

**The Florida Senate**  
**BILL ANALYSIS AND FISCAL IMPACT STATEMENT**

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

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Prepared By: The Professional Staff of the Committee on Health Policy

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**BILL:** CS/SB 272

**INTRODUCER:** Health Policy Committee and Senator Baxley

**SUBJECT:** Rare Disease Advisory Council

**DATE:** February 4, 2021      **REVISED:** \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Brown	HP	<b>Fav/CS</b>
2.			AHS	
3.			AP	

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**Please see Section IX. for Additional Information:**  
COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/SB 272 creates s. 381.99, F.S., to establish the Rare Disease Advisory Council (Council) adjunct to the Department of Health (DOH). The Council is tasked with providing recommendations to improve the health outcomes of Floridians who have a rare disease, defined as a disease that affects fewer than 200,000 people in the United States. The bill establishes the membership of the Council as well as the length of the members' terms, requires that the Council first meet on October 1, 2021, and that the Council provide its recommendations to the Governor and the State Surgeon General by July 1 of each year beginning in 2022.

The bill provides an effective date of July 1, 2021.

**II. Present Situation:**

**Advisory Councils**

Section 20.03, F.S., defines an advisory council as an advisory body created by specific statutory enactment and appointed to function on a continuing basis for the study of the problems arising in a specified functional or program area of state government and to provide recommendations and policy alternatives. Section 20.052, F.S., requires that each advisory council established may be created only when it is found to be necessary and beneficial to the furtherance of a public

purpose, and such a council must be terminated by the Legislature when it is no longer necessary.<sup>1</sup> An advisory body may not be created unless:

- It meets a statutorily defined purpose;
- Its powers and responsibilities conform with the definitions for governmental units in s. 20.03, F.S.;
- Its members, unless expressly provided otherwise in the State Constitution, are appointed for four-year staggered terms; and
- Its members, unless expressly provided otherwise by specific statutory enactment, serve without additional compensation or honorarium, and are authorized to receive only per diem and reimbursement for travel expenses as provided in s. 112.061, F.S.

The section also requires that:

- The private citizen members of an advisory body that is adjunct to an executive agency must be appointed by the Governor, the head of the department, the executive director of the department, or a Cabinet officer.
- Unless an exemption is otherwise specifically provided by law, all meetings of an advisory body, commission, board of trustees, or other collegial body adjunct to an executive agency are public meetings under s. 286.011, F.S. Minutes, including a record of all votes cast, must be maintained for all meetings.
- If an advisory body, commission, board of trustees, or other collegial body that is adjunct to an executive agency is abolished, its records must be appropriately stored, within 30 days after the effective date of its abolition, by the executive agency to which it was adjunct, and any property assigned to it must be reclaimed by the executive agency. The advisory body, commission, board of trustees, or other collegial body may not perform any activities after the effective date of its abolition.

### **Rare Disease Research**

In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people nationally. This definition was created by Congress in the Orphan Drug Act of 1983. Rare diseases became known as “orphan diseases” because drug companies were not interested in adopting them to develop treatments. The Orphan Drug Act created financial incentives to encourage companies to develop new drugs for rare diseases. The rare disease definition was needed to establish which conditions would qualify for the new incentive programs.<sup>2</sup>

There may be as many as 7,000 rare diseases. The total number of Americans living with a rare disease is estimated at between 25-30 million. This estimate has been used by the rare disease community for several decades to highlight that while individual diseases may be rare, the total number of people with a rare disease is large.<sup>3</sup>

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<sup>1</sup> The agency to which an advisory body is adjunct must advise the Legislature at the time the advisory body ceases to be essential to the furtherance of a public purpose.

<sup>2</sup> FAQs About Rare Diseases, U.S. Department of Health and Human Services, National Institutes of Health, *available at* <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases>. (last visited Jan. 27, 2021).

<sup>3</sup> *Id.*

In the United States, only a few types of rare diseases are tracked when a person is diagnosed. These include certain infectious diseases, birth defects, and cancers. It also includes the diseases on state newborn screening tests. Because most rare diseases are not tracked, it is difficult to determine the exact number of rare diseases or how many people are affected.<sup>4</sup>

Researchers have made progress in learning how to diagnose, treat, and even prevent a variety of rare diseases. However, most rare diseases have no treatments. The National Institutes of Health (NIH) supports research to improve the health of people with rare diseases. Many of the 27 Institutes and Centers at the NIH fund medical research for rare diseases. One of these Centers, the National Center for Advancing Translational Sciences (NCATS), focuses on getting new cures and treatments to all patients more quickly. NCATS supports research through collaborative projects to study common themes and causes of related diseases. This approach aims to speed the development of treatments that will eventually serve both rare and common diseases.<sup>5</sup>

The NCATS Office of Rare Diseases Research (ORDR) guides and coordinates NIH-wide activities involving research for rare diseases. Some of the NCATS programs for rare diseases include:

- Rare Diseases Clinical Research Network (RDCRN)
- Therapeutics for Rare and Neglected Diseases (TRND)
- Rare Diseases Registry Program (RaDaR)
- Genetic and Rare Diseases Information Center (GARD)

Efforts to improve and bring to market treatments for rare diseases are coordinated by the Food and Drug Administration. The Office of Orphan Products Development (OOPD) provides incentives for drug companies to develop treatments for rare diseases. Between 1973 and 1983, fewer than 10 treatments for rare diseases were approved. Since 1983, the OOPD program has helped develop and bring to market more than 400 drugs and biologic products for rare diseases.<sup>6</sup>

### III. Effect of Proposed Changes:

CS/SB 272 creates s. 381.99, F.S., to establish the Rare Disease Advisory Council. The Council is created adjunct to the DOH for the purpose of providing recommendations on ways to improve health outcomes for individuals with rare diseases. The bill defines a rare disease as a disease that affects fewer than 200,000 people in the United States.

The bill requires the Governor to appoint members to the Council as follows:

- A representative of the Department of Health.
- A representative of the Agency for Health Care Administration.
- A representative of the Office of Insurance Regulation.
- A representative of the Department of Education.
- Two representatives from academic research institutions in this state which receive any grant funding for research regarding rare diseases.

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<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

- One geneticist practicing in this state.
- One registered nurse or advanced practice registered nurse who is licensed and practicing in this state with experience treating rare diseases.
- Two physicians who are licensed and practicing in this state with experience treating rare diseases.
- One hospital administrator from a hospital in this state which provides care to individuals diagnosed with rare diseases.
- Two individuals who are 18 years of age or older who have a rare disease.
- Two individuals who are caregivers of an individual with a rare disease.
- Two representatives of organizations operating in this state which provide care or other support for individuals with rare diseases.
- A pharmacist who is licensed and practicing in this state who has experience with drugs that are used to treat rare diseases.
- A representative of the biotechnology industry.
- A representative of health insurance companies.

Members of the Council must be appointed by September 1, 2021, and are appointed for four-year terms except that half the Council is initially appointed to a two-year term to stagger the appointments. The Council is required to hold its initial meeting by October 1, 2021, and may meet upon the call of the chair or upon the request of the majority of its members thereafter. The Council is authorized to meet electronically.

The bill requires the Council to:

- Consult with experts on rare diseases and solicit public comment to assist in developing recommendations on improving the treatment of rare diseases in this state.
- Develop recommended strategies for academic research institutions in this state to facilitate continued research on rare diseases.
- Develop recommended strategies for health care providers to be informed on how to more efficiently recognize and diagnose rare diseases in order to effectively treat patients. The advisory council shall provide such strategies to the DOH for publication on the department's website.
- Provide input and feedback in writing to the DOH, the Medicaid program, and other state agencies on matters that affect people who have been diagnosed with rare diseases, including, but not limited to, pandemic or natural disaster preparedness and response.

The DOH must provide staff and administrative support to the Council. The Council is required to submit a report to the DOH and the State Surgeon General, by July 1 of each year beginning in 2022, which describes the activities of the Council in the most recent year and its findings and recommendations regarding rare disease research and care.

The bill provides an effective date of July 1, 2021.

**IV. Constitutional Issues:**

## A. Municipality/County Mandates Restrictions:

None.

## B. Public Records/Open Meetings Issues:

None.

## C. Trust Funds Restrictions:

None.

## D. State Tax or Fee Increases:

None.

## E. Other Constitutional Issues:

None.

**V. Fiscal Impact Statement:**

## A. Tax/Fee Issues:

None.

## B. Private Sector Impact:

None.

## C. Government Sector Impact:

The DOH may experience an indeterminate negative fiscal impact from CS/SB 272 due to the requirement that the DOH provide staff and administrative support to the Council.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

None.

**VIII. Statutes Affected:**

This bill substantially amends section 381.99 of the Florida Statutes.

**IX. Additional Information:**

- A. **Committee Substitute – Statement of Changes:**  
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS by Health Policy on February 4, 2021:**

The CS replaces the underlying bill's requirement that the Rare Disease Advisory Council establish a method to securely hold and distribute funds for certain uses with the requirement that the Council provide written input and feedback to state agencies on matters that affect people who have been diagnosed with a rare disease, including, but not limited to, pandemic or natural disaster preparedness and response.

- B. **Amendments:**

None.