

JAN 23 2025

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# A BILL FOR AN ACT

RELATING TO RARE DISEASES.

**BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:**

1           SECTION 1. The legislature finds that over thirty million  
2 people in the United States are affected by one of over seven  
3 thousand rare disease. Rare diseases, also known as orphan  
4 diseases, are classified as diseases that impact fewer than  
5 twenty thousand people. Because of the small population of  
6 patients, individuals suffering from rare diseases suffer many  
7 challenges, such as delays in obtaining a diagnosis, shortages  
8 of medical specialists who can provide treatment, and a lack of  
9 affordable access to therapies and medication used to treat rare  
10 diseases. The small patient population can also make the  
11 development of treatments for these diseases equally  
12 challenging, particularly when it comes to conducting clinical  
13 trials.

14           The legislature further finds that as of December 2024,  
15 twenty-nine states have established rare diseases advisory  
16 councils. These councils address the needs of rare disease  
17 patients and families by giving stakeholders an opportunity to



1 share experiences, identify barriers, and propose solutions to  
2 help the rare disease community. Members of a rare disease  
3 advisory council are typically diverse, including members of the  
4 rare disease community, health care providers, health insurers,  
5 researchers, the biotech industry, and state government.

6 The purpose of this Act is to establish a rare disease  
7 advisory council in the department of health to advise the State  
8 on the needs of rare disease patients.

9 SECTION 2. Chapter 321, Hawaii Revised Statutes, is  
10 amended by adding a new part to be appropriately designated and  
11 to read as follows:

12 **"PART . RARE DISEASE ADVISORY COUNCIL**

13 § -1 **Definitions.** For the purposes of this part:

14 "Council" means the rare disease advisory council.

15 "Department" means the department of health.

16 "Rare disease" means a disease or condition that affects  
17 fewer than twenty thousand people in the United States.

18 § -2 **Rare disease advisory council; establishment;**  
19 **duties; members; term; reports.** (a) There is established  
20 within the department, for administrative purposes only, an  
21 advisory council to be known as the rare disease advisory



1 council, which shall advise the governor, legislature, and any  
2 other government agency, as appropriate, on the needs of  
3 individuals with rare diseases living in the State.

4 (b) The council shall:

5 (1) Develop a landscape or survey of the needs of rare  
6 disease patients, caregivers, and providers in the  
7 State;

8 (2) Develop policy recommendations that:

9 (A) Improve patient access to, and quality of, rare  
10 disease specialists, affordable and comprehensive  
11 health care coverage, relevant diagnostics,  
12 timely treatment, and other needed services; and

13 (B) Research and identify priorities related to  
14 treatments and services for persons with rare  
15 diseases, including recommendations for  
16 preventing discrimination against rare disease  
17 patients, including in disaster and public health  
18 emergency-related planning;

19 (3) Research and make recommendations to the department or  
20 any other appropriate state agency, health care  
21 provider, or health insurer that provides services to



- 1 persons with rare diseases on the impact of coverage,  
2 cost-sharing, tiering, or other utilization management  
3 procedures on the provision of treatment and care  
4 services;
- 5 (4) Research and identify priorities related to treatments  
6 and services provided to persons with rare diseases in  
7 the State;
- 8 (5) Publish a list of existing, publicly accessible  
9 resources on research, diagnosis, treatment, and  
10 education relating to rare diseases in the State on  
11 the council's website;
- 12 (6) Identify areas of unmet needs for research that can  
13 inform future studies and reports by the council;
- 14 (7) Establish resources for academic institutions, state  
15 agencies, health care professionals, and other  
16 entities to provide training to employees on rare  
17 diseases in the State;
- 18 (8) Identify and distribute educational resources for  
19 health care providers to foster recognition and  
20 optimize treatment of rare diseases in the State;



1 (9) Research and identify best practices to reduce health  
2 disparities and achieve health equity in the research,  
3 diagnosis, and treatment of rare diseases in the  
4 State; and

5 (10) Establish best practices and protocols to use during a  
6 state of emergency to aid rare disease patients in the  
7 State.

8 (c) The council may hold public hearings, make inquiries,  
9 and consult with experts to carry out the activities of  
10 subsection (b).

11 (d) The council shall consist of the following fourteen  
12 members or their designees:

13 (1) The director of health, who shall serve as an ex  
14 officio voting member of the board;

15 (2) The insurance commissioner, who shall serve as an ex  
16 officio voting member of the board;

17 (3) One member of the house of representatives, to be  
18 appointed by the speaker of the house of  
19 representatives, who shall serve as a non-voting, ex-  
20 officio member;



- 1           (4) One member of the senate, to be appointed by the
- 2                 president of the senate, who shall serve as a non-
- 3                 voting, ex-officio member;
- 4           (5) Ten members who shall be appointed by the governor
- 5                 pursuant to section 26-34, as follows:
- 6                 (A) A representative from an academic research
- 7                         institution in the State that reviews grant
- 8                         funding for rare disease research;
- 9                 (B) A geneticist licensed and practicing in the
- 10                         State;
- 11                 (C) A licensed physician, registered nurse, or
- 12                         advanced practice registered nurse who has
- 13                         experience treating rare diseases and is
- 14                         practicing in the State;
- 15                 (D) A hospital administrator from an acute care
- 16                         hospital in the State that provides care to
- 17                         persons diagnosed with a rare disease;
- 18                 (E) An administrator from a biopharmaceutical
- 19                         manufacturer licensed and operating in the State;
- 20                 (F) A geneticist licensed in the State;



1 (G) A pharmacists licensed in the State with  
2 experience dispensing drugs used to treat rare  
3 diseases;

4 (H) A member of the scientific community who is  
5 engaged in rare disease research, including but  
6 not limited to a medical research with experience  
7 conducting research on rare diseases; and

8 (I) Two state residents who either have a rare  
9 disease or have experience caring for a person  
10 with a rare disease.

11 (e) The council shall annually elect a member from among  
12 its members to serve as chair.

13 (f) Except for the ex officio members or their designees,  
14 the council members shall be appointed by the governor for  
15 three-year staggered terms as provided for in section 26-34.

16 (g) No later than twenty days prior to the regular session  
17 of 2028, and every three years thereafter, the council shall  
18 submit a report to the governor and the legislature, which shall  
19 include:



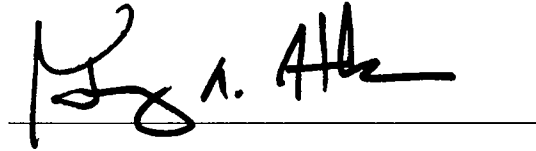
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- 1 (1) A description of the council's accomplishments and  
2 progress in carrying out the activities outlined in  
3 subsection (b); and  
4 (2) Its findings and recommendations, including any  
5 proposed legislation."

6 SECTION 3. This Act shall take effect upon its approval.

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INTRODUCED BY:

A handwritten signature in black ink, appearing to read "M. A. Alk", is written over a horizontal line.





# S.B. NO. 1497

**Report Title:**

Rare Disease Advisory Council; Establishment; DOH; Rare Disease Patients

**Description:**

Establishes a Rare Disease Advisory Council within the Department of Health to advise the State on the needs of rare disease patients.

*The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.*

