Services, or the chairpersons' designees, shall be members of the advisory council.

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- The Secretary, or the Secretary's designee, shall be an ex officio, nonvoting member of the advisory council and shall attend all meetings of the advisory council.

Appointments, First Meeting, Chair, Quorum, Per Diem, Administrative Support

- Appointments to the advisory council must be made not later than 30 days after the effective date the bill.
- The Secretary must schedule the first meeting of the advisory council, which shall be held not later than October 1, 2015.
- The members must elect the chairperson of the advisory council from among the members of the council. A majority of the council members will constitute a quorum. A majority vote of a quorum must be required for any official action of the advisory council. The advisory council must meet upon the call of the chairperson or upon the request of a majority of council members.
- 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.
- DHHS provides administrative support and other services required by the advisory council.

Powers and Duties - The advisory council has the following powers and duties:

- Coordinate statewide efforts for the study of the incidence of rare disease within the State and the status of the rare disease community.
- Act as the advisory body on rare diseases to the Secretary on research, diagnosis, treatment, and education relating to rare diseases.
- Coordinate the performance of the advisory council's duties with other rare disease advisory bodies, community based organizations, and other public and private organizations within the State for the purpose of ensuring greater cooperation regarding the research, diagnosis, and treatment of rare diseases between the State and federal agencies, including but not exclusive to, the United States National Institutes of Health (NIH) and the United States Food and Drug Administration (FDA). Such coordination shall require, when appropriate, the following:
 - Disseminating the advisory council's research, identified best practices, and policy recommendations.
 - Utilizing common research collection and dissemination procedures.
- Research and identify priorities relating to the quality and cost effectiveness of, and access to, treatment and services provided to persons with rare diseases in the State; and develop policy recommendations on those issues.
- Identify best practices for rare disease care from other states and at the national level that will improve rare disease care in this State.
- Develop recommendations for effective strategies to raise public awareness of rare diseases in the State.
- Determine recommendations for best practices for ensuring that the public and health care providers are sufficiently informed of the most effective strategies for recognizing and treating rare disease.
- Develop recommendations for effective strategies to aid in determining any genetic or environmental contributors to rare diseases.
- Report to the Joint Legislative Oversight Committee on Health and Human Services.
- Apply for, and accept, any grant of money from the federal government, private foundations, or other sources which may be available for the operation of the advisory council and State programs related to rare diseases.

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Report to Joint Legislative Oversight Committee on Health and Human Services

Not later than January 1, 2016, and annually thereafter, the advisory council shall report to the Joint Legislative Oversight Committee on Health and Human Services on the activities of the advisory council and its findings and recommendations regarding rare disease research and care in North Carolina.

EFFECTIVE DATE: This bill would become effective July 1, 2015.