



HOUSE BILL 823: Establish Advisory Council on Rare Diseases

**This Bill Analysis
reflects the contents
of the bill as it was
presented in
committee.**

2015-2016 General Assembly

Committee:	Senate Health Care	Date:	June 30, 2015
Introduced by:	Reps. Carney, Avila, Earle, Bishop	Prepared by:	Jennifer Mundt
Analysis of:	PCS to First Edition H823-CSTA-14		Committee Staff

SUMMARY: *The Proposed Committee Substitute (PCS) for House Bill 823 would establish the Advisory Council on Rare Diseases within the School of Medicine of the University of North Carolina at Chapel Hill.*

BILL ANALYSIS: The PCS for House Bill 823 would establish the Advisory Council on Rare Diseases (Advisory Council) within the School of Medicine of the University of North Carolina at Chapel Hill to advise the Governor, Secretary of Health and Human Services (Secretary), and the General Assembly on research, diagnosis, treatment, and education relating to rare diseases, as that term is defined under federal law¹. The School of Medicine would provide all administrative support and other services required by the Advisory Council.

The Advisory Council will be comprised of: (i) members with experience or expertise in rare diseases who are appointed by the Secretary, upon the recommendation of the Dean of the School of Medicine; (ii) the chairs of the Joint Legislative Oversight Committee on Health and Human Services (HHS Oversight) or the chairs' designees; and (iii) the Secretary, or the Secretary's designee. Appointments to the Advisory Council must be made no more than 30 days after the effective date of this act. The first meeting of the Advisory Council must be held by October 1, 2015.

The Advisory Council is directed to advise on coordinating statewide efforts for the study of the incidence of rare diseases within the State and the status of the rare disease community. The Advisory Council is directed to the Governor, the Secretary, and HHS Oversight, on behalf of the General Assembly by January 1, 2016, and annually thereafter on its findings and recommendations regarding rare disease research and care in North Carolina, and any recommendations for statutory changes and amendments to the structure, organization, and powers or duties of the Advisory Council.

EFFECTIVE DATE: This act is effective August 1, 2015.

BACKGROUND: According to the National Institutes of Health, there are more than 6,800 rare diseases that affect an estimated 25 to 30 million Americans. Exact causes for many rare diseases are unknown, though for many, the disease can be traced to genetic mutations. Environmental factors can also play a role. Examples of rare diseases include: cystic fibrosis; Huntington's disease; and muscular dystrophies.

¹ Under 21 U.S.C. § 360bb "rare disease or condition" is defined to mean any disease or condition which (i) affects less than 200,000 persons in the United States, or (ii) 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.

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