

## HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

**BILL #:** CS/HB 1373 Rare Disease Advisory Council

**SPONSOR(S):** Professions & Public Health Subcommittee, DuBose and others

**TIED BILLS:** **IDEN./SIM. BILLS:** CS/CS/SB 272

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**FINAL HOUSE FLOOR ACTION:** 117 Y's

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**GOVERNOR'S ACTION:** Approved

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### SUMMARY ANALYSIS

CS/HB 1373 passed the House on April 28, 2021, as CS/CS/SB 272.

The bill creates the Rare Disease Advisory Council (Council) adjunct to the Department of Health (DOH). The bill establishes the membership of the Council as well as the length of member terms. The Council must:

- 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.
- Provide written input and feedback to the DOH, the Medicaid program, and other state agencies on specified matters.

The bill requires the Council to meet by October 1, 2021, and provide its recommendations to the Governor and the State Surgeon General by July 1 of each year, beginning in 2022.

The bill has a significant, negative fiscal impact on the DOH, which current resources are adequate to absorb, and no fiscal impact on local governments.

The bill was approved by the Governor on June 21, 2021, ch. 2021-122, L.O.F., the effective date of this bill is July 1, 2021.

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### Background

##### Rare Disease

In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 7,000 rare diseases impacting the lives of 25-30 million Americans and their families. 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.

Nationally, 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. 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.<sup>1</sup>

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, such as the National Center for Advancing Translational Sciences (NCATS), which 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.

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>2</sup>

##### *Rare Disease Advisory Councils*

The National Organization for Rare Disorders (NORD), a non-profit patient advocacy organization dedicated to individuals with rare diseases and the organizations that serve them, is working to establish a Rare Disease Advisory Council (RDAC) in every state. An RDAC is an advisory body providing a platform for the rare disease community to have a stronger voice in state government.<sup>3</sup>

According to NORD, RDACs address the needs of affected patients and families by giving stakeholders an opportunity to make recommendations to state leaders on critical issues including the need for increased awareness, diagnostic tools, and access to affordable treatments and cures.<sup>4</sup> These councils are housed by a variety of organizations including departments of health, outside nonprofits, universities, or grantees from departments of health. The types of RDACs include councils, task forces, advisory commissions and work groups.

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<sup>1</sup> U.S. Department of Health & Human Services, National Institutes of Health (NIH), *FAQs About Rare Diseases*, <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases#:~:text=In%20the%20United%20States%2C%20only,on%20state%20newborn%20screening%20tests>. (last visited May 4, 2021).

<sup>2</sup> National Organization for Rare Diseases (NORD), *Rare Disease Advisory Councils (RDACs): Project RDAC*, <https://rarediseases.org/rdac-overview/> (last visited May 4, 2021).

<sup>3</sup> National Organization for Rare Diseases (NORD), *Rare Disease Advisory Councils (RDACs): Project RDAC*, <https://rarediseases.org/rdac-overview/> (last visited May 4, 2021).

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

The first RDAC was created in 2015 in North Carolina.<sup>5</sup> Currently, 14 states have RDACs: Alabama, Illinois, Kentucky, Minnesota, Missouri, Nevada, New Hampshire, North Carolina, Ohio, Pennsylvania, Tennessee, Utah, West Virginia, and Virginia.<sup>6</sup>

Florida currently does not have an RDAC. However, the Department of Health (DOH) administratively supports existing councils to promote engagement with stakeholders regarding disabilities and developmental delays:<sup>7</sup>

- The Genetics and Newborn Screening Advisory Council: Includes a large array of expertise ranging from pediatricians, audiologists, representatives from each of the four medical schools in this state, pediatric hematologist, the Florida Hospital Association, as well as executive representation from the DOH.
- The Florida Interagency Coordinating Council for Infants and Toddlers: Advises and assists the Early Steps program with its implementation of the Individuals with Disabilities Education Act, Part C, and includes representation from public and private providers, the Agency for Health Care Administration, the Department of Education, and parents.
- The Information Clearinghouse on Developmental Disabilities Advisory Council: Provides resources to parents with children with developmental disabilities via the Bright Expectations website.

### Advisory Councils in Florida

In Florida, a statutorily created advisory council is 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.<sup>8</sup> Section 20.052, F.S., governs advisory bodies and their creation and requires an advisory council specifically created as an adjunct to an executive agency to be created only after being found to be necessary and beneficial to the furtherance of a public purpose and must be terminated by the Legislature when it is no longer necessary.<sup>9</sup>

Under current law, an advisory body may not be created unless:<sup>10</sup>

- It meets a statutorily defined purpose;
- Its powers and responsibilities conform with the definitions for specified governmental units;
- 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.

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.<sup>11</sup> Unless exempt under law, all advisory council meetings are open to the public under s. 286.011, F.S., and minutes, including a record of all votes cast, must be maintained for all meetings.<sup>12</sup>

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<sup>5</sup> *Id.* See also, N.C. GEN. STAT. § 130A-33.65.

<sup>6</sup> See Act 2017-109, HJR115, which created the Alabama Rare Disease Advisory Council; 410 ILL. COMP. STAT. 445-10; KY. REV. STAT. ANN § 211.576; MINN. STAT. § 137.68; MO. REV. STAT. § 208.183; NEV. REV. STAT. § 439.5077; N.H. REV. STAT. ANN. § 126-A:79; N.C. GEN. STAT. § 130A-33.65; OHIO REV. CODE ANN. § 103.60; 35 PA. CONS. STAT. § 6266; TENN. CODE. ANN § 71-7-101; UTAH CODE ANN. § 26-1-41; and W. VA. CODE § 16-5CC-3. Virginia HB 1995 was signed into law by the Governor on Mar. 24, 2021, and has an effective date of July 1, 2021.

<sup>7</sup> Florida Department of Health (DOH), 2021 Agency Legislative Bill Analysis for House Bill 1373, p. 2 (Mar. 1, 2021).

<sup>8</sup> S. 20.03(7), F.S.

<sup>9</sup> S. 20.052, F.S.

<sup>10</sup> S. 20.052(4), F.S.

<sup>11</sup> S. 20.052(5)(a), F.S.

<sup>12</sup> S. 20.052(5)(c), F.S.

If an advisory council 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.<sup>13</sup> An advisory council is prohibited from performing any activities after the effective date of its abolition.<sup>14</sup>

### **Effect of the Bill**

HB 1373 creates s. 381.99, F.S., to establish the Rare Disease Advisory Council (Council), adjunct to the DOH. The purpose of the Council is to provide recommendations on ways to improve health outcomes for individuals with rare diseases affecting fewer than 200,000 people in the United States.

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 written input and feedback to the DOH, the Medicaid program, and other state agencies on specified matters.

The bill requires the Governor to appoint the following members to the Council:

- 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.
- 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.
- One hospital administrator from a hospital in this state which provides care to individuals diagnosed 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.

The bill requires the President of the Senate to appoint the following members to the Council:

- A representative from an academic research institution in this state which receives any grant funding for research regarding rare diseases.
- A physician who is licensed under ch. 458 or ch. 459, practices in Florida, and has experience treating rare diseases.
- An individual who is 18 years of age or older who has a rare disease.

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<sup>13</sup> S. 20.052(5)(d), F.S.

<sup>14</sup> *Id.*

- An individual who is a caregiver of an individual with a rare disease.
- A representative of an organization operating in this state which provides care or other support for individuals with rare diseases.

The bill requires the Speaker of the House of Representatives to appoint the following members to the Council:

- A representative from an academic research institution in this state which receives any grant funding for research regarding rare diseases.
- A physician who is licensed under ch. 458 or ch. 459, practices in Florida, and has experience treating rare diseases.
- An individual who is 18 years of age or older who has a rare disease.
- An individual who is a caregiver of an individual with a rare disease.
- A representative of an organization operating in this state which provides care or other support for individuals with rare diseases.

The bill requires the Governor, President of the Senate, and Speaker of the House of Representatives to appoint members by September 1, 2021, for four-year terms, except that specified members must be initially appointed to two-year terms to stagger the appointments.

The Council must 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 bill authorizes the Council to meet electronically. The DOH must provide staff and administrative support to the Council.

The bill requires the Council 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.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### 1. Revenues:

None.

#### 2. Expenditures:

The DOH will incur costs associated with staffing and supporting the Rare Disease Advisory Council created by the bill. The DOH estimates one FTE will be required and requested \$75,569 in recurring funds and \$4,429 in nonrecurring funds for Fiscal Year 2021-2022. Additionally, the DOH requested \$47,120 in recurring funds to support travel expenses for Council members to attend an estimated four meetings per year.<sup>15</sup> However, the DOH has sufficient vacancies which can be filled to support the Council.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

#### 1. Revenues:

None.

#### 2. Expenditures:

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<sup>15</sup> DOH, *supra* note 7, at 5.

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.