



HOUSE BILL 823: Establish Advisory Council on Rare Diseases

2015-2016 General Assembly

Committee:
Introduced by:
Analysis of: S.L. 2015-199

Date:
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SUMMARY: *S.L. 2015-199 establishes the Advisory Council on Rare Diseases housed within the School of Medicine of the University of North Carolina at Chapel Hill. The Advisory Council is tasked with studying, advising, and reporting annually to the Governor, the Secretary of Health and Human Services, and the General Assembly on research, diagnosis, treatment, and education relating to rare diseases.*

This act became effective August 1, 2015.

BILL ANALYSIS: S.L. 2015-199 establishes 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 law.¹ The School of Medicine is directed to provide all administrative support and other services required by the Advisory Council.

The Advisory Council is 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 by August 31, 2015, and 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 must report 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 became 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

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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House Bill 823

Page 2

also play a role. Examples of rare diseases include: cystic fibrosis; Huntington's disease; and muscular dystrophies.