

UNOFFICIAL COPY OF SENATE BILL 584

SENATE BILL 584

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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~~ State-designated health information exchange to
collect certain data for the

5 Registry and report certain data to the Department on request; 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 ~~4-302.3(g)~~, 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~~ 18-1214

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:

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Article - Health - General

4-302.3.

(g) (1) The State-designated health information exchange shall:

(i) Participate in the advisory committee established under § 13-4306(a)(1) of this article; [and]

(ii) Maintain a data set for the Maryland Commission on Health Equity and provide data from the data set consistent with the parameters defined by the advisory committee ESTABLISHED UNDER § 13-4306(A)(1) OF THIS ARTICLE; AND

(III) COLLECT DATA FOR THE PARKINSON'S DISEASE REGISTRY UNDER TITLE 18, SUBTITLE 12 OF THIS ARTICLE.

(2) If approved by the Maryland Commission on Health Equity, the State-designated health information exchange may use the data set maintained under paragraph [(1)] (1)(II) of this subsection to improve health outcomes for patients.

2 18-1201.

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

4 (b) "Advisory Committee" means the Parkinson's Disease Registry Advisory
5 Committee.

6 (c) **(1) "PARKINSONISMS" MEANS CONDITIONS RELATED TO
7 PARKINSON'S DISEASE THAT CAUSE A COMBINATION OF THE MOVEMENT
8 ABNORMALITIES SEEN IN PARKINSON'S DISEASE.**

9 **(2) "PARKINSONISMS" INCLUDES MULTIPLE SYSTEM ATROPHY,
10 DEMENTIA WITH LEWY BODIES, CORTICOBASAL DEGENERATION, AND PROGRESSIVE
11 SUPRANUCLEAR PALSY.**

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

16 **(E) "REGISTRY" MEANS THE PARKINSON'S DISEASE REGISTRY.**

17 [18-1202.

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

19 **18-1202.**

20 **THERE IS A PARKINSON'S DISEASE REGISTRY IN THE DEPARTMENT.**

21 18-1203.

22 **(A) THERE IS A PARKINSON'S DISEASE REGISTRY ADVISORY COMMITTEE
23 IN THE DEPARTMENT.**

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

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

27 (2) Determine what data shall be collected and be stored in a Parkinson's

28 Disease Registry and the methods to ensure the privacy and confidentiality of data collected
29 and stored in the registry; and

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

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

5 (i) A neurologist;

6 (ii) A movement disorder specialist;

7 (iii) A primary care provider;

8 (iv) A physician informaticist;

9 (v) A patient with Parkinson's disease;

10 (vi) A public health professional;

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

12 (viii) A Parkinson's disease researcher; and

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

14 (2) The Secretary shall establish:

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

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

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

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

22 **18-1204.**

23 **(A) (1) ~~THE BEGINNING OCTOBER 1, 2024, THE DEPARTMENT~~**
24 **STATE-DESIGNATED HEALTH INFORMATION EXCHANGE SHALL COLLECT DATA FOR THE REGISTRY,**
25 **INCLUDING DATA ON THE INCIDENCE OF PARKINSON'S DISEASE IN THE STATE AND**
RELATED EPIDEMIOLOGICAL DATA.

(2) (I) ON REQUEST OF THE DEPARTMENT, THE
STATE-DESIGNATED HEALTH INFORMATION EXCHANGE SHALL REPORT THE DATA FOR THE REGISTRY TO
THE DEPARTMENT IN A FORMAT DETERMINED BY THE DEPARTMENT.

(II) THE DATA REPORTED UNDER SUBPARAGRAPH (I) OF THIS
PARAGRAPH SHALL INCLUDE DATA AT THE PATIENT-LEVEL AND AT THE
AGGREGATE-LEVEL.

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

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

3 **(I) PATIENT DEMOGRAPHICS, INCLUDING GEOGRAPHY; AND**

4 **(II) DIAGNOSES; AND**

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

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

9 **(II) CATEGORIES OF DATA COLLECTED SHOULD BE ALTERED.**

10 **18-1205.**

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

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

17 **(B) THE DEPARTMENT, IN CONSULTATION WITH THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE**
 18 **AND THE ADVISORY**
 19 **COMMITTEE, SHALL ESTABLISH A SYSTEM FOR THE COLLECTION OF DATA FOR THE**
 20 **REGISTRY AND DISSEMINATION OF INFORMATION DETERMINING THE INCIDENCE**
 21 **AND PREVALENCE OF PARKINSON'S DISEASE AND RELATED PARKINSONISMS.**

22 **(C) (1) THE DEPARTMENT, IN CONSULTATION WITH THE STATE-DESIGNATED HEALTH INFORMATION**
 23 **EXCHANGE AND THE ADVISORY**
 24 **COMMITTEE, SHALL**

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

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

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1 (2) (I) ~~AN INDIVIDUAL WITH PARKINSON'S DISEASE OR RELATED~~
2 ~~PARKINSONISMS MAY OPT OUT OF PARTICIPATING IN THE REGISTRY BY~~
3 ~~SUBMITTING WRITTEN NOTICE TO THE DEPARTMENT~~ THE STATE-DESIGNATED HEALTH INFORMATION EXCHANGE
SHALL ALLOW AN INDIVIDUAL WITH PARKINSON'S DISEASE OR RELATED PARKINSONISMS TO OPT OUT OF
PARTICIPATING IN THE
REGISTRY IN ACCORDANCE WITH HEALTH INFORMATION REGULATIONS ADOPTED BY THE MARYLAND HEALTH CARE
COMMISSION
UNDER COMAR 10.25.18.

4 (II) IF AN INDIVIDUAL OPTS OUT OF PARTICIPATION IN THE
5 REGISTRY, THE ~~DEPARTMENT~~ STATE-DESIGNATED HEALTH INFORMATION EXCHANGE:

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

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

10 (D) THE DEPARTMENT MAY:

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

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

20 (E) AT LEAST 180 DAYS BEFORE THE ~~DEPARTMENT~~ STATE-DESIGNATED HEALTH INFORMATION
EXCHANGE ADOPTS MANDATORY
21 REPORTING OF PARKINSON'S DISEASE AND RELATED PARKINSONISMS, THE
22 DEPARTMENT SHALL PROVIDE NOTIFICATION OF THE MANDATORY REPORTING OF
23 PARKINSON'S DISEASE AND RELATED PARKINSONISMS:

24 (1) ON THE DEPARTMENT'S WEBSITE;

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

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

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

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1 RELATED PARKINSONISMS TO THE REGISTRY IN A FORMAT DETERMINED BY THE
2 ~~DEPARTMENT~~ STATE-DESIGNATED HEALTH INFORMATION EXCHANGE.

3 (2) ~~THE DEPARTMENT~~ STATE-DESIGNATED HEALTH INFORMATION EXCHANGE 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:

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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.

(C) IF INFORMATION PROVIDED UNDER THIS SUBTITLE IS PROVIDED
CONFIDENTIALLY, THE PROVISION OF THE INFORMATION MAY NOT:

(1) EXPOSE ANY PERSON TO LIABILITY FOR PROVIDING THE
INFORMATION; AND

(2) BE CONSIDERED A WAIVER OF ANY PRIVILEGE OR A VIOLATION OF A
CONFIDENTIAL RELATIONSHIP.

(D) AN INDIVIDUAL WHOSE INFORMATION IS IN THE REGISTRY SHALL
HAVE ACCESS TO THE INDIVIDUAL'S 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;

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- 1 (3) ADDRESS;
- 2 (4) ORGANIZATIONAL AFFILIATION;
- 3 (5) DATES OF ACCESS; AND
- 4 (6) PURPOSE FOR ACCESSING THE INFORMATION.

5 **18-1209.**

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

18-1210.

FOR EACH OF FISCAL YEARS 2025 THROUGH 2029, THE GOVERNOR SHALL INCLUDE IN THE ANNUAL BUDGET BILL AN APPROPRIATION SUFFICIENT TO ENSURE THE PROPER DEVELOPMENT AND MAINTENANCE OF THE REGISTRY AND ADEQUATE STAFFING TO IMPLEMENT AND MAINTAIN THE REGISTRY.

18-1211.

THE DEPARTMENT MAY INSPECT A REPRESENTATIVE SAMPLE OF THE MEDICAL RECORDS OF PATIENTS DIAGNOSED OR TREATED, INCLUDING PATIENTS ADMITTED FOR TREATMENT, FOR PARKINSON'S DISEASE AND RELATED PARKINSONISMS AT HOSPITALS AND OTHER HEALTH CARE FACILITIES THAT PROVIDE TREATMENT FOR PARKINSON'S DISEASE AND RELATED PARKINSONISMS TO ENSURE COMPLIANCE WITH THE REPORTING REQUIREMENTS ESTABLISHED UNDER THIS SUBTITLE.

18-1212.

(A) ON OR BEFORE OCTOBER 1, 2029, THE DEPARTMENT AND THE ADVISORY COMMITTEE SHALL CONDUCT A REVIEW OF THE REGISTRY, INCLUDING:

- (1) HOW THE REGISTRY IS BEING USED; AND
- (2) WHETHER THE REGISTRY IS FULFILLING ITS INTENDED PURPOSE.

(B) FOLLOWING THE REVIEW OF THE REGISTRY CONDUCTED UNDER SUBSECTION (A) OF THIS SECTION, THE DEPARTMENT SHALL DEVELOP RECOMMENDATIONS ON ANY CHANGES DETERMINED TO BE NECESSARY TO UPDATE THE REGISTRY.

18-1213.

THE DEPARTMENT SHALL CREATE AND MAINTAIN A PUBLICLY AVAILABLE WEBSITE THAT INCLUDES INFORMATION RELATED TO THE REGISTRY, INCLUDING:

- (1) A YEARLY PROGRAM SUMMARY; AND
- (2) ANY OTHER RELEVANT INFORMATION RELATED TO THE REGISTRY DETERMINED TO BE NECESSARY BY THE ADVISORY COMMITTEE.

8 ~~18-1210.~~ **18-1214.**

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

14 ~~THE STATE~~ , IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, THE FOLLOWING
INFORMATION:

(1) THE INCIDENCE AND PREVALENCE OF PARKINSON'S DISEASE IN
THE STATE BY COUNTY;

(2) THE NUMBER OF MEDICAL RECORDS THAT HAVE BEEN REPORTED TO
AND INCLUDED IN THE REGISTRY;

(3) DEMOGRAPHIC INFORMATION FROM THE REGISTRY, SUCH AS
PATIENTS BY AGE, GENDER, AND RACE, WITHOUT THE DISCLOSURE OF PERSONALLY
IDENTIFIABLE INFORMATION; AND

(4) ANY OTHER INFORMATION THE DEPARTMENT DETERMINES IS
RELEVANT TO THE REGISTRY AND PARKINSON'S DISEASE IN THE STATE.

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

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