

116TH CONGRESS
1ST SESSION

S. 1842

To protect the personal health data of all Americans.

IN THE SENATE OF THE UNITED STATES

JUNE 13, 2019

Ms. KLOBUCHAR (for herself and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To protect the personal health data of all Americans.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Protecting Personal
5 Health Data Act”.

6 **SEC. 2. FINDINGS.**

7 Congress finds as follows:

8 (1) On July 19, 2016, the Department of
9 Health and Human Services, acting through the Of-
10 fice of the National Coordinator for Health Informa-
11 tion Technology and in coordination with the Office

1 for Civil Rights of the Department of Health and
2 Human Services and the Federal Trade Commission,
3 issued a report to Congress entitled “Examining
4 Oversight of the Privacy & Security of Health Data
5 Collected by Entities Not Regulated by HIPAA” (re-
6 ferred to in this section as the “report”) about the
7 need to enact modern protections for consumers’
8 personal health data.

9 (2) The report states that “[t]he wearable fit-
10 ness trackers, social media sites where individuals
11 share health information through specific social net-
12 works, and other technologies that are common
13 today did not exist when Congress enacted the
14 Health Insurance Portability and Accountability Act
15 of 1996”.

16 (3) The report states that entities not covered
17 by the privacy protections of the Health Insurance
18 Portability and Accountability Act of 1996 (Public
19 Law 104–191), such as wearable fitness trackers
20 and health-focused social media sites, “engage in a
21 variety of practices such as online advertising and
22 marketing, commercial uses or sale of individual in-
23 formation, and behavioral tracking practices, all of
24 which indicate information use that is likely broader
25 than what individuals would anticipate”.

1 (4) The report “identifies key gaps that exist
2 between HIPAA regulated entities and those not
3 regulated by HIPAA” and “recommends addressing
4 those gaps in a way that protects consumers while
5 leveling the playing field for innovators inside and
6 outside of HIPAA”.

7 **SEC. 3. DEFINITIONS.**

8 In this Act:

9 (1) CONSUMER DEVICES, SERVICES, APPLICA-
10 TIONS, AND SOFTWARE.—

11 (A) IN GENERAL.—Except as provided in
12 subparagraph (C), the term “consumer devices,
13 services, applications, and software” means de-
14 vices, services, applications, and software—

15 (i) that are primarily designed for or
16 marketed to consumers; and

17 (ii) a substantial purpose or use of
18 which is to collect or use personal health
19 data.

20 (B) INCLUSION.—The term “consumer de-
21 vices, services, applications, and software” shall
22 include, but is not limited to—

23 (i) direct-to-consumer genetic testing
24 services;

(ii) cloud-based or mobile technologies that are designed to collect individuals' personal health data directly or indirectly with individuals' consent, which could enable sharing of such information, such as wearable fitness trackers; and

(iii) internet-based social media sites which are primarily designed for, or marketed to, consumers to collect or use personal health data, including sites that share health conditions and experiences.

(C) EXCEPTION.—The term “consumer devices, services, applications, and software” shall not include—

(i) products on which personal health data is derived solely from other information that is not personal health data, such as Global Positioning System data; or

(ii) products primarily designed for, or marketed to, covered entities and business associates (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note)).

1 (2) DIRECT-TO-CONSUMER GENETIC TESTING
2 SERVICES.—The term “direct-to-consumer genetic
3 testing service” means a service, which may include
4 a test that analyzes various aspects of an individ-
5 ual’s genetic material, that enables a consumer to
6 have access to their genetic information, or to infor-
7 mation derived therefrom, without the need to have
8 a health care provider or health insurance issuer
9 participate in the process of gaining access.

10 (3) NATIONAL COORDINATOR.—The term “Na-
11 tional Coordinator” means the National Coordinator
12 for Health Information Technology at the Depart-
13 ment of Health and Human Services.

14 (4) OPERATOR.—The term “operator” means
15 any person who operates any type of consumer de-
16 vices, services, applications, and software or who
17 provides consumer devices, services, applications,
18 and software for the use of consumers and collects
19 or maintains personal health data from or about the
20 users of such consumer devices, services, applica-
21 tions, and software.

22 (5) PERSONAL HEALTH DATA.—The term “per-
23 sonal health data” means any information, including
24 genetic information, whether oral or recorded in any
25 form or medium, that relates to the past, present, or

1 future physical or mental health or condition of an
 2 individual and that identifies the individual or with
 3 respect to which there is a reasonable basis to be-
 4 lieve that the information can be used to identify the
 5 individual.

6 (6) SECRETARY.—The term “Secretary” means
 7 the Secretary of Health and Human Services.

8 **SEC. 4. PROMULGATION OF REGULATIONS FOR OPERA-**
 9 **TORS OF CONSUMER DEVICES, SERVICES, AP-**
 10 **PLICATIONS, AND SOFTWARE.**

11 (a) IN GENERAL.—Not later than 6 months after the
 12 date on which the report is submitted under section 5(d),
 13 the Secretary, in consultation with the Chairman of the
 14 Federal Trade Commission, the National Coordinator, rel-
 15 evant stakeholders, and heads of such other Federal agen-
 16 cies as the Secretary considers appropriate, shall promul-
 17 gate regulations to help strengthen privacy and security
 18 protections for consumers’ personal health data that is col-
 19 lected, processed, analyzed, or used by consumer devices,
 20 services, applications, and software.

21 (b) REQUIREMENTS.—

22 (1) IN GENERAL.—The Secretary shall ensure
 23 that the regulations pursuant to subsection (a)—

24 (A) account for differences in the nature
 25 and sensitivity of the data collected or stored on

1 the consumer device, service, application, or
2 software; and

3 (B) include such definitions for relevant
4 terms that are necessary to accomplish the
5 goals of the regulations set forth in subsection
6 (a).

7 (2) REQUIREMENTS OF SECRETARY.—In the
8 promulgation of regulations under subsection (a),
9 the Secretary, to the extent practicable, shall—

10 (A) consider the findings in the report
11 issued by the Department of Health and
12 Human Services to Congress entitled “Exam-
13 ining Oversight of the Privacy & Security of
14 Health Data Collected by Entities Not Regu-
15 lated by HIPAA”, including findings regarding
16 individuals’ access rights, re-use of data by
17 third parties, security standards applicable to
18 data holders and users, confusion or ambiguity
19 regarding terminology related to privacy and se-
20 curity protections, and the adequacy of collec-
21 tion, use, and disclosure limitations;

22 (B) consider other regulations and guid-
23 ance issued by the Federal Trade Commission,
24 and other regulations promulgated under sec-
25 tion 264(c) of the Health Insurance Portability

1 and Accountability Act of 1996 (42 U.S.C.
2 1320d–2 note), subtitle D of the Health Infor-
3 mation Technology for Economic and Clinical
4 Health Act (42 U.S.C. 17921 et seq.), Genetic
5 Information Nondiscrimination Act (Public Law
6 110–233, 122 Stat. 881), the Common Rule as
7 contained in part 46 of title 45, Code of Fed-
8 eral Regulations, and other related Acts;

9 (C) consistent with paragraph (3), consider
10 appropriate uniform standards for consent re-
11 lated to the handling of genetic data, biometric
12 data, and personal health data;

13 (D) consider exceptions to consent require-
14 ments under subparagraph (C) for purposes
15 that may include law enforcement, academic re-
16 search or research for the sole purpose of as-
17 sessing health care utilization and outcomes,
18 emergency medical treatment, or determining
19 paternity;

20 (E) consider appropriate minimum stand-
21 ards of security that may differ according to
22 the nature and sensitivity of the data collected
23 or stored on, or processed or transferred by, the
24 consumer device, service, application, or soft-
25 ware;

1 (F) consider appropriate standards for the
 2 de-identification of personal health data;

3 (G) consider appropriate limitations on the
 4 collection, use, or disclosure of personal health
 5 data to that which is directly relevant and nec-
 6 essary to accomplish a specified purpose;

7 (H) consult with the National Coordinator,
 8 the Commissioner of Food and Drugs, and the
 9 Chairman of the Federal Trade Commission;
 10 and

11 (I) provide for initial and ongoing outreach
 12 regarding regulations affecting industries, busi-
 13 nesses, and individuals to ensure awareness of
 14 consumer privacy and security protections in
 15 the field of digital health technology.

16 (3) UNIFORM STANDARDS.—In the review of
 17 each of the areas described in paragraph (2)(C), the
 18 Secretary shall consider—

19 (A) the development of standards for ob-
 20 taining user consent based on how information
 21 will be shared to ensure that prior to the collec-
 22 tion, analysis, use, or disclosure of consumers’
 23 personal health data, an operator of a consumer
 24 device, service, application, or software specifies

1 the uses of the personal health data and who
2 will have access to the information;

3 (B) the manner in which consent is ob-
4 tained in a way that uses clear, concise, and
5 well-organized language that is easily accessible,
6 of reasonable length, at an appropriate level of
7 readability, and clearly distinguishable from
8 other matters;

9 (C) a process to limit the transfer of per-
10 sonal health data to third parties and provide
11 consumers with greater control over how their
12 personal health data is used for marketing pur-
13 poses;

14 (D) secondary uses outside of the primary
15 purpose of the service as initially indicated
16 when consent was first obtained;

17 (E) a process to permit a withdrawal of
18 consent to ensure that a user is able to remove
19 consent for the terms of service for use of the
20 consumer device, service, application, or soft-
21 ware, including the collection and use of per-
22 sonal health data as easily as the user is able
23 to give such consent;

24 (F) providing a right to access a copy of
25 the personal health data that the operator has

1 collected, analyzed, or used, free of charge and
2 in an electronic and easily accessible format, in-
3 cluding a list of each entity that received the
4 personal health data from the operator, whether
5 through sale or other means; and

6 (G) providing a right to delete and amend
7 personal health data, to the extent practicable,
8 that the operator has collected, analyzed, or
9 used.

10 (c) UPDATES.—The Secretary shall review and, if
11 necessary, update the regulations promulgated under sub-
12 section (a) in accordance with the requirements under sub-
13 section (b).

14 (d) PUBLIC AVAILABILITY.—The Department of
15 Health and Human Services shall make prominently avail-
16 able to the public on the Department’s internet website,
17 clear and concise information about available resources re-
18 lated to the regulations promulgated under subsection (a)
19 and all updates to such resources.

20 (e) CONSISTENCY OF RESOURCES PUBLISHED BY
21 FEDERAL AGENCIES.—If a Federal agency publishes re-
22 sources to help protect consumers’ personal health data,
23 the head of such Federal agency, to the degree practicable,
24 shall make such resources consistent with the regulations
25 promulgated under subsection (a).

1 (f) OTHER FEDERAL PRIVACY AND SECURITY RE-
2 QUIREMENTS.—Nothing in this section shall be construed
3 to supersede, alter, or otherwise affect any privacy and
4 security requirements enforced by Federal agencies.

5 **SEC. 5. NATIONAL TASK FORCE ON HEALTH DATA PROTEC-**
6 **TION.**

7 (a) ESTABLISHMENT.—The Secretary, in consulta-
8 tion with the Chairman of the Federal Trade Commission,
9 the National Coordinator, and relevant stakeholders, shall
10 establish a task force, to be known as the National Task
11 Force on Health Data Protection (referred to in this sec-
12 tion as the “Task Force”).

13 (b) DUTIES.—The Task Force shall—

14 (1) study the long-term effectiveness of de-iden-
15 tification methodologies for genetic data and biomet-
16 ric data;

17 (2) evaluate and provide input on the develop-
18 ment of security standards, including encryption
19 standards and transfer protocols, for consumer de-
20 vices, services, applications, and software;

21 (3) evaluate and provide input with respect to
22 addressing cybersecurity risks and security concerns
23 related to consumer devices, services, applications,
24 and software;

1 (4) evaluate and provide input with respect to
2 the privacy concerns and protection standards re-
3 lated to consumer and employee health data;

4 (5) review and advise on the need, if any, to up-
5 date the report issued by the Department of Health
6 and Human Services to Congress entitled “Exam-
7 ining Oversight of the Privacy & Security of Health
8 Data Collected by Entities Not Regulated by
9 HIPAA”; and

10 (6) provide advice and consultation in the es-
11 tablishment and dissemination of resources to edu-
12 cate and advise consumers about the basics of genet-
13 ics and direct-to-consumer genetic testing, and the
14 risks, benefits, and limitations of such testing.

15 (c) MEMBERS.—The Secretary, in consultation with
16 the Chairman of the Federal Trade Commission, the Na-
17 tional Coordinator, and relevant stakeholders, shall ap-
18 point not more than 15 members to the Task Force. In
19 appointing such members, the Secretary shall ensure that
20 the total membership of the Task Force is an odd number
21 and represents a diverse set of stakeholder perspectives.

22 (d) REPORTING.—Not later than 1 year after the
23 date of enactment of this Act, the Task Force shall pre-
24 pare and submit to the Committee on Commerce, Science,
25 and Transportation of the Senate, the Committee on

1 Health, Education, Labor, and Pensions of the Senate, the
2 Committee on Homeland Security and Governmental Af-
3 fairs of the Senate, the Committee on Energy and Com-
4 merce of the House of Representatives, the Committee on
5 Homeland Security of the House of Representatives, the
6 Secretary, the Chairman of the Federal Trade Commis-
7 sion, and the Commissioner of Food and Drugs, a report
8 on the findings of the Task Force.

9 (e) AUTHORIZATION OF APPROPRIATIONS.—There
10 are authorized to be appropriated such sums as may be
11 necessary to carry out this section.

12 (f) FEDERAL ADVISORY COMMITTEE ACT.—The
13 Federal Advisory Committee Act (5 U.S.C. App.) shall
14 apply to the Task Force.

15 (g) SUNSET.—

16 (1) IN GENERAL.—The Task Force shall termi-
17 nate on the date that is 5 years after the date of the
18 first meeting of the Task Force.

19 (2) RECOMMENDATION.—Not later than the
20 date that is one year prior to the termination of the
21 Task Force under paragraph (1), the Secretary shall
22 submit to Congress a recommendation on whether
23 the Task Force should be extended.

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