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AB-2613 Jacqueline Marie Zbur Rare Disease Advisory Council. (2023-2024)

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Assembly Bill No. 2613

CHAPTER 726

An act to add and repeal Part 4.6 (commencing with Section 124965) of Division 106 of the Health and Safety Code, relating to public health.

[Approved by Governor September 27, 2024. Filed with Secretary of State September 27, 2024.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2613, Zbur. Jacqueline Marie Zbur Rare Disease Advisory Council.

Existing law establishes the California Health and Human Services Agency, which includes the State Department of Public Health, among other state departments charged with the administration of health, social, and other human services. Under existing law, the State Department of Public Health has authority over various programs promoting public health, including genetic disease testing.

This bill, upon appropriation by the Legislature, would establish within the agency, until January 1, 2029, the Jacqueline Marie Zbur Rare Disease Advisory Council appointed by the State Public Health Officer, as specified. The council would generally act as the advisory body on rare diseases to the Legislature and state and private entities that provide services to, or that are charged with the care of, persons with rare diseases. The council specifically would be required, among other duties, to publish on its web page publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases in California to foster recognition and access to treatment. The bill would require the council to report on its web page on the activities of the advisory council and its findings and recommendations on issues, as specified. The bill would make legislative findings and declarations in support of its provisions.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) Under federal law, including the Orphan Drug Act of 1983, and its amendments, and the Rare Diseases Act of 2002, a rare disease is generally defined as a disease that affects fewer than 200,000 persons in the United States. Rare diseases are sometimes called orphan diseases. There are about 10,000 known rare diseases affecting approximately 30 million men, women, and children in the United States.

(b) The exact cause for many rare diseases remains unknown. However, 80 percent of rare diseases are genetic in origin and can be linked to mutations in a single gene or in multiple genes. Those diseases are referred to as genetic diseases. A genetic disease can be passed down from generation to generation, explaining why certain rare diseases run in families. It is also estimated that about one-half of all rare diseases affect children.

(c) A person suffering from a rare disease in this state faces a wide range of obstacles, including, but not limited to, delays in obtaining a diagnosis, a misdiagnosis, a shortage of medical specialists familiar with and who can provide treatment for rare diseases, the prohibitive costs of treatment, and the inability to access therapies and medication that are used by physicians to treat rare diseases but that have not been approved by the United States Food and Drug Administration (FDA) for that specific purpose.

(d) In recent years, researchers have made considerable progress in developing diagnostic tools and novel treatment for, and in discovering ways to prevent, a variety of rare diseases. However, much more remains to be done in the areas of rare disease research and the search for, and development of, new therapeutics. Additionally, the equitable access to newly approved therapies, such as gene therapies, are in jeopardy due to the significant up-front costs that require novel and nontraditional approaches to coverage that do not yet exist.

(e) It is, therefore, an appropriate public policy for this state to establish an advisory body whose membership would be comprised of persons with suitable qualifications in the field of rare diseases, including persons living with rare diseases, to educate medical professionals, government agencies, and the public about rare diseases as an important public health issue, and to encourage and fund research in the development of new treatments for rare diseases.

SEC. 2. Part 4.6 (commencing with Section 124965) is added to Division 106 of the Health and Safety Code, to read:

PART 4.6. Jacqueline Marie Zbur Rare Disease Advisory Council

124965. (a) Upon appropriation by the Legislature, there is established, within the California Health and Human Services Agency, the Jacqueline Marie Zbur Rare Disease Advisory Council. The council is advisory in nature and shall have no regulatory authority.

(b) Unless the context requires otherwise, for purposes of this part, the following definitions shall apply:

(1) "Advisory council" or "council" means the Jacqueline Marie Zbur Rare Disease Advisory Council.

(2) "Rare disease" has the same meaning as provided in Section 360bb of Title 21 of the United States Code, or its successor.

124965.2. (a) The Secretary of Health and Human Services shall appoint the chair of the advisory council. The chair shall not hold any other position, employment, or appointment within state government.

(b) Members of the advisory council shall be appointed by the State Public Health Officer, shall either reside in California or be employed by a California-based company or organization, and include all of the following:

(1) Two physicians and surgeons licensed to practice in this state who have experience in treating patients with rare diseases, at least one of whom shall also treat children.

(2) One registered professional nurse licensed to practice in this state who has experience in providing care to patients with rare diseases.

(3) One hospital administrator employed by a hospital that treats rare disease patients.

(4) One representative of the California health care coverage industry.

(5) One representative of the biopharmaceutical industry.

(6) One representative of the scientific community who is engaged in rare disease research.

(7) One rare disease geneticist or genetic counselor.

(8) Up to five individuals who are either a rare disease patient or a caregiver to a rare disease patient. The advisory council shall not include more than three individuals from each category.

(9) One medical social worker or mental health provider who works with rare disease patients.

(10) Up to two representatives of patient advocacy organizations that operate within this state.

(c) The advisory council may advise the California Health and Human Services Agency on additional at-large appointments to the advisory council that may be necessary to carry out its duties. At-large appointments to the advisory council may serve on an ad hoc basis.

(d) All members of the advisory council shall serve without compensation, but the members appointed pursuant to subdivision (b) may be reimbursed for travel and other miscellaneous expenses necessary to perform their duties if funds are made available to the advisory council for its purposes.

(e) Members of the advisory council appointed pursuant to subdivision (b) shall serve for the duration of this part. Any vacancy in the membership of the advisory council shall be filled in the same manner as provided for in the original appointment.

(f) Each member of the advisory council shall annually sign a conflict of interest statement disclosing any economic or other relationship with an entity that could influence the member's decisions. At least 20 percent of the advisory council's members shall not have a conflict of interest with respect to an insurer, pharmaceutical benefits manager, or pharmaceutical manufacturer.

124965.6. (a) The advisory council shall meet periodically, but at least twice annually.

(b) The advisory council may call to its assistance, and avail itself of the services of, the employees of any state, county, or municipal department, board, bureau, commission, or agency as it may require and as may be available to it for its purposes, if those employees elect to participate.

124965.8. The advisory council shall perform all of the following duties:

(a) Act as the advisory body on rare diseases to the Legislature, and state departments, agencies, commissions, and authorities, and private agencies, that provide services to, or that are charged with the care of, persons with rare diseases.

(b) Consult with experts on rare diseases to develop recommendations to improve patient access to, and quality of, rare disease specialists, affordable and comprehensive health care coverage, relevant diagnostics, timely treatment, and other needed services.

(c) Create and maintain an internet web page for the advisory council.

(d) Identify, consolidate, and publish on the advisory council's web page publicly accessible resources on research, diagnosis, treatment, and education relating to rare diseases in California to foster recognition and access to treatment.

(e) Identify areas of unmet need for research and opportunities for collaboration with stakeholders and rare disease advisory councils in other states that can inform future studies and work done by the advisory council.

124965.10. The advisory council shall apply for, and accept, any grant of funds from the federal government, private foundations, or other sources that may be available for programs related to rare diseases. The advisory council shall not accept any funds from the employer of a currently seated council member.

124965.12. The advisory council shall report on the activities of the advisory council and its findings and recommendations on issues relating to the quality and cost-effectiveness of, and access to, treatment and services provided to persons with rare diseases in this state on the advisory council's web page.

124965.14. This part shall remain in effect only until January 1, 2029, and as of that date is repealed.