

SENATE BILL 584

J1

3lr2191
CF HB 703

By: **Senators Gile and Elfreth**

Introduced and read first time: February 6, 2023

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Public Health – Parkinson’s Disease Registry – Established**

3 FOR the purpose of establishing a Parkinson’s Disease Registry in the Maryland
4 Department of Health; requiring the Department to collect certain data for the
5 Registry; authorizing the Department to share certain information in the Registry
6 with certain entities under certain conditions; providing for the confidentiality of
7 information collected under this Act; requiring the Department to maintain a record
8 of individuals granted access to confidential information in the Registry; and
9 generally relating to the establishment of a Parkinson’s Disease Registry.

10 BY repealing and reenacting, with amendments,
11 Article – Health – General
12 Section 18–1201 and 18–1203
13 Annotated Code of Maryland
14 (2019 Replacement Volume and 2022 Supplement)

15 BY repealing
16 Article – Health – General
17 Section 18–1202
18 Annotated Code of Maryland
19 (2019 Replacement Volume and 2022 Supplement)

20 BY adding to
21 Article – Health – General
22 Section 18–1202 and 18–1204 through 18–1210
23 Annotated Code of Maryland
24 (2019 Replacement Volume and 2022 Supplement)

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



Article – Health – General

18–1201.

(a) In this subtitle the following words have the meanings indicated.

(b) “Advisory Committee” means the Parkinson’s Disease Registry Advisory Committee.

(c) **(1) “PARKINSONISMS” MEANS CONDITIONS RELATED TO PARKINSON’S DISEASE THAT CAUSE A COMBINATION OF THE MOVEMENT ABNORMALITIES SEEN IN PARKINSON’S DISEASE.**

(2) “PARKINSONISMS” INCLUDES MULTIPLE SYSTEM ATROPHY, DEMENTIA WITH LEWY BODIES, CORTICOBASAL DEGENERATION, AND PROGRESSIVE SUPRANUCLEAR PALSY.

(D) “Parkinson’s disease” means a chronic and progressive disorder resulting from deficiency of the neurotransmitter dopamine as the consequence of specific degenerative changes in the area of the brain called the basal ganglia, characterized by tremors at rest, slow movements, muscle rigidity, stooped posture, and unsteady or shuffling gait.

(E) “REGISTRY” MEANS THE PARKINSON’S DISEASE REGISTRY.

[18–1202.

There is a Parkinson’s Disease Registry Advisory Committee in the Department.]

18–1202.

THERE IS A PARKINSON’S DISEASE REGISTRY IN THE DEPARTMENT.

18–1203.

(A) THERE IS A PARKINSON’S DISEASE REGISTRY ADVISORY COMMITTEE IN THE DEPARTMENT.

[(a)] (B) The Advisory Committee shall:

(1) Assist in the development and implementation of a Parkinson’s Disease Registry;

(2) Determine what data shall be collected and be stored in a Parkinson’s Disease Registry and the methods to ensure the privacy and confidentiality of data collected and stored in the registry; and

(3) Advise the Department on Parkinson's disease and maintaining a Parkinson's Disease Registry.

[(b)] (C) (1) The Secretary shall appoint individuals to serve on the Advisory Committee, including:

(i) A neurologist;

(ii) A movement disorder specialist;

(iii) A primary care provider;

(iv) A physician informaticist;

(v) A patient with Parkinson's disease;

(vi) A public health professional;

(vii) A population health researcher familiar with disease registries;

(viii) A Parkinson's disease researcher; and

(ix) Any other individuals the Secretary determines are necessary.

(2) The Secretary shall establish:

(i) The duration of term limits for members of the Advisory Committee;

(ii) The frequency of meetings of the Advisory Committee;

(iii) Rules and procedures for conducting business of the Advisory Committee; and

(iv) Any other rules necessary for the Advisory Committee to function effectively.

18-1204.

(A) THE DEPARTMENT SHALL COLLECT DATA FOR THE REGISTRY, INCLUDING DATA ON THE INCIDENCE OF PARKINSON'S DISEASE IN THE STATE AND RELATED EPIDEMIOLOGICAL DATA.

(B) THE ADVISORY COMMITTEE, IN CONSULTATION WITH THE DEPARTMENT, SHALL:

**(1) IDENTIFY CATEGORIES OF DATA TO BE COLLECTED FOR THE
REGISTRY RELATED TO:**

(I) PATIENT DEMOGRAPHICS, INCLUDING GEOGRAPHY; AND

(II) DIAGNOSES; AND

**(2) PERIODICALLY REVIEW THE DATA COLLECTED FOR THE
REGISTRY TO ASSESS WHETHER THE:**

**(I) DATA INCLUDES SUFFICIENT INFORMATION TO ENSURE
THERE ARE NO DUPLICATED PATIENT RECORDS IN THE REGISTRY; AND**

(II) CATEGORIES OF DATA COLLECTED SHOULD BE ALTERED.

18-1205.

**(A) (1) UNLESS OTHERWISE PROVIDED IN THIS SUBTITLE, ALL
INFORMATION COLLECTED FOR THE REGISTRY UNDER THIS SUBTITLE SHALL BE
CONFIDENTIAL.**

**(2) THE DEPARTMENT SHALL IMPLEMENT A CODING SYSTEM THAT
REMOVES ANY PERSONALLY IDENTIFIABLE INFORMATION OF AN INDIVIDUAL FROM
COLLECTED DATA.**

**(B) THE DEPARTMENT, IN CONSULTATION WITH THE ADVISORY
COMMITTEE, SHALL ESTABLISH A SYSTEM FOR THE COLLECTION OF DATA FOR THE
REGISTRY AND DISSEMINATION OF INFORMATION DETERMINING THE INCIDENCE
AND PREVALENCE OF PARKINSON'S DISEASE AND RELATED PARKINSONISMS.**

**(C) (1) THE DEPARTMENT, IN CONSULTATION WITH THE ADVISORY
COMMITTEE, SHALL:**

**(I) NOTIFY, IN WRITING AND ORALLY, ALL INDIVIDUALS IN THE
STATE DIAGNOSED WITH PARKINSON'S DISEASE OR RELATED PARKINSONISMS
ABOUT THE CREATION OF THE REGISTRY, DATA COLLECTION ASSOCIATED WITH
THE REGISTRY, AND THE RIGHT TO OPT OUT OF PARTICIPATION IN THE REGISTRY;
AND**

**(II) PROVIDE AN OPPORTUNITY TO OPT OUT OF PARTICIPATION
IN THE REGISTRY.**

(2) (I) AN INDIVIDUAL WITH PARKINSON'S DISEASE OR RELATED PARKINSONISMS MAY OPT OUT OF PARTICIPATING IN THE REGISTRY BY SUBMITTING WRITTEN NOTICE TO THE DEPARTMENT.

(II) IF AN INDIVIDUAL OPTS OUT OF PARTICIPATION IN THE REGISTRY, THE DEPARTMENT:

1. SHALL RECORD AN INCIDENCE OF A PATIENT WITH PARKINSON'S DISEASE; AND

2. MAY NOT RECORD ANY ADDITIONAL INFORMATION ABOUT THE INDIVIDUAL.

(D) THE DEPARTMENT MAY:

(1) CREATE, REVIEW, AND REVISE A LIST OF DATA POINTS REQUIRED AS PART OF MANDATED PARKINSON'S DISEASE REPORTING UNDER THIS SECTION, INCLUDING NECESSARY TRIGGERING DIAGNOSTIC CONDITIONS THAT ARE CONSISTENT WITH THE LATEST INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS; AND

(2) IMPLEMENT THE COLLECTION OF DATA POINTS ON THE LIST CREATED UNDER ITEM (1) OF THIS SUBSECTION THROUGH A BULLETIN, OR SIMILAR INSTRUCTION, TO NURSE PRACTITIONERS, PHYSICIANS, AND PHYSICIAN ASSISTANTS.

(E) AT LEAST 180 DAYS BEFORE THE DEPARTMENT ADOPTS MANDATORY REPORTING OF PARKINSON'S DISEASE AND RELATED PARKINSONISMS, THE DEPARTMENT SHALL PROVIDE NOTIFICATION OF THE MANDATORY REPORTING OF PARKINSON'S DISEASE AND RELATED PARKINSONISMS:

(1) ON THE DEPARTMENT'S WEBSITE;

(2) DIRECTLY TO ASSOCIATIONS REPRESENTING HOSPITALS, HEALTH CARE PROFESSIONALS, AND OTHER HEALTH CARE PROVIDERS IN THE STATE; AND

(3) DIRECTLY TO THE STATE BOARD OF NURSING AND THE STATE BOARD OF PHYSICIANS.

(F) (1) A NURSE PRACTITIONER, PHYSICIAN, OR PHYSICIAN ASSISTANT WHO DIAGNOSES PATIENTS WITH PARKINSON'S DISEASE AND RELATED PARKINSONISMS SHALL REPORT EACH CASE OF PARKINSON'S DISEASE AND

1 RELATED PARKINSONISMS TO THE REGISTRY IN A FORMAT DETERMINED BY THE
2 DEPARTMENT.

3 (2) THE DEPARTMENT MAY USE EXISTING REPORTING PROCEDURES
4 TO IMPLEMENT THE REQUIREMENT UNDER PARAGRAPH (1) OF THIS SUBSECTION
5 FOR DIAGNOSIS REPORTING AND DATA SUBMISSION BY A NURSE PRACTITIONER,
6 PHYSICIAN, OR PHYSICIAN ASSISTANT.

7 18-1206.

8 (A) THE DEPARTMENT MAY ENTER INTO AGREEMENTS TO PROVIDE DATA
9 COLLECTED IN THE REGISTRY WITH PARKINSON'S DISEASE REGISTRIES IN OTHER
10 STATES, FEDERAL PARKINSON'S DISEASE CONTROL AGENCIES, LOCAL HEALTH
11 DEPARTMENTS, OR HEALTH RESEARCHERS FOR THE STUDY OF PARKINSON'S
12 DISEASE AND RELATED PARKINSONISMS.

13 (B) (1) BEFORE CONFIDENTIAL INFORMATION IS DISCLOSED UNDER
14 SUBSECTION (A) OF THIS SECTION, THE DEPARTMENT SHALL RECEIVE A WRITTEN
15 AGREEMENT FROM THE PARTNERING ENTITY TO MAINTAIN THE CONFIDENTIALITY
16 OF THE INFORMATION.

17 (2) IF THE ENTITY RECEIVING CONFIDENTIAL DATA FROM THE
18 REGISTRY IS A RESEARCH ENTITY, THE RESEARCH ENTITY SHALL:

19 (I) OBTAIN APPROVAL FROM THE COMMITTEE AT THE
20 RESEARCH ENTITY THAT NORMALLY REVIEWS RESEARCH PROJECTS FOR THE
21 PROTECTION OF HUMAN SUBJECTS ESTABLISHED IN ACCORDANCE WITH TITLE 45
22 OF THE CODE OF FEDERAL REGULATIONS; AND

23 (II) PROVIDE DOCUMENTATION TO THE DEPARTMENT THAT
24 DEMONSTRATES, TO THE DEPARTMENT'S SATISFACTION, THAT THE RESEARCH
25 ENTITY HAS ESTABLISHED PROCEDURES AND THE ABILITY TO MAINTAIN THE
26 CONFIDENTIALITY OF THE DISCLOSED INFORMATION.

27 (C) THE DEPARTMENT SHALL ESTABLISH PROCEDURES TO REVIEW AND
28 APPROVE REQUESTS TO USE REGISTRY DATA FOR SCIENTIFIC RESEARCH.

29 18-1207.

30 (A) NOTWITHSTANDING ANY OTHER PROVISION OF LAW OR RULE OF
31 PROCEDURE OR EVIDENCE IN THE MARYLAND RULES:

32 (1) A DATA DISCLOSURE AUTHORIZED BY THIS SUBTITLE MAY NOT:

1 (I) INCLUDE INFORMATION OTHER THAN THE INFORMATION
2 NECESSARY FOR THE PURPOSE OF THE DISCLOSURE;

3 (II) BE USED FOR A PURPOSE OTHER THAN THE PURPOSE FOR
4 THE DISCLOSURE; OR

5 (III) BE FURTHER DISCLOSED;

6 (2) THE CONFIDENTIAL INFORMATION COLLECTED FOR THE
7 REGISTRY MAY NOT BE MADE AVAILABLE FOR SUBPOENA, DISCLOSED,
8 DISCOVERABLE, OR COMPELLED TO BE PRODUCED IN ANY CIVIL, CRIMINAL,
9 ADMINISTRATIVE, OR OTHER PROCEEDING; AND

10 (3) THE CONFIDENTIAL INFORMATION COLLECTED FOR THE
11 REGISTRY MAY NOT BE DEEMED ADMISSIBLE AS EVIDENCE IN ANY CIVIL, CRIMINAL,
12 ADMINISTRATIVE, TRIBUNAL, OR OTHER PROCEEDING.

13 (B) (1) THIS SECTION DOES NOT PREEMPT THE AUTHORITY OF A HEALTH
14 CARE PROVIDER, AS DEFINED IN § 19-132 OF THIS ARTICLE, PROVIDING
15 DIAGNOSTIC SERVICES OR TREATMENT TO PATIENTS WITH PARKINSON'S DISEASE
16 OR RELATED PARKINSONISMS TO MAINTAIN A PARKINSON'S DISEASE REGISTRY.

17 (2) THIS SECTION DOES NOT PROHIBIT THE PUBLICATION OF
18 REPORTS AND STATISTICAL COMPILATIONS THAT DO NOT IDENTIFY INDIVIDUALS
19 WITH PARKINSON'S DISEASE OR RELATED PARKINSONISMS OR INDIVIDUAL
20 SOURCES OF INFORMATION.

21 18-1208.

22 (A) THE DEPARTMENT SHALL MAINTAIN A RECORD OF INDIVIDUALS
23 GRANTED ACCESS TO CONFIDENTIAL INFORMATION FROM THE REGISTRY.

24 (B) THE DEPARTMENT MAY NOT DENY A REQUEST FOR INSPECTION OF THE
25 RECORD MAINTAINED UNDER SUBSECTION (A) OF THIS SECTION UNDER TITLE 4 OF
26 THE GENERAL PROVISIONS ARTICLE.

27 (C) THE RECORD MAINTAINED UNDER SUBSECTION (A) OF THIS SECTION
28 SHALL INCLUDE THE ACCESSING INDIVIDUAL'S:

29 (1) NAME;

30 (2) TITLE;

(3) ADDRESS;

(4) ORGANIZATIONAL AFFILIATION;

(5) DATES OF ACCESS; AND

(6) PURPOSE FOR ACCESSING THE INFORMATION.

18-1209.

THE DEPARTMENT SHALL ADOPT REGULATIONS NECESSARY TO CARRY OUT THIS SUBTITLE.

18-1210.

(A) ON OR BEFORE DECEMBER 1 EACH YEAR, BEGINNING IN 2023, THE ADVISORY COMMITTEE SHALL REPORT TO THE SECRETARY OF HEALTH AND, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE ON THE REGISTRY AND THE PREVALENCE OF PARKINSON'S DISEASE IN THE STATE.

(B) THE DEPARTMENT SHALL POST THE REPORT REQUIRED UNDER SUBSECTION (A) OF THIS SECTION ON A DEDICATED WEBSITE ACCESSIBLE TO THE PUBLIC.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2023.