

SENATE BILL 188

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3lr0310
CF HB 302

By: **Senators Lam, Rosapepe, Salling, Muse, Carozza, Kramer, and Benson**

Introduced and read first time: January 20, 2023

Assigned to: Finance

Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: February 21, 2023

CHAPTER _____

1 AN ACT concerning

2 **Public Health – Rare Disease Advisory Council**

3 FOR the purpose of establishing the Rare Disease Advisory Council to study and make
4 recommendations on matters relating to individuals with rare diseases in the State;
5 and generally relating to the Rare Disease Advisory Council.

6 BY adding to

7 Article – Health – General

8 Section 13–4801 through 13–4804 to be under the new subtitle “Subtitle 48. Rare
9 Disease Advisory Council”

10 Annotated Code of Maryland

11 (2019 Replacement Volume and 2022 Supplement)

12 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
13 That the Laws of Maryland read as follows:

14 **Article – Health – General**

15 **SUBTITLE 48. RARE DISEASE ADVISORY COUNCIL.**

16 **13–4801.**

17 **THERE IS A RARE DISEASE ADVISORY COUNCIL.**

18 **13–4802.**

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



(A) THE COUNCIL CONSISTS OF THE FOLLOWING MEMBERS:

(1) ONE MEMBER OF THE SENATE OF MARYLAND, APPOINTED BY THE PRESIDENT OF THE SENATE;

(2) ONE MEMBER OF THE HOUSE OF DELEGATES, APPOINTED BY THE SPEAKER OF THE HOUSE;

(3) THE SECRETARY, OR THE SECRETARY'S DESIGNEE; ~~AND~~

(4) THE CHAIR OF THE STATE ADVISORY COUNCIL ON HEREDITARY AND CONGENITAL DISORDERS, OR THE CHAIR'S DESIGNEE;

(5) ONE REPRESENTATIVE OF THE OFFICE OF MINORITY HEALTH AND HEALTH DISPARITIES, DESIGNATED BY THE DIRECTOR OF THE OFFICE;

(6) ONE REPRESENTATIVE OF THE MARYLAND MEDICAL ASSISTANCE PROGRAM, DESIGNATED BY THE SECRETARY;

(7) ONE REPRESENTATIVE OF THE MARYLAND INSURANCE ADMINISTRATION, DESIGNATED BY THE MARYLAND INSURANCE COMMISSIONER; AND

(8) THE FOLLOWING MEMBERS, APPOINTED BY THE GOVERNOR:

(I) ONE REPRESENTATIVE OF AN ACADEMIC RESEARCH INSTITUTION THAT RECEIVES GRANT FUNDING FOR RARE DISEASE RESEARCH;

~~(II) ONE REPRESENTATIVE OF THE OFFICE OF MINORITY HEALTH AND HEALTH DISPARITIES;~~

~~(III) ONE REPRESENTATIVE OF THE MARYLAND MEDICAL ASSISTANCE PROGRAM;~~

~~(IV) ONE REPRESENTATIVE OF THE MARYLAND INSURANCE ADMINISTRATION;~~

~~(V)~~ (II) ONE GENETICIST LICENSED AND PRACTICING IN THE STATE;

~~(VI)~~ (III) ONE REGISTERED NURSE OR ADVANCED PRACTICE REGISTERED NURSE LICENSED AND PRACTICING IN THE STATE WITH EXPERIENCE TREATING RARE DISEASES;

~~(VII)~~ (IV) ONE PHYSICIAN LICENSED IN THE STATE WITH
EXPERIENCE TREATING RARE DISEASES;

~~(VIII)~~ (V) ONE HOSPITAL ADMINISTRATOR, OR THE DESIGNEE
OF A HOSPITAL ADMINISTRATOR, FROM A HOSPITAL IN THE STATE THAT PROVIDES
CARE TO INDIVIDUALS DIAGNOSED WITH A RARE DISEASE;

~~(IX)~~ (VI) ONE PHARMACIST LICENSED IN THE STATE WITH
EXPERIENCE DISPENSING DRUGS USED TO TREAT RARE DISEASES;

~~(X)~~ (VII) TWO INDIVIDUALS WHO HAVE BEEN DIAGNOSED WITH
A RARE DISEASE;

~~(XI)~~ (VIII) ONE CAREGIVER OF AN INDIVIDUAL WITH A RARE
DISEASE;

~~(XII)~~ (IX) ONE REPRESENTATIVE OF A RARE DISEASE PATIENT
ORGANIZATION THAT OPERATES IN THE STATE;

~~(XIII)~~ (X) ONE REPRESENTATIVE OF THE BIOPHARMACEUTICAL
INDUSTRY;

~~(XIV)~~ (XI) ONE REPRESENTATIVE OF A HEALTH INSURANCE
CARRIER PROVIDING HEALTH INSURANCE COVERAGE IN THE STATE; ~~AND~~

~~(XV)~~ (XII) ONE MEMBER OF THE SCIENTIFIC COMMUNITY WHO
IS ENGAGED IN RARE DISEASE RESEARCH; AND

(XIII) ONE REPRESENTATIVE OF AN ORGANIZATION THAT
PROVIDES CARE MANAGEMENT FOR INDIVIDUALS ENROLLED IN THE STATE'S RARE
AND EXPENSIVE CASE MANAGEMENT PROGRAM.

(B) FOR THE APPOINTED MEMBERS OF THE COUNCIL, THE APPOINTMENT
PROCESS SHALL BE CONDUCTED IN A TRANSPARENT MANNER TO PROVIDE
INTERESTED INDIVIDUALS AN OPPORTUNITY TO APPLY.

(C) ALL MEMBERS OF THE COUNCIL MUST BE FULL-TIME RESIDENTS OF
THE STATE.

(D) (1) THE TERM OF AN APPOINTED MEMBER IS 3 YEARS.

(2) IF A VACANCY OCCURS ON THE COUNCIL, THE MEMBERS OF THE
COUNCIL SHALL APPOINT AN INDIVIDUAL TO FILL THE VACANCY BY MAJORITY
VOTE.

(E) (1) THE GOVERNOR SHALL DESIGNATE THE INITIAL CHAIR OF THE COUNCIL TO SERVE A TERM OF 3 YEARS.

(2) THE INITIAL CHAIR DESIGNATED BY THE GOVERNOR MAY NOT HOLD A POSITION WITHIN STATE GOVERNMENT.

(3) AT THE END OF THE TERM OF THE INITIAL CHAIR, THE MEMBERS OF THE COUNCIL SHALL DESIGNATE A NEW CHAIR BY MAJORITY VOTE.

(4) EXCEPT AS PROVIDED IN PARAGRAPH (1) OF THIS SUBSECTION, THE TERM OF A CHAIR OF THE COUNCIL IS 2 YEARS.

(F) THE DEPARTMENT SHALL PROVIDE STAFF FOR THE COUNCIL.

(G) A MEMBER OF THE COUNCIL:

(1) MAY NOT RECEIVE COMPENSATION AS A MEMBER OF THE COUNCIL; BUT

(2) IS ENTITLED TO REIMBURSEMENT FOR EXPENSES UNDER THE STANDARD STATE TRAVEL REGULATIONS, AS PROVIDED IN THE STATE BUDGET.

(H) (1) THE INITIAL MEETING OF THE COUNCIL SHALL OCCUR ON OR BEFORE DECEMBER 30, 2024.

(2) ON OR BEFORE OCTOBER 1, 2025, THE COUNCIL SHALL MEET AT LEAST ONCE PER MONTH IN PERSON OR THROUGH AN ONLINE MEETING PLATFORM AT A TIME DESIGNATED BY THE CHAIR.

(3) AFTER OCTOBER 1, 2025, THE COUNCIL SHALL MEET AT LEAST ONCE PER QUARTER IN PERSON OR THROUGH AN ONLINE MEETING PLATFORM AT A TIME DESIGNATED BY THE CHAIR.

13-4803.

(A) THE COUNCIL SHALL:

(1) CONVENE PUBLIC HEARINGS, MAKE INQUIRIES, AND SOLICIT COMMENTS FROM THE PUBLIC TO ASSIST THE COUNCIL WITH A FIRST-YEAR SURVEY OF THE NEEDS OF RARE DISEASE PATIENTS, CAREGIVERS, AND HEALTH CARE PROVIDERS IN THE STATE;

1 (2) CONSULT WITH EXPERTS ON RARE DISEASES TO DEVELOP POLICY
2 RECOMMENDATIONS TO IMPROVE PATIENT ACCESS TO AND THE QUALITY OF RARE
3 DISEASE SPECIALISTS, AFFORDABLE AND COMPREHENSIVE HEALTH CARE
4 COVERAGE, RELEVANT DIAGNOSTICS, TIMELY TREATMENT, AND OTHER NEEDED
5 SERVICES;

6 (3) RESEARCH AND MAKE RECOMMENDATIONS TO STATE AGENCIES
7 AND INSURERS THAT PROVIDE SERVICES TO INDIVIDUALS WITH A RARE DISEASE ON
8 THE IMPACT OF PRIOR AUTHORIZATION, COST-SHARING, TIERING, OR OTHER
9 UTILIZATION MANAGEMENT PROCEDURES ON THE PROVISION OF TREATMENT AND
10 CARE FOR PATIENTS;

11 (4) ESTABLISH BEST PRACTICES AND PROTOCOLS TO INCLUDE IN
12 STATE PLANNING RELATED TO NATURAL DISASTERS AND PUBLIC HEALTH
13 EMERGENCIES OR OTHER EMERGENCY DECLARATIONS TO ENABLE CONTINUITY OF
14 CARE FOR RARE DISEASE PATIENTS AND ENSURE THAT SAFEGUARDS AGAINST
15 DISCRIMINATION FOR RARE DISEASE PATIENTS ARE IN PLACE;

16 ~~(5) EVALUATE AND MAKE RECOMMENDATIONS TO IMPLEMENT~~
17 ~~NECESSARY IMPROVEMENTS TO STATE NEWBORN SCREENING PROGRAMS;~~

18 ~~(6)~~ (5) EVALUATE AND MAKE RECOMMENDATIONS REGARDING
19 COVERAGE OF PRESCRIPTION DRUGS FOR RARE DISEASE PATIENTS, INCLUDING
20 PATIENTS WITH PRIVATE HEALTH INSURANCE COVERAGE AND PATIENTS ENROLLED
21 IN THE MARYLAND MEDICAL ASSISTANCE PROGRAM, TO IMPROVE COVERAGE OF
22 DIAGNOSTICS, AND TO FACILITATE ACCESS TO NECESSARY HEALTH CARE
23 PROVIDERS WITH EXPERTISE IN THE TREATMENT OF RARE DISEASES;

24 ~~(7)~~ (6) PUBLISH A LIST OF EXISTING AND PUBLICLY ACCESSIBLE
25 RESOURCES ON RESEARCH, DIAGNOSIS, TREATMENT, AND EDUCATION RELATING TO
26 RARE DISEASES ON THE COUNCIL'S ~~WEBSITE~~ WEBPAGE;

27 ~~(8)~~ (7) IDENTIFY AREAS OF UNMET NEEDS FOR RESEARCH THAT
28 CAN INFORM FUTURE STUDIES AND REPORTS BY THE COUNCIL;

29 ~~(9)~~ (8) IDENTIFY AND DISTRIBUTE EDUCATIONAL RESOURCES FOR
30 HEALTH CARE PROVIDERS TO FOSTER RECOGNITION AND OPTIMIZE TREATMENT OF
31 RARE DISEASES IN THE STATE; AND

32 ~~(10)~~ (9) RESEARCH AND IDENTIFY BEST PRACTICES TO ENSURE
33 CONTINUITY OF CARE FOR RARE DISEASE PATIENTS TRANSITIONING FROM
34 PEDIATRIC TO ADULT CARE.

(B) THE COUNCIL SHALL PROVIDE OPPORTUNITIES FOR THE PUBLIC TO HEAR UPDATES AND PROVIDE INPUT ON THE COUNCIL'S ACTIVITIES.

(C) THE COUNCIL SHALL MAINTAIN A ~~WEBSITE~~ WEBPAGE FOR THE PURPOSES OF:

(1) POSTING MEETING MINUTES AND NOTICES OF UPCOMING MEETINGS;

(2) ALLOWING THE PUBLIC TO SUBMIT COMMENTS TO THE COUNCIL;
AND

(3) POSTING A LIST OF RESOURCES AS REQUIRED UNDER SUBSECTION (A)(7) OF THIS SECTION.

(D) (1) THE COUNCIL MAY SOLICIT FUNDS ON ITS BEHALF, INCLUDING BY APPLYING FOR AVAILABLE FEDERAL OR STATE GRANTS.

(2) THE COUNCIL SHALL SET UP A METHOD TO SECURELY HOLD AND DISTRIBUTE FUNDS TO SUPPORT THE DUTIES OF THE COUNCIL.

13-4804.

(A) ON OR BEFORE DECEMBER 1 EACH YEAR, BEGINNING IN 2024, THE COUNCIL SHALL SUBMIT A REPORT TO THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, THE GENERAL ASSEMBLY.

(B) THE REPORT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION SHALL:

(1) DESCRIBE THE ACTIVITIES OF THE COUNCIL UNDER § 13-4803(A) OF THIS SUBTITLE;

(2) DESCRIBE THE FUNDING SOURCES OF THE COUNCIL, INCLUDING GRANTS THAT WERE APPLIED FOR AND ACCEPTED AND THE REMAINING BALANCES OF ANY CURRENT GRANTS; AND

(3) PROVIDE RECOMMENDATIONS ON THE WAYS TO ADDRESS THE NEEDS OF INDIVIDUALS LIVING WITH RARE DISEASES IN THE STATE.

SECTION 2. AND BE IT FURTHER ENACTED, That the terms of the members of the Rare Disease Advisory Council appointed by the Governor under § 13-4802 of the Health – General Article, as enacted by Section 1 of this Act, shall expire as follows:

(1) ~~four~~ seven members, including one member appointed under § 13-4802(a)(8)(vii) of the Health – General Article, in ~~2025~~; 2028; and

(2) ~~six~~ seven members, including one member appointed under § 13-4802(a)(8)(vii) of the Health – General Article, in ~~2026~~; and 2030.

~~(3) six members in 2027.~~

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2023.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.