

117TH CONGRESS
2D SESSION

S. 3620

To establish the Commission for the Comprehensive Study of Health Data
Use and Privacy Protection.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 9, 2022

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

A BILL

To establish the Commission for the Comprehensive Study
of Health Data Use and Privacy Protection.

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 “Health Data Use and
5 Privacy Commission Act”.

6 **SEC. 2. FINDINGS; RULE OF CONSTRUCTION; SENSE OF**
7 **CONGRESS.**

8 (a) FINDINGS.—Congress finds the following:

9 (1) The people of the United States are increas-
10 ingly concerned about their civil liberties and the

1 confidentiality, security, and use of their personal
2 health information.

3 (2) Commercial entities are increasingly aware
4 that consumers expect them to adopt privacy policies
5 and take appropriate steps to protect consumers'
6 personal health information.

7 (3) Due to a lack of Federal guidelines and a
8 range of different State and local rules regarding
9 privacy protection for individually identifiable health
10 information, there is a growing concern about the
11 confidentiality of personal health information col-
12 lected outside the context of health care delivery,
13 payment, and the practice of medicine generally.

14 (4) There is a need to ensure that accurate and
15 timely health information flows to meet the needs of
16 patients, reduce costs in the health care system, co-
17 ordinate care, and improve health care outcomes.

18 (5) Access to accurate and complete health in-
19 formation is critical to ensure the equitable, safe,
20 and effective delivery of care, the development of
21 novel treatments and cures, the promotion of public
22 health, and the refinement of health care delivery.

23 (6) During the public health emergency with re-
24 spect to COVID-19 declared by the Secretary of
25 Health and Human Services under section 319 of

1 the Public Health Service Act (42 U.S.C. 247d),
2 some Federal and State privacy rules have been
3 waived, modified, or not enforced to help contain the
4 pandemic. As a result, the COVID–19 contagion has
5 uncovered areas where current State and Federal
6 privacy rules may impede patient care, public health
7 management, and efforts to control the pandemic.
8 Moreover, the pandemic has spurred innovation in-
9 cluding the development of new technologies and
10 technology platforms that may not be covered by
11 current regulatory constructs.

12 (7) Privacy regulations promulgated under the
13 Health Insurance Portability and Accountability Act
14 of 1996 (Public Law 104–191) have provided clearly
15 defined responsibilities and enforcement for entities
16 and business associates covered by such regulations,
17 however, the regulations should be assessed to ac-
18 count for the evolution of emerging technologies,
19 data and data management tools, and the mod-
20 ernization of health care delivery.

21 (8) New rules and policies from the Federal
22 Government encouraging the flow of health informa-
23 tion to improve care and patient access to their own
24 health information, including the rules promulgated
25 under the 21st Century Cures Act (Public Law 114–

1 255), raise the issue of protected health information
2 flowing to entities that are not subject to standard-
3 ized privacy protections, including the privacy regu-
4 lations promulgated under the Health Information
5 Portability and Accountability Act of 1996 (Public
6 Law 104–191), the Health Information Technology
7 for Economic and Clinical Health Act (Public Law
8 111–5) (including the amendments made by such
9 Act), and section 444 of the General Education Pro-
10 visions Act (20 U.S.C. 1232g; commonly known as
11 the “Family Educational Rights and Privacy Act of
12 1974”).

13 (9) Given the extensive proliferation of laws and
14 proposals concerning the privacy of health informa-
15 tion in light of recent changes in technology, applica-
16 tions, social media, and other platforms, and the in-
17 creasing generation, collection, use, sharing, and
18 selling of personal health information, a coordinated
19 and comprehensive review is necessary to evaluate
20 the effectiveness of existing protections of personal
21 health information compiled by the health care, in-
22 surance, financial services, consumer electronics, ad-
23 vertising, technology, and other industries.

24 (10) Use of the internet as a medium for com-
25 mercial, social, and health related activities will con-

1 tinue to grow, and more data, including personal
2 health information, will be generated, exchanged,
3 and used by an increasing number of entities en-
4 gaged in the digital marketplace.

5 (11) An increasing number of people of the
6 United States are using consumer health tech-
7 nologies, including wearable technology, with about
8 20 percent of people of the United States reporting
9 using such technology in 2020, and generating data
10 about their personal health and well-being.

11 (12) The United States is the leading economic
12 and social force in the global information economy,
13 and it is important for the United States to continue
14 that leadership. As countries and governing bodies
15 around the world continue to establish privacy
16 standards, these standards will directly affect the
17 United States.

18 (13) The shift from an industry-focused econ-
19 omy to an information-focused economy calls for a
20 swift reassessment of the most effective ways to bal-
21 ance personal privacy against information use for le-
22 gitimate purposes, keeping in mind the potential for
23 unintended effects on technology and product devel-
24 opment, innovation, and medical research.

1 (b) RULE OF CONSTRUCTION.—This Act shall not be
2 construed to prohibit the enactment of privacy legislation
3 by Congress during the existence of the Commission on
4 Health Data Use and Privacy Protection established
5 under section 3.

6 (c) SENSE OF CONGRESS.—It is the sense of Con-
7 gress that—

8 (1) it is the responsibility of Congress to act to
9 protect the privacy of individuals, including individ-
10 uals’ medical information, and to foster the improve-
11 ment our Nation’s health care system; and

12 (2) further study by the Commission estab-
13 lished under section 3 should not be considered a
14 prerequisite for further consideration or enactment
15 of health privacy or other related privacy legislation
16 by Congress.

17 **SEC. 3. ESTABLISHMENT.**

18 There is established a commission to be known as the
19 “Commission on Health Data Use and Privacy Protec-
20 tion” (referred to in this Act as the “Commission”).

21 **SEC. 4. DUTIES OF COMMISSION.**

22 (a) STUDY.—The Commission shall conduct a study
23 of issues relating to protection of individual privacy and
24 the appropriate balance to be achieved between protecting
25 individual privacy and allowing and advancing appropriate

1 uses of personal health information, including the fol-
2 lowing issues:

3 (1) The monitoring, collection, and distribution
4 of personal health information by Federal, State,
5 and local governments, such as the collection of in-
6 formation to combat the spread of infectious dis-
7 eases such as COVID–19, the threat of substance
8 use disorders involving opioids and other substances,
9 and other public health threats and benefits.

10 (2) Current efforts to address the access, ex-
11 change, and use of personal health information by
12 Federal and State governments, individuals, or enti-
13 ties, including—

14 (A) existing statutes and regulations relat-
15 ing to the protection of individual privacy, such
16 as section 552a of title 5, United States Code
17 (commonly known as the “Privacy Act of
18 1974”), section 552 of title 5, United States
19 Code (commonly known as the “Freedom of In-
20 formation Act”), the Federal Trade Commis-
21 sion Act (15 U.S.C. 42 et seq.), the Common
22 Rule and other applicable regulations promul-
23 gated under the Health Information Portability
24 and Accountability Act of 1996 (Public Law
25 104–191), the Health Information Technology

for Economic and Clinical Health Act (Public Law 111–5) (including the amendments made by such Act), the 21st Century Cures Act (Public Law 114–255) (including the amendments made by such Act), and section 444 of the General Education Provisions Act (20 U.S.C. 1232g; commonly known as the “Family Educational Rights and Privacy Act of 1974”);

(B) relevant legislation pending before Congress and State legislatures;

(C) privacy protection efforts undertaken by—

(i) the Federal Government;

(ii) State governments; or

(iii) foreign governments and international governing bodies;

(D) privacy protection efforts undertaken by the private sector, including any relevant recommendations, frameworks, or proposals; and

(E) self-regulatory efforts initiated or proposed by the private sector to respond to privacy issues.

(3) The differences and similarities between Federal, State, and international rules for protecting

1 the privacy of health information and the degree to
2 which such similarities or differences create or ad-
3 dress problems related to collecting, sharing, and
4 using health information to improve care and lower
5 costs, and any trade-offs related to patient privacy
6 and patient control over health information.

7 (4) The need for consistency in deidentification
8 standards for health data to avoid conflicting re-
9 quirements that could impede the improvement of
10 health care through clinical trials, technology devel-
11 opment, public health surveillance, monitoring of
12 general health trends, and medical research.

13 (5) Technologies and data currently used for
14 treatment, payment, and health care operations,
15 compared with technologies used when the privacy
16 regulations promulgated under section 264 of the
17 Health Insurance Portability and Accountability Act
18 of 1996 (42 U.S.C. 1320d-2 note) were first issued,
19 including an assessment of any gaps in the privacy
20 protections under such regulations resulting from
21 data collection and use by non-covered entities, tak-
22 ing into account recommendations of the National
23 Committee on Vital and Health Statistics and the
24 Office for the National Coordinator for Health In-
25 formation Technology.

1 (6) The monitoring, collection, and distribution
2 of personal information by individuals or entities, in-
3 cluding access to, and use of, personal health infor-
4 mation and medical records, and the ability to access
5 and restrict the information.

6 (7) Employer practices and policies with respect
7 to the health information of employees, including—

8 (A) the extent to which employers collect,
9 use, or disclose employee health information for
10 marketing, employment, or insurance under-
11 writing purposes;

12 (B) what restrictions employers place on
13 disclosure or use of employee health informa-
14 tion; and

15 (C) practices of employer medical depart-
16 ments with respect to disclosing employee
17 health information to administrative or other
18 personnel of the employer.

19 (8) Current enforcement of privacy laws and
20 rules through the Federal Trade Commission, the
21 Office for Civil Rights of the Department of Health
22 and Human Services, the Civil Rights Division of
23 the Department of Justice, State agencies (including
24 State attorneys general), and private rights of ac-
25 tion. Such evaluation shall include an examination of

1 efficacy, recommendations, and advantages and dis-
2 advantages of different enforcement mechanisms,
3 and the potential for consolidation of enforcement.

4 (9) Varying notices of privacy practices and
5 whether such practices are effective in informing
6 consumers of their rights and responsibilities, includ-
7 ing, as appropriate, an assessment of best practices.

8 (10) Varying statutory and regulatory employee
9 training requirements, including, as appropriate, an
10 assessment of best practices and whether har-
11 monized training requirements may be more effective
12 in encouraging efficient and effective training of em-
13 ployees in sound practices concerning personal
14 health data.

15 (11) Challenges and potential solutions to con-
16 sent requirements and processes, particularly related
17 to medical research.

18 (12) The degree to which personal health infor-
19 mation is sold with or without consent, and the uses
20 of such information.

21 (b) FIELD HEARINGS.—The Commission may con-
22 duct field hearings in the United States.

23 (c) REPORT.—

1 (1) IN GENERAL.—Not later than 6 months
2 after the appointment of all members of the Com-
3 mission—

4 (A) a majority of the members of the Com-
5 mission shall approve a report described in
6 paragraph (2); and

7 (B) the Commission shall submit the ap-
8 proved report to the Committee on Health,
9 Education, Labor, and Pensions of the Senate,
10 the Committee on Energy and Commerce of the
11 House of Representatives, the Secretary of
12 Health and Human Services, and the President.

13 (2) CONTENTS.—The report required under
14 paragraph (1) shall include a detailed statement of
15 findings, conclusions, and recommendations, includ-
16 ing the following:

17 (A) Findings from the study conducted by
18 the Commission pursuant to section 4(a), in-
19 cluding potential threats posed to individual
20 health privacy and to legitimate business and
21 policy interests.

22 (B) Analysis of purposes for which sharing
23 of health information is appropriate and bene-
24 ficial to consumers and the threat to health out-

1 comes and costs if privacy rules are too strin-
2 gent.

3 (C) Analysis of the effectiveness of existing
4 statutes, regulations, private sector self-regu-
5 latory efforts, technology advances, and market
6 forces in protecting individual health privacy.

7 (D) Recommendations on whether Federal
8 legislation is necessary, and if so, specific sug-
9 gestions on proposals to reform, streamline,
10 harmonize, unify, or augment current laws and
11 regulations relating to individual health privacy,
12 including reforms or additions to existing law
13 related to enforcement, preemption, consent,
14 penalties for misuse, transparency, and notice
15 of privacy practices.

16 (E) Analysis of whether additional regula-
17 tions may impose costs or burdens, or cause un-
18 intended consequences in other policy areas,
19 such as security, law enforcement, medical re-
20 search, health care cost containment, improved
21 patient outcomes, public health, or critical in-
22 frastructure protection, and whether such costs
23 or burdens are justified by the additional regu-
24 lations or benefits to privacy, including whether

1 such benefits may be achieved through less on-
2 erous means.

3 (F) Cost analysis of legislative or regu-
4 latory changes proposed in the report.

5 (G) Recommendations on non-legislative
6 solutions to individual health privacy concerns,
7 including education, market-based measures, in-
8 dustry best practices, and new technologies.

9 (H) Review of the effectiveness and utility
10 of third-party statements of privacy principles
11 and private sector self-regulatory efforts, as
12 well as third-party certification or accreditation
13 programs meant to ensure compliance with pri-
14 vacy requirements.

15 (d) ADDITIONAL REPORT.—Together with the report
16 under subsection (c), the Commission shall submit to Con-
17 gress and the President any additional report of dissenting
18 opinions or minority views by a member or members of
19 the Commission.

20 (e) INTERIM REPORT.—The Commission may submit
21 to Congress and the President an interim report approved
22 by a majority of the members of the Commission.

23 **SEC. 5. MEMBERSHIP.**

24 (a) NUMBER AND APPOINTMENT.—The Commission
25 shall—

1 (1) be composed of 17 members to be appointed
2 by the Comptroller General; and

3 (2) reflect the views of health providers, ancil-
4 lary health care workers, health care purchasers,
5 health plans, health technology developers, research-
6 ers, consumers, public health experts, civil liberties
7 experts, genomics experts, educators, the consumer
8 electronics industry, and relevant Federal agencies,
9 and other entities as the Secretary of Health and
10 Human Services determines appropriate.

11 (b) TERMS.—Each member of the Commission shall
12 be appointed for the life of the Commission.

13 (c) VACANCIES.—A vacancy in the Commission shall
14 be filled in the same manner in which the original appoint-
15 ment was made.

16 (d) COMPENSATION; TRAVEL EXPENSES.—Members
17 of the Commission shall serve without pay, but shall re-
18 ceive travel expenses, including per diem in lieu of subsist-
19 ence, in accordance with sections 5702 and 5703 of title
20 5, United States Code.

21 (e) QUORUM.—A majority of the members of the
22 Commission shall constitute a quorum, but a lesser num-
23 ber may hold hearings.

24 (f) MEETINGS.—

1 (1) IN GENERAL.—The Commission shall meet
2 at the call of the Chair or a majority of its members.

3 (2) INITIAL MEETING.—Not later than 60 days
4 after the date of the enactment of this Act, the
5 Commission shall hold its initial meeting.

6 (3) VIRTUAL OR IN-PERSON MEETINGS.—Meet-
7 ings may be held in person or virtually.

8 (g) ETHICAL DISCLOSURE.—The Comptroller Gen-
9 eral shall establish a system for public disclosure by mem-
10 bers of the Commission of financial and other potential
11 conflicts of interest relating to such members. Members
12 of the Commission shall be treated as employees of Con-
13 gress for purposes of applying title I of the Ethics in Gov-
14 ernment Act of 1978 (5 U.S.C. App.).

15 **SEC. 6. DIRECTOR; STAFF; EXPERTS AND CONSULTANTS.**

16 (a) DIRECTOR.—

17 (1) IN GENERAL.—Not earlier than 45 days
18 after the date of enactment of this Act, the Commis-
19 sion shall appoint a Director of the Commissioner
20 (referred to in this Act as the “Director”) without
21 regard to the provisions of title 5, United States
22 Code, governing appointments to the competitive
23 service.

24 (2) PAY.—The Director shall be paid at the
25 rate payable for level III of the Executive Schedule

1 established under section 5314 of title 5, United
2 States Code.

3 (b) STAFF.—The Director may appoint staff as the
4 Director determines appropriate.

5 (c) APPLICABILITY OF CERTAIN CIVIL SERVICE
6 LAWS.—

7 (1) IN GENERAL.—The staff of the Commission
8 shall be appointed without regard to the provisions
9 of title 5, United States Code, governing appoint-
10 ments in the competitive service.

11 (2) PAY.—The staff of the Commission shall be
12 paid in accordance with the provisions of chapter 51
13 and subchapter III of chapter 53 of that title relat-
14 ing to classification and General Schedule pay rates,
15 but at rates not in excess of the maximum rate for
16 grade GS-15 of the General Schedule under section
17 5332 of that title.

18 (d) EXPERTS AND CONSULTANTS.—The Director
19 may procure temporary and intermittent services under
20 section 3109(b) of title 5, United States Code.

21 (e) STAFF OF FEDERAL AGENCIES.—

22 (1) IN GENERAL.—Upon request of the Direc-
23 tor, the head of any Federal department or agency
24 may detail, on a reimbursable basis, any of the per-

1 sonnel of that department or agency to the Commis-
2 sion to assist it in carrying out this Act.

3 (2) NOTIFICATION.—Before making a request
4 under this subsection, the Director shall give notice
5 of the request to each member of the Commission.

6 **SEC. 7. POWERS OF COMMISSION.**

7 (a) HEARINGS AND SESSIONS.—The Commission
8 may, for the purpose of carrying out this Act, hold hear-
9 ings, sit and act at times and places, take testimony, and
10 receive evidence as the Commission considers appropriate.
11 The Commission may administer oaths or affirmations to
12 witnesses appearing before it.

13 (b) POWERS OF MEMBERS AND AGENTS.—Any mem-
14 ber or agent of the Commission may, if authorized by the
15 Commission, take any action which the Commission is au-
16 thorized to take by this section.

17 (c) OBTAINING OFFICIAL INFORMATION.—

18 (1) IN GENERAL.—Except as provided in para-
19 graph (2), if the Chair of the Commission submits
20 a request to a Federal department or agency for in-
21 formation necessary to enable the Commission to
22 carry out this Act, the head of that department or
23 agency shall furnish that information to the Com-
24 mission.

1 (2) EXCEPTION FOR NATIONAL SECURITY.—If
2 the head of the department or agency determines
3 that it is necessary to guard such information from
4 disclosure to protect the national security interests
5 of the United States, the head shall not furnish that
6 information to the Commission.

7 (d) MAILS.—The Commission may use the United
8 States mails in the same manner and under the same con-
9 ditions as other departments and agencies of the United
10 States.

11 (e) ADMINISTRATIVE SUPPORT SERVICES.—Upon
12 the request of the Director, the Administrator of General
13 Services shall provide to the Commission, on a reimburs-
14 able basis, the administrative support services necessary
15 for the Commission to carry out this Act.

16 (f) GIFTS AND DONATIONS.—The Commission may
17 accept, use, and dispose of gifts or donations of services
18 or property to carry out this Act, but only to the extent
19 or in the amounts provided in advance in appropriation
20 Acts.

21 (g) CONTRACTS.—The Commission may contract
22 with and compensate persons and government agencies for
23 supplies and services, without regard to section 3709 of
24 the Revised Statutes (41 U.S.C. 5).

25 (h) SUBPOENA POWER.—

1 (1) IN GENERAL.—The Commission may issue
2 subpoenas requiring the attendance and testimony of
3 witnesses and the production of any evidence relat-
4 ing to any matter that the Commission is empow-
5 ered to investigate by section 4. The attendance of
6 witnesses and the production of evidence may be re-
7 quired by such subpoena from any place within the
8 United States and at any specified place of hearing
9 within the United States.

10 (2) FAILURE TO OBEY A SUBPOENA.—If a per-
11 son refuses to obey a subpoena issued under para-
12 graph (1), the Commission may apply to a United
13 States district court for an order requiring that per-
14 son to appear before the Commission to give testi-
15 mony, produce evidence, or both, relating to the
16 matter under investigation. The application may be
17 made within the judicial district where the hearing
18 is conducted or where that person is found, resides,
19 or transacts business. Any failure to obey the order
20 of the court may be punished by the court as civil
21 contempt.

22 (3) SERVICE OF SUBPOENAS.—The subpoenas
23 of the Commission shall be served in the manner
24 provided for subpoenas issued by a United States

1 district court under the Federal Rules of Civil Pro-
2 cedure for the United States district courts.

3 (4) SERVICE OF PROCESS.—All process of any
4 court to which application is made under paragraph
5 (2) may be served in the judicial district in which
6 the person required to be served resides or may be
7 found.

8 **SEC. 8. TERMINATION.**

9 The Commission shall terminate 30 days after sub-
10 mitting a report under section 4(c).

11 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

12 (a) IN GENERAL.—There are authorized to be appro-
13 priated to the Commission such sums as may be necessary
14 to carry out this Act.

15 (b) AVAILABILITY.—Any sums appropriated pursu-
16 ant to the authorization in subsection (a) shall remain
17 available until expended.

18 **SEC. 10. BUDGET ACT COMPLIANCE.**

19 Any new contract authority authorized by this Act
20 shall be effective only to the extent or in the amounts pro-
21 vided in advance in appropriation Acts.

22 **SEC. 11. PRIVACY PROTECTIONS.**

23 (a) DESTRUCTION OR RETURN OF INFORMATION RE-
24 QUIRED.—Upon the conclusion of the matter or need for
25 which individually identifiable information was disclosed

1 to the Commission, the Commission shall either destroy
2 the individually identifiable information or return it to the
3 person or entity from which it was obtained, unless the
4 individual that is the subject of the individually identifi-
5 able information has authorized its disclosure.

6 (b) DISCLOSURE OF INFORMATION PROHIBITED.—
7 The Commission—

8 (1) shall protect individually identifiable infor-
9 mation from improper use; and

10 (2) may not disclose such information to any
11 person, including Congress or the President, unless
12 the individual that is the subject of the information
13 has authorized such a disclosure.

14 (c) PROPRIETARY BUSINESS INFORMATION AND FI-
15 NANCIAL INFORMATION.—The Commission shall protect
16 from improper use, and may not disclose to any person,
17 proprietary business information and proprietary financial
18 information that may be viewed or obtained by the Com-
19 mission in the course of carrying out its duties under this
20 Act.

○