

117TH CONGRESS  
1ST SESSION

# S. 500

To prohibit the transfer or sale of certain consumer health information,  
and for other purposes.

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IN THE SENATE OF THE UNITED STATES

MARCH 1, 2021

Mr. CASSIDY (for himself and Ms. ROSEN) introduced the following bill; which  
was read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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## A BILL

To prohibit the transfer or sale of certain consumer health  
information, and for other purposes.

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 “Stop Marketing And  
5 Revealing The Wearables And Trackers Consumer Health  
6 Data Act” or the “SMARTWATCH Data Act”.

7 **SEC. 2. DEFINITIONS.**

8 In this Act:

9 (1) **AGGREGATED.**—The term “aggregated”,  
10 with respect to consumer health information—

1 (A) means the removal of individual con-  
2 sumer identities, so that the information is not  
3 linked or reasonably linkable to any consumer,  
4 including a personal consumer device; and

5 (B) does not include one or more indi-  
6 vidual consumer records that have not been  
7 deidentified.

8 (2) BIOMETRIC INFORMATION.—The term “bio-  
9 metric information”—

10 (A) means the physiological, biological, or  
11 behavioral characteristics of an individual, and  
12 the recorded, copied, captured, converted,  
13 stored derivatives of any such characteristics,  
14 that can be used, singly or in combination with  
15 each other or with other identifying data, to es-  
16 tablish the identity of an individual; and

17 (B) includes deoxyribonucleic acid, imagery  
18 of the iris, retina, fingerprint, face, hand, palm,  
19 vein patterns, and voice recordings, from which  
20 an identifier template, such as a faceprint, a  
21 minutiae template, or a voiceprint, can be ex-  
22 tracted.

23 (3) BUSINESS ASSOCIATE; COVERED ENTITY;  
24 PROTECTED HEALTH INFORMATION.—The terms  
25 “business associate”, “covered entity”, and “pro-

1 tected health information” have the meanings given  
2 such terms in section 160.103 of title 45, Code of  
3 Federal Regulations (or any successor regulations).

4 (4) COMMERCIAL PURPOSES.—The term “com-  
5 mercial purposes”—

6 (A) means an action intended—

7 (i) to advance the commercial or eco-  
8 nomic interests of a person, such as by in-  
9 ducing another person to buy, rent, lease,  
10 join, subscribe to, provide, or exchange  
11 products, goods, property, information, or  
12 services; or

13 (ii) to enable or affect, directly or in-  
14 directly, a commercial transaction; and

15 (B) does not include engaging in speech  
16 that State or Federal courts have recognized as  
17 noncommercial speech, including political  
18 speech and journalism.

19 (5) CONSUMER DEVICE.—The term “consumer  
20 device”—

21 (A) means a commercially produced piece  
22 of equipment, application software, or mecha-  
23 nism that has the primary function or capa-  
24 bility to collect, store, or transmit consumer  
25 health information; and

1 (B) may include a device, as defined in  
2 section 201(h) of the Federal Food, Drug, and  
3 Cosmetic Act (21 U.S.C. 321(h)).

4 (6) CONSUMER HEALTH INFORMATION.—The  
5 term “consumer health information” means any in-  
6 formation about the health status, personal biomet-  
7 ric information, or personal kinesthetic information  
8 about a specific individual that is created or col-  
9 lected by a personal consumer device, whether de-  
10 tected from sensors or input manually.

11 (7) DEIDENTIFIED.—The term “deidentified”  
12 means information that cannot reasonably identify,  
13 relate to, describe, be capable of being associated  
14 with, or be linked, directly or indirectly, to a par-  
15 ticular consumer, computer, or other device.

16 (8) INFORMATION BROKER.—The term “infor-  
17 mation broker” means any entity that collects con-  
18 sumers’ personal information and resells or shares  
19 that information with another person.

20 (9) KINESTHETIC INFORMATION.—The term  
21 “kinesthetic information” means keystroke patterns  
22 or rhythms, gait patterns or rhythms, sleep informa-  
23 tion, and other data that relates to the personal  
24 health of an individual.

1 **SEC. 3. PROHIBITIONS.**

2 (a) IN GENERAL.—Subject to subsection (b), no enti-  
3 ty that collects consumer health information may—

4 (1) transfer, sell, share, or allow access to any  
5 consumer health information (unless aggregated or  
6 anonymized) or any other individually identifiable  
7 consumer health information collected, recorded, or  
8 derived from personal consumer devices to any do-  
9 mestic information broker or other domestic entity  
10 if—

11 (A) the primary business function of such  
12 domestic information broker or other domestic  
13 entity is collecting or analyzing consumer infor-  
14 mation for profit; or

15 (B) the purpose for transferring, selling,  
16 sharing, or allowing access to such information  
17 is to otherwise add value to the entity that col-  
18 lects consumer health information, for commer-  
19 cial purposes; or

20 (2) transfer, sell, or allow access to any con-  
21 sumer health information collected, stored, recorded,  
22 or derived from personal consumer devices to any in-  
23 formation broker or any entity outside of the juris-  
24 diction of the United States.

25 (b) EXCEPTIONS.—

1           (1) IN GENERAL.—Subject to paragraph (3),  
2           the prohibition under subsection (a)(1) shall not  
3           apply if—

4                   (A) the entity obtains the informed consent  
5                   of the consumer;

6                   (B) the information is provided to a cov-  
7                   ered entity, as defined in section 160.103 of  
8                   title 45, Code of Federal Regulations (or any  
9                   successor regulations);

10                  (C) such information is provided to a gov-  
11                  ernment organization or agency, including law  
12                  enforcement or regulators, to comply with appli-  
13                  cable laws, regulations, or rules, or requests of  
14                  law enforcement, regulatory, or other govern-  
15                  mental agencies or in response to a legal proc-  
16                  ess in connection with a subpoena, warrant, dis-  
17                  covery order, or other request or order from a  
18                  law enforcement agency;

19                  (D) such information is provided to the en-  
20                  tity's affiliates or other trusted businesses or  
21                  persons to process the information as part of  
22                  the entity's external processing procedures,  
23                  based on the entity's instructions and in compli-  
24                  ance with privacy protections and any other ap-  
25                  propriate confidentiality and security measures;

1           (E) such information is provided in con-  
2           nection with a substantial corporate transaction  
3           of the entity, such as the transfer of ownership,  
4           a merger, consolidation, asset sale, or bank-  
5           ruptcy or insolvency; or

6           (F) such information is provided to aca-  
7           demic, medical, research institutions, or other  
8           nonprofit organizations acting in the public in-  
9           terest for the purpose of detecting or respond-  
10          ing to security incidents; preventing fraud; con-  
11          ducting scientific, historical, or statistical re-  
12          search; or preserving the security and safety of  
13          people or property.

14          (2) TRANSFERS TO FOREIGN ENTITIES.—Sub-  
15          ject to paragraph (3), the prohibition under sub-  
16          section (a)(2) shall not apply if—

17                (A) the transfer is made only for limited  
18                and specific purposes consistent with the con-  
19                sent provided by the individual and with assur-  
20                ances that the recipient will notify the entity  
21                providing the data if such recipient makes a de-  
22                termination that it can no longer use the data  
23                consistent with such consent;

24                (B) the entity transferring the information  
25                determines that the recipient of the information

1 will provide the same level of privacy protection  
2 as is required by the entity transferring the in-  
3 formation;

4 (C) the entity transferring the information  
5 takes reasonable and appropriate steps to en-  
6 sure that the third party effectively processes  
7 the personal information transferred in a man-  
8 ner consistent with the third party's obligations  
9 under the second party's privacy principles; and

10 (D) the entity transferring the information  
11 agrees to take reasonable steps to stop and re-  
12 mediate unauthorized processing of information  
13 by the entity to whom such information is  
14 transferred.

15 (3) LIMITATION.—None of the exceptions under  
16 paragraphs (1) and (2) shall supersede any contrary  
17 rule promulgated by the Federal Trade Commission  
18 that is in effect on the date of enactment of this  
19 Act.

20 (c) TREATMENT OF CONSUMER HEALTH INFORMA-  
21 TION AS PROTECTED HEALTH INFORMATION.—If a cov-  
22 ered entity or business associate, acting in its capacity as  
23 a business associate, receives consumer health information  
24 generated by a personal consumer device at any time for  
25 any reason, such consumer health information is consid-



1 ered protected health information and is subject to the  
2 same protections and restrictions under parts 162 and 164  
3 of title 45, Code of Federal Regulations (or any successor  
4 regulations), as any other protected health information.

5 **SEC. 4. ENFORCEMENT.**

6       The Secretary of Health and Human Services shall  
7 enforce the requirements of section 3 against an entity  
8 that collects or receives consumer health information in  
9 the same manner and to the same extent, as such sec-  
10 retary enforces the privacy regulations promulgated under  
11 section 264(c) of the Health Insurance Portability and Ac-  
12 countability Act of 1996 (Public Law 104–191; 110 Stat.  
13 2033) against a covered entity.

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