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HOUSE BILL NO. 1995

Offered January 13, 2021

Prefiled January 11, 2021

A *BILL to amend the Code of Virginia by adding in Chapter 2 of Title 32.1 an article numbered 19, consisting of sections numbered 32.1-73.14, 32.1-73.15, and 32.1-73.16, relating to Rare Disease Advisory Council; report.*

Patrons—Murphy, Adams, D.M., Carter, Hope, Keam, Levine, Plum, Reid, Roem, Simon, Simonds and Subramanyam

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Chapter 2 of Title 32.1 an article numbered 19, consisting of sections numbered 32.1-73.14, 32.1-73.15, and 32.1-73.16, as follows:

*Article 19.**Rare Disease Advisory Council.***§ 32.1-73.14. Rare Disease Advisory Council.**

There is hereby created in the executive branch of state government the Rare Disease Advisory Council (the Council). The purpose of the Council is to (i) advise the General Assembly and other agencies, departments, commissions, and authorities in the Commonwealth on the needs of individuals with rare diseases in the Commonwealth; (ii) explore challenges that such individuals face, including delays in obtaining a diagnosis or the receipt of a misdiagnosis, shortages of medical specialists who can provide treatment, and lack of access to therapies and medication used to treat rare diseases; and (iii) secure funding for research for the development of new treatments for rare diseases and support for persons with rare diseases in the Commonwealth.

§ 32.1-73.15. Powers and duties of the Council.

The Council shall have the following powers and duties:

1. Within the first year, convene public hearings, make inquiries, and solicit comments from the general public in the Commonwealth to assist the Council in understanding rare diseases in the Commonwealth.

2. Research and consult with experts on rare diseases on the Council and externally as needed to develop policy recommendations to the Governor, General Assembly, state agencies, and insurers on the following:

a. Access to insurance, specialists, and other needed services for patients with rare diseases;
b. The impact of coverage, cost sharing, tiers, or other utilization management procedures on the provision of treatment and care services; and

c. Including coverage under the state program for medical assistance services for approved treatments and medications for rare disease patients.

3. Publish a list of existing publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases in the Commonwealth on the Council's webpage.

4. Submit an annual report to the Governor and the General Assembly for publication as a report document as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports. The annual report shall (i) describe the activities and processes of the Council; (ii) provide an update on the status of funding of the Council, including any grants sought out, accepted by, or used by the Council, and any remaining balances; and (iii) provide recommendations to the Governor regarding ways to address the needs of individuals with rare diseases in the Commonwealth.

§ 32.1-73.16. Membership; terms; quorum; meetings.

A. The Council shall have a total membership of 21 members that shall consist of 18 nonlegislative members and three ex officio members. Representatives from the Department of Health, the Department of Medical Assistance Services, or the Department of Education, or their designees, shall serve ex officio with nonvoting privileges. The Governor shall appoint a chairman and vice-chairman who shall be residents of the Commonwealth and shall not be employed by any federal or state government. The chairman and vice-chairman shall appoint the following nonlegislative citizen members of the Council who shall be residents of the Commonwealth: one representative from an academic research institution in the Commonwealth that receives any grant funding for rare disease research; one geneticist licensed and currently practicing in the Commonwealth; one registered nurse or advanced practice registered nurse licensed and currently practicing in the Commonwealth, with experience in treating rare diseases;

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58 *two physicians with expertise in rare diseases who are licensed and currently practicing medicine in the*
59 *Commonwealth; one hospital administrator, or his designee, from a hospital in the Commonwealth that*
60 *provides care to persons diagnosed with rare diseases; two persons who are 18 or older who have been*
61 *diagnosed with a rare disease; two caregivers of persons with a rare disease; two representatives of*
62 *rare disease patient organizations operating in the Commonwealth; one licensed pharmacist with*
63 *experience with drugs used to treat rare diseases; one representative from the biopharmaceutical*
64 *industry; one representative from health plan companies; and one member from the scientific community*
65 *who is engaged in rare disease research, including a medical researcher with experience conducting*
66 *research on rare diseases.*

67 *Ex officio members of the Council shall serve terms coincident with their terms of office.*
68 *Appointments to fill vacancies, other than by expiration of a term, shall be for the unexpired terms.*
69 *Vacancies shall be filled in the same manner as the original appointments. Any vacancy shall not affect*
70 *the ability of the remaining Council members to execute the Council's work. After the initial staggering*
71 *of terms, nonlegislative members shall be appointed for a term of three years.*

72 *B. The Council shall meet quarterly and the chairman and vice-chairman shall establish a meeting*
73 *schedule on an annual basis and determine a mechanism whereby Council members can communicate*
74 *outside of meetings. A majority of the members shall constitute a quorum.*

75 *C. Members of the Council shall serve without compensation or reimbursement.*

76 *D. Staff to the Council shall be provided by the Department of Health. All agencies of the*
77 *Commonwealth shall provide assistance to the Council, upon request.*

78 *E. The chairman and vice-chairman may solicit funds on behalf of the Council. The Council shall set*
79 *up a method to securely hold and distribute any such funds.*

80 **2. That the Rare Disease Advisory Council shall submit the first annual report as designated**
81 **under § 32.1-73.15 of the Code of Virginia, as created by this act, to the Governor and General**
82 **Assembly within one year of the effective date of this act.**

83 **3. That the first meeting of the Rare Disease Advisory Council shall occur within the first 90 days**
84 **of the effective date of this act.**

85 **4. That the initial appointments of nonlegislative citizen members of the Rare Disease Advisory**
86 **Council shall be staggered as follows: (i) two persons who are 18 or older who have been**
87 **diagnosed with a rare disease, two caregivers of persons with a rare disease, and two**
88 **representatives of rare disease patient organizations operating in the Commonwealth shall be**
89 **appointed for a term of one year; (ii) one licensed pharmacist, one registered nurse or advanced**
90 **practice registered nurse licensed and currently practicing medicine in the Commonwealth, and**
91 **the chairman and vice-chairman appointed by the Governor shall be appointed for a term of two**
92 **years; (iii) one hospital administrator, or his designee, one representative from the**
93 **biopharmaceutical industry, and one representative from health plan companies shall be appointed**
94 **for a term of three years; and (iv) one representative from an academic research institution in the**
95 **Commonwealth that receives any grant funding for rare disease research, one geneticist licensed**
96 **and currently practicing in the Commonwealth, two physicians with expertise in rare diseases who**
97 **are licensed and currently practicing medicine in the Commonwealth, and one member from the**
98 **scientific community who is engaged in rare disease research shall be appointed for a term of four**
99 **years.**