

Calendar No. 538

119TH CONGRESS
2D SESSION**S. 3097**

To provide additional protections with respect to health information, and
for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 4, 2025

Mr. CASSIDY introduced the following bill; which was read twice and referred
to the Committee on Health, Education, Labor, and Pensions

AUGUST 4, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

A BILL

To provide additional protections with respect to 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 “Health Information
5 Privacy Reform Act”.

1 **SEC. 2. PROTECTIONS FOR APPLICABLE HEALTH INFORMA-**
 2 **TION.**

3 (a) IN GENERAL.—The Secretary of Health and
 4 Human Services, in consultation with the Federal Trade
 5 Commission, shall promulgate regulations setting privacy,
 6 security, and breach notifications standards for the proc-
 7 essing of applicable health information by regulated enti-
 8 ties and their service providers. Such standards shall pro-
 9 vide protections that are at least commensurate with, and
 10 wherever feasible and appropriate harmonize with, the
 11 protections provided through the privacy, security, and
 12 breach notification rules promulgated under section 264(e)
 13 of the Health Insurance Portability and Accountability
 14 Act of 1996 (42 U.S.C. 1320d–2 note) and section 13402
 15 of the HITECH Act (42 U.S.C. 17932) that apply to cov-
 16 ered entities and business associates with respect to pro-
 17 tected health information under such rules. Such regula-
 18 tions promulgated under this section shall include the fol-
 19 lowing:

20 (1) Privacy requirements, including the fol-
 21 lowing:

22 (A) Permitted uses and disclosures of ap-
 23 plicable health information without an individ-
 24 ual's written authorization that are consistent
 25 with the individual's reasonable expectations.

1 ~~(B) Other permitted uses and disclosures~~
2 ~~of applicable health information without an in-~~
3 ~~dividual's written authorization for certain pub-~~
4 ~~lie policy purposes, such as public health, health~~
5 ~~oversight, law enforcement, judicial and admin-~~
6 ~~istrative proceedings, and any conditions for~~
7 ~~such uses and disclosures.~~

8 ~~(C) Uses and disclosures of applicable~~
9 ~~health information that require the individual's~~
10 ~~written authorization and the requirements re-~~
11 ~~lated to such written authorizations.~~

12 ~~(D) Prohibited uses and disclosures of ap-~~
13 ~~plicable health information.~~

14 ~~(E) Minimum necessary requirements for~~
15 ~~the request, use, and disclosure of applicable~~
16 ~~health information and any exceptions.~~

17 ~~(F) Standards and requirements related to~~
18 ~~legal representatives of the individual.~~

19 ~~(G) Standards and requirements related to~~
20 ~~service providers.~~

21 ~~(H) Individual rights with respect to appli-~~
22 ~~cable health information, including the right of~~
23 ~~the individual to receive a privacy notice from~~
24 ~~the regulated entity, access to applicable health~~
25 ~~information, amendment of applicable health in-~~

1 formation, deletion of applicable health informa-
2 tion, and portability of applicable health infor-
3 mation, and any exceptions to such rights (such
4 as with respect to applicable health information
5 collected for research purposes), any conditions
6 on such rights, and any other requirements re-
7 lated to such rights, including timeframes for
8 responding to requests.

9 (I) Administrative safeguards, including
10 designation of a privacy officer, policies and
11 procedures, training of workforce members,
12 non-retaliation, documentation, and mitigation.

13 (2) Security requirements, including the fol-
14 lowing:

15 (A) Physical, technical, and administrative
16 safeguards for applicable health information in
17 any form.

18 (B) For electronic applicable health infor-
19 mation, such safeguards shall be based on well-
20 established national frameworks, such as cyber-
21 security performance goals of the National In-
22 stitute of Standards and Technology or the De-
23 partment of Health and Human Services.

24 (3) Breach notification requirements in the
25 event of a breach of applicable health information

1 that are substantially similar to the breach notifica-
2 tion requirements under subpart D of part 164 of
3 title 45, Code of Federal Regulations (or any suc-
4 cessor regulations).

5 (b) ENFORCEMENT AUTHORITY.—The Secretary, in
6 consultation with the Federal Trade Commission, is au-
7 thorized to enforce all provisions of this Act as described
8 in subsection (c).

9 (c) CIVIL PENALTIES.—In addition to any other
10 sanctions or remedies that may be available under any
11 provision of Federal law, in the case of a regulated entity
12 or service provider that violates this section, subpart D
13 of part 160 of title 45, Code of Federal Regulations (or
14 any successor regulations), shall apply to the regulated en-
15 tity or service provider with respect to such violation of
16 this section in the same manner that such subpart applies
17 to a person with respect to a violation of part 160 of title
18 45, Code of Federal Regulations (or any successor regula-
19 tions).

20 (d) EXTENSION OF HITECH ACT AMENDMENT TO
21 REGULATED ENTITIES AND SERVICE PROVIDERS.—The
22 privacy and security practices under section 13412 of the
23 Health Information Technology for Economic and Clinical
24 Health Act (42 U.S.C. 17941) shall apply to regulated en-
25 tities and service providers with respect to applicable

1 health information in the same manner that such section
 2 applies to covered entities and business associates.

3 ~~(c) DEFINITIONS.—In this section:~~

4 ~~(1) APPLICABLE HEALTH INFORMATION.—The~~
 5 ~~term “applicable health information”—~~

6 ~~(A) means information (including demo-~~
 7 ~~graphic information) that—~~

8 ~~(i) identifies an individual or with re-~~
 9 ~~spect to which there is a reasonable basis~~
 10 ~~to believe that the information could be~~
 11 ~~used to identify an individual; and~~

12 ~~(ii) relates to the past, present, or fu-~~
 13 ~~ture physical or mental health or condition~~
 14 ~~of an individual, the provision of health~~
 15 ~~care to an individual, or the past, present,~~
 16 ~~or future payment for the provision of~~
 17 ~~health care to an individual; and~~

18 ~~(B) may include information described in~~
 19 ~~subparagraph (A) that was not created or re-~~
 20 ~~ceived by a health care provider, health plan,~~
 21 ~~employer, or health care clearinghouse.~~

22 ~~(2) COVERED ENTITIES; BUSINESS ASSOCI-~~
 23 ~~ATES.—The terms “covered entities” and “business~~
 24 ~~associates” have the meanings given such terms in~~

1 section 160.103 of title 45, Code of Federal Regula-
 2 tions (or any successor regulations).

3 ~~(3) REGULATED ENTITY.~~—The term “regulated
 4 entity”—

5 (A) means a natural or legal person that,
 6 alone or jointly with others, determines the pur-
 7 pose and means of processing applicable health
 8 information; and

9 (B) does not include—

10 (i) a governmental entity such as a
 11 body, authority, board, bureau, commis-
 12 sion, district, agency, or political subdivi-
 13 sion of the Federal, State, or local govern-
 14 ment;

15 (ii) a person or an entity that is col-
 16 lecting, processing, or transferring covered
 17 data on behalf of or a Federal, State, Trib-
 18 al, territorial, or local government entity;
 19 and

20 (iii) a covered entity or business asso-
 21 ciate, as such terms are defined in section
 22 160.103 of title 45, Code of Federal Regu-
 23 lations (or any successor regulations).

24 ~~(4) SERVICE PROVIDER.~~—The term “service
 25 provider” means a natural or legal entity that proc-

esses applicable health information on a behalf of a regulated entity and that is not a covered entity or business associate, as such terms are defined in section 160.103 of title 45, Code of Federal Regulations (or any successor regulations).

SEC. 3. RIGHTS AND REQUIREMENTS REGARDING ACCESS TO CERTAIN PROTECTED HEALTH INFORMATION.

(a) TIME AND MANNER OF ACCESS.—In applying section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935(e)) or section 164.524(e)(3)(ii) of title 45, Code of Federal Regulations (or any successor regulations), in the case that an individual requests that a covered entity or any business associate of a covered entity transmit, produce, or provide access to a copy of the individual's protected health information to a person, including an entity, designated by the individual, and except where permitted without authorization under section 164.506(e) of title 45, Code of Federal Regulations (or any successor regulations)—

(1) the individual's request shall meet all requirements of a valid authorization under section 164.508(b) of title 45, Code of Federal Regulations (or any successor regulations); and

(2) the covered entity or business associate may condition the transmittal, production, or provision of access upon the person to whom the information is to be transmitted or produced or to whom access is to be provided—

(A) paying fees, in accordance with applicable State law and consistent with subsection (b), in advance of such transmittal, production, or access; and

(B) acknowledging and accepting the terms, limitations, and conditions of use and disclosure contained in the request made by the individual as the legally binding obligation of the person receiving the information.

(b) FEES.—

(1) IN GENERAL.—In applying section 13405(e)(3) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935(e)(3)) or section 164.524(e)(4) of title 45, Code of Federal Regulations (or any successor regulations), each such section shall apply only—

(A) to the provision of access to, or the production, copying, or transmittal of, protected health information directly to—

1 (i) the individual, or the individual's
 2 personal representative for health care pur-
 3 poses as described in section 164.502(g) of
 4 title 45, Code of Federal Regulations (or
 5 any successor regulations);

6 (ii) subject to paragraph (2) and sec-
 7 tion 164.510(b) of title 45, Code of Fed-
 8 eral Regulations (or any successor regula-
 9 tion); any other person identified in, and
 10 subject to the limitations of, such section;
 11 or

12 (iii) the individual's health care pro-
 13 vider or the business associates of such
 14 provider; and

15 (B) as directed by the individual, to the
 16 electronic transmittal of the individual's elec-
 17 tronic health record to the patient portal or mo-
 18 bile medical application used and maintained by
 19 the individual's health care provider or for the
 20 health care provider by its business associate.

21 (2) ~~ADDITIONAL LIMITATIONS.~~—In the case of
 22 the provision of access to, or the production, copy-
 23 ing, or transmittal of, protected health information
 24 under paragraph (1)(A) directly to a person de-
 25 scribed in clause (ii) of such paragraph, such pro-

1 tected health information shall, in accordance with
 2 section ~~164.510(b)~~ of title 45, Code of Federal Reg-
 3 ulations (or any successor regulations), be limited to
 4 only such information that is—

5 (A) directly relevant to the person’s in-
 6 volvement with the care of the individual or
 7 with the payment relevant to the care of the in-
 8 dividual; or

9 (B) needed for notification purposes de-
 10 scribed in such section.

11 (c) DEFINITIONS.—In this section, the terms “busi-
 12 ness associate”, “covered entity”, “health care provider”,
 13 “individual”, “person”, and “protected health informa-
 14 tion” have the meanings given such terms in section
 15 ~~160.103~~ of title 45, Code of Federal Regulations (or any
 16 successor regulations).

17 (d) GUIDANCE.—Not later than 180 days after the
 18 date of enactment of this Act, the Secretary of Health and
 19 Human Services shall amend existing guidance as nec-
 20 essary to implement subsections (a) and (b).

21 **SEC. 4. CONFIDENTIALITY OF RECORDS.**

22 Section ~~543~~ of the Public Health Service Act (~~42~~
 23 U.S.C. ~~290dd-2~~) is amended—

24 (1) in subsection (a), by striking “subsection
 25 (b)” and inserting “the HIPAA regulations”;

1 (2) in subsection (b)—

2 (A) in paragraph (2), by redesignating
3 subparagraphs (A) through (D) as paragraphs
4 (1) through (4), respectively, and adjusting the
5 margins accordingly; and

6 (B) by striking “(b) PERMITTED DISCLO-
7 SURE” and all that follows through “(2) METH-
8 OD FOR DISCLOSURE—Whether” and inserting
9 the following:

10 “(b) PERMITTED DISCLOSURE.—Whether”;

11 (3) in subsection (c), in the matter preceding
12 paragraph (1), by striking “subsection (b)(2)(C)”
13 and inserting “subsection (b)(3)”; and

14 (4) in subsection (e), by striking “subsection
15 (b)(2)(C)” and inserting “subsection (b)(3)”.

16 **SEC. 5. NAS STUDY ON COMPENSATION TO PATIENTS FOR**
17 **SHARING IDENTIFIABLE DATA FOR RE-**
18 **SEARCH PURPOSES.**

19 (a) **IN GENERAL.**—Not later than 60 days after the
20 date of enactment of this Act, the Secretary of Health and
21 Human Services shall seek to enter into a contract with
22 the National Academies of Sciences, Engineering, and
23 Medicine to conduct a study examining potential risks and
24 benefits of paying compensation to patients for sharing
25 their identifiable data for research purposes.

1 (b) INCLUSIONS.—The study conducted pursuant to
 2 the contract under subsection (a) shall include an exam-
 3 ination of—

4 (1) the risks to patient privacy posed by the in-
 5 tegration of identifiable, de-identified, and aggre-
 6 gated health information into datasets used for re-
 7 search;

8 (2) privacy enhancing tools and methods for the
 9 protection of patient health data;

10 (3) the feasibility of tracking patient data and
 11 consent for the integration of patient health data
 12 into datasets used for research;

13 (4) ethical considerations for compensating pa-
 14 tients for use of their identifiable and de-identified
 15 health data;

16 (5) whether the existing exemptions permitting
 17 de-identified data to be used for research should
 18 consider whether a patient was given an opportunity
 19 to opt-in or opt-out of participation; and

20 (6) risk of re-identification of de-identified data.

21 **SEC. 6. PATIENT NOTIFICATION REQUIREMENTS UNDER**
 22 **THE HIPAA PRIVACY REGULATIONS.**

23 (a) PATIENT NOTIFICATION UPON REMOVAL.—Any
 24 regulated entity or service provider who gains access to
 25 the protected health information of an individual through

1 the patient right of access under section 164.524 of title
 2 45, Code of Federal Regulations (or any successor regula-
 3 tions) shall—

4 (1) provide a written plain language notification
 5 to such individual prior to accessing such informa-
 6 tion—

7 (A) that such protected health information
 8 will no longer be subject to the protections
 9 under the HIPAA privacy regulation; and

10 (B) that includes an explanation of how
 11 and to which entities such protected health in-
 12 formation may be redisclosed; and

13 (2) require the consent of the individual before
 14 selling such protected health information to third
 15 parties.

16 (b) PATIENT NOTIFICATION REGARDING WELLNESS
 17 DATA.—

18 (1) IN GENERAL.—Any regulated entity or serv-
 19 ice provider who offers digital technology that gen-
 20 erates wellness data about individuals shall, with re-
 21 spect to each individual who uses such technology—

22 (A) provide a written plain language notifi-
 23 cation to the individual in advance of initiating
 24 the generation of such data that such data will

1 not be subject to the protections of the HIPAA
2 privacy regulation; and

3 (B) offer the individual an opportunity to
4 opt out of such wellness data generation.

5 (2) WELLNESS DATA.—In this subsection, the
6 term “wellness data” means data generated for the
7 purpose of promoting health or preventing disease,
8 which may include vital statistics, step counts, and
9 medical regimen compliance.

10 (c) DEFINITIONS.—In this section—

11 (1) the terms “business associate”, “covered en-
12 tity”, and “protected health information” have the
13 meanings given such terms in section 160.103 of
14 title 45, Code of Federal Regulations (or any suc-
15 cessor regulations);

16 (2) the term “HIPAA privacy regulation” has
17 the meaning given such term in section 1180(b)(3)
18 of the Social Security Act (42 U.S.C. 1320d-
19 9(b)(3)); and

20 (3) the terms “regulated entity” and “service
21 provider” have the meanings given such terms in
22 section 2.

23 (d) EFFECTIVE DATE.—This section shall take effect
24 beginning one year after the date of enactment of this Act.

1 **SEC. 7. MINIMUM NECESSARY GUIDANCE.**

2 Not later than 1 year after the date of enactment
 3 of this Act, the Secretary of Health and Human Services
 4 shall publish guidance on the application of the minimum
 5 necessary standard to data used for artificial intelligence
 6 and other machine learning applications and relevant re-
 7 quirements, including health data interoperability require-
 8 ments under section 3001(c)(9) of the Public Health Serv-
 9 ice Act (42 U.S.C. 300jj–11(c)(9)) and the use of limited
 10 data sets pursuant to section 13405(b) of the HITECH
 11 Act (42 U.S.C. 17935(b)).

12 **SEC. 8. DE-IDENTIFIED INFORMATION.**

13 (a) ESTABLISHMENT OF STANDARDS.—Not later
 14 than 1 year after the date of enactment of this Act, the
 15 Secretary of Health and Human Services shall promulgate
 16 regulations establishing unified national standards for
 17 rendering applicable health information as de-identified
 18 information, in a manner similar to the manner in which
 19 individually identifiable health information may be ren-
 20 dered de-identified information pursuant to part 164 of
 21 title 45, Code of Federal Regulations (or any successor
 22 regulations).

23 (b) COMPOSITION OF STANDARDS.—Such standards
 24 shall—

25 (1) be at least equivalent to or exceed the de-
 26 identification standard specified in section

1 164.514(b) of title 45, Code of Federal Regulations
 2 (or any successor regulations);

3 (2) specify standards for the use of privacy-en-
 4 hancing technologies as a method for creating de-
 5 identified information; and

6 (3) specify that information shall not qualify as
 7 de-identified information when provided by a regu-
 8 lated entity, service provider, covered entity, or busi-
 9 ness associate to another person or entity unless
 10 such person or entity contractually agrees in writing
 11 not to re-identify or attempt to re-identify the infor-
 12 mation; and to require the same of any person or en-
 13 tity to whom such person or entity provides the in-
 14 formation.

15 (c) DEFINITIONS.—In this section—

16 (1) the term “applicable health information”
 17 has the meaning given such term in section 2;

18 (2) the terms “business associate”, “covered en-
 19 tity”, and “individually identifiable health informa-
 20 tion” have the meanings given such terms in section
 21 160.103 of title 45, Code of Federal Regulations (or
 22 any successor regulations); and

23 (3) the term “privacy enhancing technologies”
 24 means any software or hardware solution, technical
 25 process, or other technological means of mitigating

1 individuals' privacy risks arising from data proc-
 2 essing by enhancing predictability, manageability,
 3 disassociability, and confidentiality.

4 **SEC. 9. PREEMPTION.**

5 Section 160.203 of title 45, Code of Federal Regula-
 6 tions (or any successor regulations) shall apply to the re-
 7 quirements set forth under this Act in the same manner
 8 and to the same extent as such section applies to the
 9 standards, requirements, and implementation specifica-
 10 tions under subchapter C of chapter I of subtitle A of title
 11 45, Code of Federal Regulations (or any successor regula-
 12 tions).

13 **SECTION 1. SHORT TITLE.**

14 *This Act may be cited as the “Health Information Pri-
 15 vacy Reform Act”.*

16 **SEC. 2. PROTECTIONS FOR APPLICABLE HEALTH INFORMA-
 17 TION.**

18 *(a) IN GENERAL.—Not later than 18 months after the
 19 date of enactment of this Act, the Secretary of Health and
 20 Human Services (referred to in this section as the “Sec-
 21 retary”), in consultation with the Federal Trade Commis-
 22 sion, shall promulgate regulations establishing and imple-
 23 menting privacy, security, and breach notification stand-
 24 ards for the processing of applicable health information by
 25 regulated entities and their service providers. Such stand-*

ards shall provide rights and protections that are at least
 equivalent to, and that, wherever feasible and appropriate,
 harmonize with, the rights and protections provided
 through the privacy, security, and breach notification rules
 promulgated under section 264(c) of the Health Insurance
 Portability and Accountability Act of 1996 (42 U.S.C.
 1320d–2 note) and section 13402 of the HITECH Act (42
 U.S.C. 17932) that apply to covered entities and business
 associates with respect to protected health information
 under such rules. Such regulations promulgated under this
 section shall include the following:

(1) Privacy requirements, including the fol-
 lowing:

(A) Permitted uses and disclosures of appli-
 cable health information without an individual's
 written authorization that are consistent with
 the individual's reasonable expectations, taking
 into consideration the context in which the ap-
 plicable health information was obtained, pro-
 vided that such regulations shall not authorize
 such a use or disclosure to investigate, or to im-
 pose liability on, any individual in connection
 with the seeking, obtaining, providing, or facili-
 tating of health care.

1 (B) *Uses and disclosures of applicable*
2 *health information that require the individual's*
3 *written authorization and the requirements re-*
4 *lated to such written authorizations, including*
5 *how the individual may revoke such authoriza-*
6 *tion, which shall include requiring the individ-*
7 *ual's written authorization for any sale, licens-*
8 *ing, transfer, or marketing of applicable health*
9 *information.*

10 (C) *Prohibited uses and disclosures of appli-*
11 *cable health information.*

12 (D) *Minimum necessary requirements for*
13 *the request, use, and disclosure of applicable*
14 *health information and any exceptions that are*
15 *necessary for purpose specification, collection*
16 *limitation, data minimization, and limitation*
17 *on secondary use and that are consistent with*
18 *subsection (b).*

19 (E) *Standards and requirements for an in-*
20 *dividual to be authorized to exercise the rights*
21 *granted in this section with respect to applicable*
22 *health information of another individual.*

23 (F) *Standards and requirements related to*
24 *service providers.*

1 (G)(i) *Individual rights with respect to ap-*
2 *plicable health information, including the fol-*
3 *lowing:*

4 (I) *The right of the individual to re-*
5 *ceive a privacy notice from the regulated*
6 *entity, which shall describe the purposes for*
7 *which the regulated entity uses and discloses*
8 *applicable health information, the rights of*
9 *the individual under this subparagraph,*
10 *and the manner in which such rights may*
11 *be exercised.*

12 (II) *The right of access to applicable*
13 *health information, including the ability of*
14 *the individual to direct the transmission of*
15 *applicable health information held in an*
16 *electronic health record to a third party.*

17 (III) *The right to amendment of appli-*
18 *cable health information.*

19 (IV) *The right to deletion of applicable*
20 *health information, not later than 30 days*
21 *after the regulated entity or service provider*
22 *receives a request for such a deletion, and*
23 *allowing for the regulated entity or service*
24 *provider to communicate with the indi-*

1 *vidual making such request prior to ful-*
 2 *filling such request.*

3 *(V) The right to portability of applica-*
 4 *ble health information, including the ability*
 5 *of the individual to transfer such informa-*
 6 *tion between applications, services, or de-*
 7 *vices.*

8 *(ii) Any exception to, or condition or other*
 9 *requirement on, a right described in any of sub-*
 10 *clauses (I) through (V) of clause (i), including*
 11 *an exception with respect to applicable health in-*
 12 *formation collected for research purposes and a*
 13 *timeframe for responding to a request of an indi-*
 14 *vidual for applicable health information.*

15 *(H) Administrative safeguards, including*
 16 *designation of a privacy officer, policies and*
 17 *procedures, training of workforce members, non-*
 18 *retaliation, documentation, and mitigation.*

19 *(2) Security requirements, including the fol-*
 20 *lowing:*

21 *(A) Physical, technical, and administrative*
 22 *safeguards for applicable health information in*
 23 *written or oral form.*

24 *(B) The application of the standards under*
 25 *subpart C of part 164 of title 45, Code of Federal*

1 *Regulations (or any successor regulations) to*
 2 *electronic applicable health information in the*
 3 *same manner as such standards apply to elec-*
 4 *tronic protected health information.*

5 *(3) Breach notification requirements in the event*
 6 *of a breach of applicable health information that are*
 7 *substantially similar to the breach notification re-*
 8 *quirements under subpart D of part 164 of title 45,*
 9 *Code of Federal Regulations (or any successor regula-*
 10 *tions) for applicable health information that is not*
 11 *subject to the health breach notification rule at part*
 12 *318 of title 16, Code of Federal Regulations (or any*
 13 *successor regulations).*

14 *(b) REQUIREMENTS FOR REGULATED ENTITIES AND*
 15 *SERVICE PROVIDERS.—*

16 *(1) DATA MINIMIZATION.—A regulated entity or*
 17 *service provider may not collect, process, or transfer*
 18 *applicable health information beyond what a covered*
 19 *entity is permitted to collect, process, or transfer*
 20 *under sections 164.502(b) and 164.514(d) of title 45,*
 21 *Code of Federal Regulations (or any successor regula-*
 22 *tions).*

23 *(2) RETENTION.—A regulated entity or service*
 24 *provider may not retain applicable health informa-*
 25 *tion for longer than is reasonably necessary to carry*

1 *out the purpose for which such information was col-*
 2 *lected.*

3 (3) *EXCEPTIONS.—Paragraphs (1) and (2) shall*
 4 *not apply to the collection, processing, or transfer of*
 5 *applicable health information to the extent reasonably*
 6 *necessary for any of the following purposes:*

7 (A) *To complete a transaction or provide a*
 8 *product or service specifically requested by the*
 9 *individual to whom such information relates.*

10 (B) *To comply with a legal obligation, or to*
 11 *establish, exercise, or defend a legal claim.*

12 (C) *To prevent, detect, or respond to a secu-*
 13 *rity incident, fraud, or harm to an individual.*

14 (D) *To carry out a public health activity*
 15 *permitted under the regulations promulgated*
 16 *under subsection (a).*

17 (E) *To conduct research subject to part 46*
 18 *of title 45, Code of Federal Regulations, or part*
 19 *50 or 56 of title 21, Code of Federal Regulations*
 20 *(or any successor regulations).*

21 (c) *ENFORCEMENT.—*

22 (1) *COORDINATION.—Not later than 180 days*
 23 *after the date of enactment of this Act, the Secretary*
 24 *and the Federal Trade Commission shall enter into a*
 25 *memorandum of understanding that allocates pri-*

1 *mary enforcement responsibility under this section,*
2 *provides for mutual notification of investigations into*
3 *violations of this section, and ensures that a regulated*
4 *entity or service provider is not subject to duplicative*
5 *civil penalties for the same act or omission.*

6 (2) *RULE OF CONSTRUCTION.—Nothing in this*
7 *Act shall be construed to limit or supersede the au-*
8 *thority of the Federal Trade Commission under sec-*
9 *tion 5 of the Federal Trade Commission Act (15*
10 *U.S.C. 45).*

11 (3) *CIVIL PENALTIES.—In addition to any other*
12 *sanctions or remedies that may be available under*
13 *any provision of Federal law, in the case of a regu-*
14 *lated entity or service provider that violates this sec-*
15 *tion, subpart D of part 160 of title 45, Code of Fed-*
16 *eral Regulations (or any successor regulations) shall*
17 *apply to the regulated entity or service provider with*
18 *respect to such violation of this section in the same*
19 *manner that such subpart applies to a person with*
20 *respect to a violation of part 160, 162, or 164 of sub-*
21 *chapter C of chapter I of subtitle A of title 45, Code*
22 *of Federal Regulations (or any successor regulations).*
23 *Any funds collected through civil penalties under this*
24 *paragraph shall be used to support enforcement activ-*
25 *ity under this section.*

1 (d) *EXTENSION OF HITECH ACT AMENDMENT TO*
 2 *REGULATED ENTITIES AND SERVICE PROVIDERS.*—*The*
 3 *privacy and security practices under section 13412 of the*
 4 *Health Information Technology for Economic and Clinical*
 5 *Health Act (42 U.S.C. 17941) shall apply to regulated enti-*
 6 *ties and service providers with respect to applicable health*
 7 *information in the same manner that such section applies*
 8 *to covered entities and business associates. Not later than*
 9 *18 months after the date of enactment of this Act, the Sec-*
 10 *retary shall promulgate regulations to carry out this sub-*
 11 *section.*

12 (e) *GOVERNMENT ACCESS.*—*A regulated entity or serv-*
 13 *ice provider may not sell or otherwise transfer applicable*
 14 *health information to a Federal, State, local, Tribal, or ter-*
 15 *ritorial governmental entity except as compelled by war-*
 16 *rant, subpoena, court order, or other compulsory process.*

17 (f) *DEFINITIONS.*—*In this section:*

18 (1) *APPLICABLE HEALTH INFORMATION.*—*The*
 19 *term “applicable health information”*—

20 (A) *means information (including demo-*
 21 *graphic information)*—

22 (i) *that identifies an individual or*
 23 *with respect to which there is a reasonable*
 24 *basis to believe that the information could*
 25 *be used to identify an individual; and*

1 (ii) that relates to the past, present, or
 2 future physical or mental health or condi-
 3 tion of such individual, the past, present, or
 4 future provision of health care to such indi-
 5 vidual, or past, present, or future payment
 6 for the provision of health care to such indi-
 7 vidual;

8 (B) includes—

9 (i) information described in subpara-
 10 graph (A) that was not created or received
 11 by a health care provider, health plan, em-
 12 ployer, or health care clearinghouse; and

13 (ii) precise geolocation information
 14 that could reasonably indicate an attempt
 15 by an individual to acquire or receive a
 16 health service or supply; and

17 (C) does not include—

18 (i) information subject to—

19 (I) title V of the Gramm-Leach-
 20 Bliley Act (15 U.S.C. 6801 et seq.);

21 (II) the requirements regarding
 22 the confidentiality of substance use dis-
 23 order information under section 543 of
 24 the Public Health Service Act (42
 25 U.S.C. 290dd-2);

1 (III) *section 444 of the General*
 2 *Education Provisions Act (20 U.S.C.*
 3 *1232g; commonly known as the “Fam-*
 4 *ily Educational Rights and Privacy*
 5 *Act of 1974”)* and part 99 of title 34,
 6 *Code of Federal Regulations (or any*
 7 *successor regulations) to the extent such*
 8 *regulated entity or service provider is*
 9 *an educational agency or institution*
 10 *as defined in such section of such Act*
 11 *or section 99.3 of title 34, Code of Fed-*
 12 *eral Regulations (or any successor reg-*
 13 *ulations);*

14 (IV) *provisions for the protection*
 15 *of identifiable private information that*
 16 *is collected pursuant to—*

17 (aa) *the Federal require-*
 18 *ments for the protection of human*
 19 *subjects under part 46 of title 45,*
 20 *Code of Federal Regulations or*
 21 *part 50 or 56 of title 21, Code of*
 22 *Federal Regulations (or any suc-*
 23 *cessor regulations); or*

24 (bb) *the good clinical prac-*
 25 *tice guidelines issued by the Inter-*

1 *national Council for*
 2 *Harmonisation of Technical Re-*
 3 *quirements for Pharmaceuticals*
 4 *for Human Use;*

5 *(V) the Health Care Quality Im-*
 6 *provement Act of 1986 (42 U.S.C.*
 7 *11101 et seq.); or*

8 *(VI) part C of title IX of the Pub-*
 9 *lic Health Service Act (42 U.S.C.*
 10 *299b–21 et seq.);*

11 *(ii) publicly available information; or*
 12 *(iii) information collected, processed,*
 13 *or transferred by an individual in the*
 14 *course of a purely personal or household ac-*
 15 *tivity.*

16 *(2) COVERED ENTITIES; BUSINESS ASSOCI-*
 17 *ATES.—The terms “covered entities” and “business*
 18 *associates” have the meanings given such terms in*
 19 *section 160.103 of title 45, Code of Federal Regula-*
 20 *tions (or any successor regulations).*

21 *(3) DATA BROKER.—The term “data broker”*
 22 *means a regulated entity whose principal source of*
 23 *revenue is derived from processing or transferring ap-*
 24 *plicable health information that the entity did not*

1 *collect directly from the individuals to whom such in-*
 2 *formation relates.*

3 (4) *REGULATED ENTITY.*—*The term “regulated*
 4 *entity”—*

5 (A) *means a natural or legal person, in-*
 6 *cluding a data broker, that, alone or jointly with*
 7 *others, determines the purpose and means of*
 8 *processing applicable health information; and*

9 (B) *does not include—*

10 (i) *a covered entity or business asso-*
 11 *ciate, with respect to protected health infor-*
 12 *mation; or*

13 (ii) *an individual who is the subject of*
 14 *the applicable health information or who*
 15 *obtains applicable health information in a*
 16 *personal or household capacity.*

17 (5) *SERVICE PROVIDER.*—*The term “service pro-*
 18 *vider” means a natural or legal entity that processes*
 19 *applicable health information on behalf of a regulated*
 20 *entity and that is not a covered entity or business as-*
 21 *sociate.*

22 (g) *REGULATIONS.*—*The Secretary may promulgate*
 23 *regulations to carry out this section.*

1 **SEC. 3. RIGHTS AND REQUIREMENTS REGARDING ACCESS**
 2 **TO CERTAIN PROTECTED HEALTH INFORMA-**
 3 **TION.**

4 (a) *TIME AND MANNER OF ACCESS.*—In applying sec-
 5 tion 13405(e) of the Health Information Technology for
 6 Economic and Clinical Health Act (42 U.S.C. 17935(e)) or
 7 section 164.524(c)(3)(ii) of title 45, Code of Federal Regula-
 8 tions (or any successor regulations), in the case that an in-
 9 dividual requests that a covered entity or any business asso-
 10 ciate of a covered entity transmit, produce, or provide ac-
 11 cess to a copy of the individual's protected health informa-
 12 tion in an electronic health record to a person designated
 13 by the individual, the covered entity or business associate
 14 may condition the transmittal, production, or provision of
 15 access upon the person to whom the information is to be
 16 transmitted or produced or to whom access is to be pro-
 17 vided—

18 (1) *paying fees, in accordance with applicable*
 19 *State law and consistent with subsection (b), in ad-*
 20 *vance of such transmittal, production, or access; and*

21 (2) *acknowledging and accepting the terms, limi-*
 22 *tations, and conditions of use and disclosure con-*
 23 *tained in the request made by the individual as the*
 24 *legally binding obligation of the person receiving the*
 25 *information.*

1 (b) *FEES*.—In applying section 13405(e)(3) of the
 2 *Health Information Technology for Economic and Clinical*
 3 *Health Act* (42 U.S.C. 17935(e)(3)) or section 164.524(c)(4)
 4 of title 45, *Code of Federal Regulations* (or any successor
 5 regulations), each such section shall apply only to the provi-
 6 sion of access to, or the production, copying, or transmittal
 7 of, protected health information to—

8 (1) the individual, or the individual’s personal
 9 representative;

10 (2) the individual’s health care provider or the
 11 business associates of such provider; or

12 (3) a personal health record managed and con-
 13 trolled by the individual.

14 (c) *DEFINITIONS*.—In this section—

15 (1) the terms “business associate”, “covered enti-
 16 ty”, “health care provider”, “individual”, “person”,
 17 and “protected health information” have the mean-
 18 ings given such terms in section 160.103 of title 45,
 19 *Code of Federal Regulations* (or any successor regula-
 20 tions); and

21 (2) the term “personal health record” has the
 22 meaning given such term in section 13400 of the
 23 *Health Information Technology for Economic and*
 24 *Clinical Health Act* (42 U.S.C. 17921).

1 (d) *GUIDANCE*.—Not later than 180 days after the date
 2 of enactment of this Act, the Secretary of Health and
 3 Human Services shall amend existing guidance as nec-
 4 essary to implement subsections (a) and (b).

5 (e) *RULES OF CONSTRUCTION*.—Nothing in this sec-
 6 tion shall be construed to—

7 (1) permit a covered entity or business associate
 8 to deny, delay, or condition a transmission directed
 9 by an individual in a manner that constitutes infor-
 10 mation blocking under section 3022 of the Public
 11 Health Service Act (42 U.S.C. 300jj–52) or part 171
 12 of title 45, Code of Federal Regulations (or any suc-
 13 cessor regulations);

14 (2) treat an individual or the individual’s per-
 15 sonal representative who receives or accesses the indi-
 16 vidual’s protected health information on the individ-
 17 ual’s behalf and at the direction of the individual as
 18 a person to whom a fee or condition may be applied
 19 under subsection (a), with respect to a personal health
 20 record that is selected, managed, and controlled by the
 21 individual or the individual’s personal representative;
 22 or

23 (3) alter the rights or responsibilities of covered
 24 entities and individuals under section 13405(e) of the
 25 HITECH Act (42 U.S.C. 17935).

1 **SEC. 4. MINIMUM NECESSARY GUIDANCE.**

2 (a) *RULEMAKING.*—Not later than 1 year after the
 3 date of enactment of this Act, the Secretary of Health and
 4 Human Services (referred to in this section as the “Sec-
 5 retary”), in coordination with the Commissioner of Food
 6 and Drugs and the National Coordinator for Health Infor-
 7 mation Technology, shall promulgate regulations regarding
 8 the application of the minimum necessary standard under
 9 section 164.502(b) of title 45, Code of Federal Regulations,
 10 to applicable health information and protected health infor-
 11 mation, including such information used to train, develop,
 12 validate, modify, or operate an artificial intelligence or
 13 other machine learning model.

14 (b) *CONTENTS.*—The regulations promulgated under
 15 subsection (a) shall—

16 (1) clarify that such minimum necessary stand-
 17 ard does not permit a covered entity, business asso-
 18 ciate, regulated entity, or service provider to deny,
 19 delay, or condition a use or disclosure that is other-
 20 wise required or permitted, including a disclosure re-
 21 quired under section 3022 of the Public Health Serv-
 22 ice Act (42 U.S.C. 300jj–52), on the ground that lim-
 23 iting the disclosure to the minimum necessary infor-
 24 mation is not technically feasible, and, as applicable,
 25 the minimum necessary standard is satisfied by rea-
 26 sonable efforts to limit the information used or dis-

1 *closed, even where further technical limitation is not*
 2 *feasible;*

3 *(2) specify how the minimum necessary standard*
 4 *applies to the use of applicable health information*
 5 *and protected health information to develop, train,*
 6 *validate, or fine-tune an artificial intelligence or ma-*
 7 *chine learning model, including the circumstances*
 8 *under which the use of a larger data set is reasonably*
 9 *necessary for such development, and the extent to*
 10 *which de-identification, data minimization, or pri-*
 11 *vacv-enhancing technologies satisfy the standard; and*

12 *(3) address the minimum necessary standard*
 13 *with respect to the health data interoperability re-*
 14 *quirements under sections 3001(c)(9) and 3022 of the*
 15 *Public Health Service Act (42 U.S.C. 300jj–11(c)(9),*
 16 *300jj–52) and part 171 of title 45, Code of Federal*
 17 *Regulations (or any successor regulations).*

18 *(c) PERIODIC REVIEW.—The Secretary shall review,*
 19 *and update as appropriate, the regulations promulgated*
 20 *under subsection (a) not less frequently than once every 3*
 21 *years.*

22 **SEC. 5. DE-IDENTIFIED INFORMATION.**

23 *(a) ESTABLISHMENT OF STANDARDS.—Not later than*
 24 *1 year after the date of enactment of this Act, the Secretary*
 25 *of Health and Human Services shall promulgate regula-*

1 *tions establishing unified national standards for rendering*
 2 *applicable health information as de-identified information,*
 3 *in a manner similar to the manner in which individually*
 4 *identifiable health information may be rendered de-identi-*
 5 *fied information pursuant to part 164 of title 45, Code of*
 6 *Federal Regulations (or any successor regulations).*

7 (b) COMPOSITION OF STANDARDS.—*The standards*
 8 *under subsection (a) shall—*

9 (1) *be at least as protective as the de-identifica-*
 10 *tion standard specified in section 164.514(b)(1) of*
 11 *title 45, Code of Federal Regulations (or any suc-*
 12 *cessor regulations) (relating to expert determination),*
 13 *and may not permit information to be rendered de-*
 14 *identified information solely through the method spec-*
 15 *ified in section 164.514(b)(2) of such title (relating to*
 16 *safe harbor);*

17 (2) *specify standards for the use of privacy-en-*
 18 *hancing technologies as a method for creating de-iden-*
 19 *tified information;*

20 (3) *specify that information shall not qualify as*
 21 *de-identified information when provided by a regu-*
 22 *lated entity, service provider, covered entity, or busi-*
 23 *ness associate to another person or entity unless such*
 24 *person or entity contractually agrees in writing not*
 25 *to re-identify or attempt to re-identify the informa-*

1 *tion, and to require the same of any person or entity*
 2 *to whom such person or entity provides the informa-*
 3 *tion; and*

4 *(4) account for evolving methods of re-identifica-*
 5 *tion, including methods that use artificial intelligence*
 6 *or machine learning.*

7 *(c) PROHIBITION ON RE-IDENTIFICATION.—An entity*
 8 *that is the recipient of de-identified information may not*
 9 *re-identify, or attempt to re-identify, such information. A*
 10 *violation of this subsection shall be enforceable and subject*
 11 *to the civil penalties under section 2(c).*

12 *(d) DEFINITIONS.—In this section—*

13 *(1) the term “applicable health information” has*
 14 *the meaning given such term in section 2;*

15 *(2) the terms “business associate”, “covered enti-*
 16 *ty”, and “individually identifiable health informa-*
 17 *tion” have the meanings given such terms in section*
 18 *160.103 of title 45, Code of Federal Regulations (or*
 19 *any successor regulations); and*

20 *(3) the term “privacy-enhancing technologies”*
 21 *means any software or hardware solution, technical*
 22 *process, or other technological means of mitigating in-*
 23 *dividuals’ privacy risks arising from data processing*
 24 *by enhancing predictability, manageability,*
 25 *disassociability, and confidentiality.*

1 **SEC. 6. PREEMPTION.**

2 *Section 160.203 of title 45, Code of Federal Regula-*
3 *tions (or any successor regulations) shall apply to the re-*
4 *quirements set forth under this Act in the same manner*
5 *and to the same extent as such section applies to the stand-*
6 *ards, requirements, and implementation specifications*
7 *under subchapter C of chapter I of subtitle A of title 45,*
8 *Code of Federal Regulations (or any successor regulations).*

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A BILL

To provide additional protections with respect to health information, and for other purposes.

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