

105TH CONGRESS
2^D SESSION

H. R. 3900

To establish Federal penalties for prohibited uses and disclosures of individually identifiable health information, to establish a right in an individual to inspect and copy their own health information, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 19, 1998

Mr. SHAYS (for himself and Mr. BARRETT of Wisconsin) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Government Reform and Oversight, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish Federal penalties for prohibited uses and disclosures of individually identifiable health information, to establish a right in an individual to inspect and copy their own 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Consumer Health and Research Technology (CHART)
6 Protection Act”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—RESTRICTIONS ON USE AND DISCLOSURE

Sec. 101. General prohibitions and exceptions.
 Sec. 102. Special rules for anonymized information.
 Sec. 103. General requirements for authorization of disclosure of information.
 Sec. 104. Disclosure in civil proceedings.
 Sec. 105. Disclosure for criminal law enforcement purposes.
 Sec. 106. Disclosures for archival research.

TITLE II—INDIVIDUALS' RIGHTS

Sec. 201. Inspection and copying of health information.
 Sec. 202. Amendment of individually identifiable health information.
 Sec. 203. Notice of confidentiality practices.

TITLE III—ENFORCEMENT

Sec. 301. Criminal penalties.
 Sec. 302. Civil action.
 Sec. 303. Program exclusions.

TITLE IV—GENERAL PROVISIONS

Sec. 401. Standards for electronic disclosures.
 Sec. 402. Authorized representatives.
 Sec. 403. Relationship to other laws.
 Sec. 404. Reports analyzing impact of Act.
 Sec. 405. Effective date.
 Sec. 406. Definitions.

3 **TITLE I—RESTRICTIONS ON USE** 4 **AND DISCLOSURE**

5 **SEC. 101. GENERAL PROHIBITIONS AND EXCEPTIONS.**

6 Except as otherwise provided in this Act, and subject
 7 to the following exceptions, the following prohibited ac-
 8 tions and inactions on the part of a person shall be consid-
 9 ered a violation of this Act:

10 (1) DISCLOSURE IN ABSENCE OF, OR INCON-
 11 SISTENT WITH, AUTHORIZATION.—

1 (A) IN GENERAL.—Subject to the excep-
2 tions described in subparagraph (B)—

3 (i) a negligent or intentional disclo-
4 sure of individually identifiable health in-
5 formation without an authorization with
6 respect to the information that satisfies
7 the requirements of section 103, is prohib-
8 ited, unless the disclosure is governed by
9 section 104 or 105; and

10 (ii) a negligent or intentional disclo-
11 sure of individually identifiable health in-
12 formation, by a person granted authority
13 under an authorization with respect to the
14 information that satisfies the requirements
15 of section 103, that is inconsistent with the
16 provisions of the authorization, is prohib-
17 ited.

18 (B) EXCEPTIONS.—A disclosure otherwise
19 prohibited under subparagraph (A) is not pro-
20 hibited when—

21 (i) made by an individual whose
22 health or health care is the subject of the
23 information (or an authorized representa-
24 tive of such an individual, pursuant to sec-
25 tion 402);

1 (ii) made for the purpose of providing,
2 or facilitating the provision of, health care
3 to an individual described in clause (i);

4 (iii) made for the purpose of facilitat-
5 ing payment activities related to health
6 care provided to an individual described in
7 clause (i);

8 (iv) made pursuant to a specific af-
9 firmative authorization, or a requirement,
10 under State or Federal law, for use in le-
11 gally authorized—

12 (I) reporting of abuse, domestic
13 violence, or neglect information about
14 any individual;

15 (II) disease or injury reporting
16 about any individual;

17 (III) public health surveillance,
18 such as birth and death reporting;

19 (IV) public health investigation
20 or intervention;

21 (V) management audits, financial
22 audits, or program monitoring and
23 evaluation; or

24 (VI) licensure, certification, ac-
25 creditation, utilization review, quality

1 assurance activities, benchmarking, or
2 outcomes management and assess-
3 ment;

4 (v) made pursuant to an authorization
5 granted in a contract providing health care
6 benefits for an individual described in
7 clause (i), for the purpose of licensure, cer-
8 tification, accreditation, utilization review,
9 quality assurance activities, benchmarking,
10 or outcomes management and assessment;

11 (vi) made to a health researcher—

12 (I) in accordance with a research
13 protocol approved by an institutional
14 review board; or

15 (II) in accordance with section
16 106(a); or

17 (vii) made to a party to, or potential
18 party to, a merger or acquisition of a com-
19 mercial enterprise, in anticipation of, or
20 upon, the merger or acquisition.

21 (2) FAILURE TO PROVIDE FOR REASONABLE
22 PROTECTIONS AGAINST PROHIBITED DISCLO-
23 SURES.—

24 (A) IN GENERAL.—Subject to the excep-
25 tion described in subparagraph (B), a negligent

1 or intentional failure to provide for reasonable
2 protections against disclosures of individually
3 identifiable health information that are prohib-
4 ited under this Act is prohibited, including—

5 (i) a failure to establish and enforce
6 reasonable and appropriate administrative,
7 technical, and physical safeguards—

8 (I) to ensure the confidentiality
9 of individually identifiable health in-
10 formation; and

11 (II) to protect against—

12 (aa) any reasonably antici-
13 pated threats or hazards to the
14 security or integrity of such in-
15 formation; and

16 (bb) unauthorized uses or
17 disclosures of the information;

18 (ii) a failure to establish procedures
19 for determining a response to a subpoena,
20 warrant, court order, or other request from
21 a government authority for disclosure of
22 such information; and

23 (iii) a failure to provide for secure de-
24 struction of such information, where de-
25 struction of the information is desired.

1 (B) EXCEPTION.—A failure described in
2 subparagraph (A) is not prohibited when it is
3 by an individual whose health or health care is
4 the subject of the information (or an authorized
5 representative of such an individual, pursuant
6 to section 402).

7 (3) FAILURE TO IMPLEMENT WRITTEN POLI-
8 CIES FOR COMPLIANCE.—

9 (A) IN GENERAL.—Subject to the excep-
10 tion described in subparagraph (B), with re-
11 spect to a person whose employees, agents, or
12 contractors come in contact with individually
13 identifiable health information in the course of
14 their employment, agency, or contract execu-
15 tion, a negligent or intentional failure to estab-
16 lish and implement written policies concerning
17 compliance with this Act is prohibited, includ-
18 ing—

19 (i) a failure to establish procedures
20 for monitoring access to individually identi-
21 fiable health information;

22 (ii) a failure to establish rules limiting
23 access to such information to persons
24 whose duties require such access; and

1 (iii) a failure to provide for the en-
2 forcement of such policies.

3 (B) EXCEPTION.—A failure described in
4 subparagraph (A) is not prohibited when it is
5 by an individual whose health or health care is
6 the subject of the information (or an authorized
7 representative of such an individual, pursuant
8 to section 402).

9 (4) FAILURE TO ENTER INTO WRITTEN AGREE-
10 MENT WITH BUSINESS ASSOCIATES RESPECTING
11 COMPLIANCE.—A negligent or intentional failure to
12 enter into a written agreement with an agent, con-
13 tractor, or other person to whom individually identi-
14 fiable health information is disclosed for a business
15 purpose (such as persons who encode or encrypt in-
16 formation, data management contractors, and utili-
17 zation review and accreditation organizations), prior
18 to such disclosure, specifying the limitations on their
19 use and retention of such information and informing
20 them of their responsibilities under this Act, is pro-
21 hibited.

22 (5) COMPLIANCE WITH RESEARCH REQUIRE-
23 MENTS.—A negligent or intentional action is prohib-
24 ited where it consists of—

1 (A) a disclosure for health research pur-
2 poses of individually identifiable health informa-
3 tion that—

4 (i) has not been approved by an insti-
5 tutional review board; or

6 (ii) does not satisfy the requirements
7 of section 106; or

8 (B) a use or disclosure of individually iden-
9 tifiable health information in violation of—

10 (i) a research protocol approved by an
11 institutional review board or any other re-
12 quirement or condition concerning such use
13 or disclosure established by such a review
14 board; or

15 (ii) any requirement or condition con-
16 cerning such use or disclosure established
17 by a person making, or approving, a disclo-
18 sure under section 106.

19 (6) ANONYMIZED INFORMATION.—A use of
20 anonymized information, or an encryption key or
21 coding system used to anonymize information, in
22 violation of section 102, is prohibited.

23 (7) CIVIL PROCEEDING.—A negligent or inten-
24 tional disclosure of individually identifiable health in-
25 formation pursuant to a subpoena or discovery re-

1 quest related to a civil proceeding, in violation of
2 section 104, is prohibited.

3 (8) CRIMINAL PROCEEDING.—A negligent or in-
4 tentional disclosure of individually identifiable health
5 information for a criminal law enforcement purpose,
6 in violation of section 105, or a negligent or inten-
7 tional use of information obtained pursuant to such
8 section in violation of the section, is prohibited.

9 (9) SALE OR COMMERCIAL PUBLICATION.—

10 (A) IN GENERAL.—Subject to the excep-
11 tions described in subparagraph (B), an inten-
12 tional disclosure of individually identifiable
13 health information that constitutes a sale or
14 commercial publication of the information, is
15 prohibited.

16 (B) EXCEPTIONS.—A disclosure otherwise
17 prohibited under subparagraph (A) is not pro-
18 hibited when—

19 (i) the disclosure is made by an indi-
20 vidual whose health or health care is the
21 subject of the information (or an author-
22 ized representative of such an individual,
23 pursuant to section 402); or

24 (ii) the disclosure is made to a person
25 having a written authorization permitting

1 the disclosure that satisfies the require-
2 ments of section 103.

3 (10) FRAUD OR MISREPRESENTATION.—Use of
4 fraud, duress, deceit, or misrepresentation to obtain
5 access to individually identifiable health information
6 is prohibited.

7 **SEC. 102. SPECIAL RULES FOR ANONYMIZED INFORMA-**
8 **TION.**

9 (a) DEFINITION.—For purposes of this Act, the term
10 “anonymized information” means individually identifiable
11 health information from which personal identifiers and
12 means of directly contacting any subject of the informa-
13 tion (including name, address, and social security num-
14 ber), have been removed, encrypted, or replaced with a
15 code, in a manner such that the identity of any such sub-
16 ject is not apparent from the facts contained in the infor-
17 mation, but may, in the case of encrypted or coded infor-
18 mation, be determined by a person with access to the
19 encryption key or coding system. Such term does not in-
20 clude any such encryption key or coding system.

21 (b) USE.—

22 (1) IN GENERAL.—Subject to paragraph (2), a
23 person may use anonymized information, or an
24 encryption key or coding system described in sub-

1 section (c)(2), for any lawful purpose, if the person,
2 in such use, does not—

3 (A) attempt to identify any individual with
4 respect to whom information has been removed,
5 encrypted, or replaced with a code; or

6 (B) intentionally use the anonymized infor-
7 mation, the key, or the coding system in any
8 way that results in the identification of any
9 such individual.

10 (2) EXCEPTIONS.—A use otherwise prohibited
11 under paragraph (1) is not prohibited when any of
12 the following circumstances apply:

13 (A) The use is by an individual whose
14 health or health care is the subject of the infor-
15 mation (or an authorized representative of such
16 an individual, pursuant to section 402).

17 (B) The use is by a person having an au-
18 thorization permitting the use that satisfies the
19 requirements of section 103.

20 (C) The use is for the purpose of provid-
21 ing, or facilitating the provision of, health care
22 to an individual described in subparagraph (A).

23 (D) The use is for the purpose of facilitat-
24 ing payment activities related to health care

1 provided to an individual described in subpara-
2 graph (A).

3 (E) The use is pursuant to a specific af-
4 firmative authorization, or a requirement, under
5 State or Federal law, for legally authorized—

6 (i) disease or injury reporting;

7 (ii) public health surveillance, such as
8 birth and death reporting, and reporting
9 incidents of abuse, domestic violence, or
10 neglect;

11 (iii) public health investigation or
12 intervention;

13 (iv) management audits, financial au-
14 dits, or program monitoring and evalua-
15 tion; or

16 (v) licensure, certification, accredita-
17 tion, utilization review, quality assurance
18 activities, benchmarking, or outcomes man-
19 agement and assessment.

20 (F) The use is pursuant to an authoriza-
21 tion granted in a contract providing health care
22 benefits for an individual described in subpara-
23 graph (A), for the purpose of licensure, certifi-
24 cation, accreditation, utilization review, quality

1 assurance activities, benchmarking, or outcomes
2 management and assessment.

3 (G) The use is by a health researcher and
4 is—

5 (i) in accordance with a research pro-
6 tocol approved by an institutional review
7 board and any other requirement or condi-
8 tion concerning such use established by
9 such a review board; or

10 (ii) in accordance with any require-
11 ment or condition concerning such use es-
12 tablished by a person making, or approv-
13 ing, a disclosure under section 106.

14 (H) The use is by a party to, or potential
15 party to, a merger or acquisition of a commer-
16 cial enterprise, in anticipation of, or upon, the
17 merger or acquisition.

18 (c) DISCLOSURE.—

19 (1) ANONYMIZED INFORMATION.—For purposes
20 of this Act, disclosure of anonymized information
21 shall not be considered disclosure of individually
22 identifiable health information, unless it is disclosed
23 with an encryption key or coding system described in
24 paragraph (2) in manner such that the combined in-

1 formation satisfies the requirements of section
2 406(8).

3 (2) ENCRYPTION KEY OR CODE.—For purposes
4 of this Act, disclosure of an encryption key or coding
5 system that is used to determine the identity of any
6 individual with respect to whom information has
7 been removed, encrypted, or replaced with a code, in
8 order to create anonymized information, shall not be
9 considered disclosure of individually identifiable
10 health information, unless it is disclosed with
11 anonymized information in manner such that the
12 combined information satisfies the requirements of
13 section 406(8).

14 (d) DECODED INFORMATION.—Formerly anonymized
15 information that has been manipulated to reveal a part
16 of the information that had been removed, encrypted, or
17 replaced with a code in order to render it anonymized in-
18 formation is individually identifiable health information
19 and is subject, beginning on the date of such manipula-
20 tion, to all of the requirements of this part relating to indi-
21 vidually identifiable information.

1 **SEC. 103. GENERAL REQUIREMENTS FOR AUTHORIZATION**
2 **OF DISCLOSURE OF INFORMATION.**

3 (a) IN GENERAL.—For purposes of section 101, an
4 authorization satisfies the requirements of this section if
5 it—

6 (1) is in writing;

7 (2) is executed by an individual whose health or
8 health care is the subject of the information (or an
9 authorized representative of such an individual, pur-
10 suant to section 402); and

11 (3) satisfies the requirements of subsection (b).

12 (b) REQUIREMENTS.—An authorization satisfies the
13 requirements in this subsection if—

14 (1) it includes the following:

15 (A) a general statement of the purposes
16 for which the individually identifiable health in-
17 formation disclosed pursuant to the authoriza-
18 tion may be used;

19 (B) a general description of the persons
20 who are authorized to use such information;

21 (C) a valid signature of an individual
22 whose health or health care is the subject of the
23 information (or an authorized representative of
24 such individual);

25 (D) the date of the signature;

1 (E) an expiration date upon which the au-
2 thorization is no longer valid; and

3 (F) reasonable procedures permitting such
4 individual or representative to revoke the au-
5 thorization; and

6 (2) in a case in which the purposes under para-
7 graph (1)(A) include health research, the provisions
8 of the authorization that relate to such research—

9 (A) include each of the elements described
10 in paragraph (1);

11 (B) are set out separately from the re-
12 maining provisions and are independent from
13 them; and

14 (C) are subject to separate revocation pro-
15 cedures, the use of which does not per se effect
16 a revocation of the remaining provisions.

17 (c) EFFECT OF GOOD FAITH RELIANCE ON AUTHOR-
18 IZATION.—A person shall not be liable, or subject to pun-
19 ishment under State or Federal law, for a disclosure of
20 individually identifiable health information, where the dis-
21 closure—

22 (1) was made in good faith reliance on an au-
23 thorization executed by the individual that satisfies
24 the requirements of this section; and

1 (2) was consistent with the provisions of the au-
2 thorization.

3 **SEC. 104. DISCLOSURE IN CIVIL PROCEEDINGS.**

4 (a) IN GENERAL.—A person may not disclose individ-
5 ually identifiable health information for use in a civil law
6 enforcement investigation, a civil administrative action, or
7 a civil action brought in Federal or State court, in the
8 absence of—

9 (1) an otherwise valid discovery request, an ad-
10 ministrative subpoena or summons, or a judicial sub-
11 poena; and

12 (2) an order issued by the presiding judge or
13 official upon a determination that the need for the
14 information of the person requesting the disclosure
15 substantially outweighs the privacy interest of each
16 individual whose health or health care is the subject
17 of the information.

18 (b) CONSTRUCTION.—This section shall not be con-
19 strued to supersede any ground that may otherwise apply
20 under Federal or State law for an objection to the dislo-
21 sure of individually identifiable health information in any
22 civil action.

1 **SEC. 105. DISCLOSURE FOR CRIMINAL LAW ENFORCEMENT**
2 **PURPOSES.**

3 (a) IN GENERAL.—A person may not disclose individ-
4 ually identifiable health information for a criminal law en-
5 forcement purpose—

6 (1) in the absence of—

7 (A) a subpoena issued under the authority
8 of a grand jury;

9 (B) an administrative subpoena or sum-
10 mons or a judicial subpoena or warrant; or

11 (C) a request otherwise authorized by law
12 from a law enforcement agency; and

13 (2) in the case of a disclosure under subpara-
14 graph (B) or (C) of paragraph (1), in the absence
15 of a court order issued upon a determination that
16 the need for the information of the person request-
17 ing the disclosure substantially outweighs the pri-
18 vacy interest of each individual whose health or
19 health care is the subject of the information.

20 (b) DESTRUCTION OR RETURN OF INFORMATION.—
21 When the proceeding for which individually identifiable
22 health information was disclosed is concluded, including
23 any derivative matters arising from such proceeding, the
24 person to whom the disclosure was made shall either de-
25 stroy the individually identifiable health information, or
26 return it to the person from whom it was obtained.

1 (c) REDACTIONS.—To the extent practicable, and
2 consistent with the requirements of due process, a criminal
3 law enforcement agency shall redact personally identifying
4 information from individually identifiable health informa-
5 tion prior to the public disclosure of such information in
6 a judicial or administrative proceeding.

7 (d) USE OF INFORMATION.—Individually identifiable
8 health information obtained by a criminal law enforcement
9 agency pursuant to this section may only be used for pur-
10 poses of a legitimate criminal law enforcement activity.

11 **SEC. 106. DISCLOSURES FOR ARCHIVAL RESEARCH.**

12 (a) IN GENERAL.—A person described in subsection
13 (b) may disclose individually identifiable health informa-
14 tion, that was previously created or collected by the person
15 and maintained by the person in an archive or other repos-
16 itory, to a health researcher pursuant to this subsection,
17 if—

18 (1) the disclosure is made for the purpose of
19 permitting the health researcher to carry out health
20 research that involves analysis of the information;

21 (2) the disclosure has been reviewed and ap-
22 proved, by a board, committee, or other group for-
23 mally designated by the person to review requests
24 for such information, in accordance with written
25 standards for confidentiality that specify permissible

1 and impermissible uses of such information for
2 health research;

3 (3) the person enters into a written agreement
4 with the health researcher that is consistent with
5 this Act and specifies the permissible and impermis-
6 sible future uses and disclosures of the information;

7 (4) the person provides notice to the health re-
8 searcher that any future use or disclosure of the in-
9 formation that is prohibited under this Act or the
10 agreement described in paragraph (3) may provide a
11 basis for a civil action against the researcher or may
12 result in other adverse consequences for the re-
13 searcher; and

14 (5) the person maintains a permanent record
15 documenting the scope and substance of the disclo-
16 sure.

17 (b) PERSONS DESCRIBED.—A person described in
18 this subsection is any of the following:

19 (1) A health care provider.

20 (2) A health plan.

21 (3) A public health authority.

22 (4) An employer.

23 (5) A health or life insurer.

24 (6) A school or university.

1 TITLE II—INDIVIDUALS’ RIGHTS**2 SEC. 201. INSPECTION AND COPYING OF HEALTH INFORMA-**
3 TION.

4 (a) IN GENERAL.—Subject to subsections (b) and (c),
5 a person who is a health care provider, health plan, em-
6 ployer, health or life insurer, school, or university shall
7 permit an individual who is the subject of individually
8 identifiable health information, or the individual’s des-
9 ignee, to inspect and copy individually identifiable health
10 information concerning the individual, including records
11 created under section 202, that the person maintains. The
12 person may set forth appropriate procedures to be followed
13 for such inspection and copying and may require an indi-
14 vidual to pay reasonable fees associated with such inspec-
15 tion and copying and may require an individual to provide
16 written authorization of a provider designated by such in-
17 dividual through which the requested information will be
18 made available.

19 (b) EFFECT OF OTHER LAW.—

20 (1) DISCLOSURE PROHIBITED BY OTHER
21 LAW.—A person described in subsection (a) may not
22 permit the inspection or copying of individually iden-
23 tifiable health information under such subsection, if
24 such inspection or copying is prohibited by any pro-
25 vision of law other than this Act.

1 (2) DISCLOSURE LIMITED BY OTHER LAW.—A
2 person described in subsection (a) shall limit the in-
3 spection or copying of individually identifiable health
4 information under such subsection to the extent re-
5 quired by, and consistent with, any limitation on
6 such inspection or copying in any provision of law
7 other than this Act that is applicable to the person.

8 (c) ADDITIONAL EXCEPTIONS.—A person described
9 in subsection (a) is not required to permit the inspection
10 or copying of individually identifiable health information
11 if any of the following exceptions apply:

12 (1) ENDANGERMENT TO LIFE OR SAFETY.—
13 The person determines that the disclosure of the in-
14 formation could reasonably be expected to endanger
15 the life or physical safety of any individual.

16 (2) CONFIDENTIAL SOURCE.—The information
17 identifies, or could reasonably lead to the identifica-
18 tion of, a person who provided information under a
19 promise of confidentiality to a health care provider
20 or life insurer concerning the individual who is the
21 subject of the information.

22 (3) INFORMATION COMPILED IN ANTICIPATION
23 OF LITIGATION.—The information is compiled prin-
24 cipally—

1 (A) in the anticipation of a civil, criminal,
2 or administrative action or proceeding; or

3 (B) for use in such action or proceeding.

4 (4) RESEARCH PURPOSES.—The information
5 was collected for or during a clinical trial monitored
6 by an institutional review board in which the individ-
7 ual was a participant.

8 (d) DENIAL OF A REQUEST FOR INSPECTION OR
9 COPYING.—If a person described in subsection (a) denies
10 an individual's request for inspection or copying pursuant
11 to subsection (b) or (c), the person shall inform the indi-
12 vidual of—

13 (1) the reasons for the denial of the request for
14 inspection or copying;

15 (2) any procedures for further review of the de-
16 nial; and

17 (3) the individual's right to file with the person
18 a concise statement setting forth the request for in-
19 spection or copying.

20 (e) STATEMENT REGARDING REQUEST.—If an indi-
21 vidual has filed a statement under subsection (d)(3), the
22 person, in any subsequent disclosure of the portion of the
23 information requested under subsection (a), shall in-
24 clude—

1 (1) a notation that such individual has filed a
2 request for inspection and that such request was de-
3 nied; and

4 (2) a concise statement of the reasons for deny-
5 ing the request for inspection or copying.

6 (f) DEADLINE.—A person described in subsection (a)
7 shall comply with or deny, in accordance with subsection
8 (d), a request for inspection or copying of individually
9 identifiable health information under this section not later
10 than 45 days after the date on which the person receives
11 the request.

12 (g) RULES GOVERNING AGENTS.—An agent of a per-
13 son described in subsection (a) shall not be required to
14 provide for the inspection and copying of individually iden-
15 tifiable health information, except where—

16 (1) the individually identifiable health informa-
17 tion is retained by the agent; and

18 (2) the agent has been asked by the person to
19 fulfill the requirements of this section.

20 (h) RULE OF CONSTRUCTION.—This section shall not
21 be construed to require a person described in subsection
22 (a) to conduct a formal, informal, or other hearing or pro-
23 ceeding concerning a request for inspection or copying of
24 individually identifiable health information.

1 **SEC. 202. AMENDMENT OF INDIVIDUALLY IDENTIFIABLE**
2 **HEALTH INFORMATION.**

3 (a) IN GENERAL.—Not later than 45 days after the
4 date on which a person who is a health care provider,
5 health plan, employer, health or life insurer, school, or uni-
6 versity receives from an individual who is a subject of indi-
7 vidually identifiable health information a request in writ-
8 ing to amend the information, the person—

9 (1) shall make the amendment requested;

10 (2) shall inform the individual of the amend-
11 ment that has been made; and

12 (3) shall make reasonable efforts to inform any
13 person who is identified by the individual, who is not
14 an officer, employer, or agent of the entity, and to
15 whom the unamended portion of the information was
16 disclosed during the preceding year, of any nontech-
17 nical amendment that has been made.

18 (b) REFUSAL TO AMEND.—If a person described in
19 subsection (a) refuses to make an amendment requested
20 by an individual under such subsection, the person shall
21 inform the individual of—

22 (1) the reasons for the refusal to make the
23 amendment;

24 (2) any procedures for further review of the re-
25 fusal; and

1 (3) the individual's right to file with the person
2 a concise statement setting forth the requested
3 amendment and the individual's reasons for dis-
4 agreeing with the refusal.

5 (c) STATEMENT OF DISAGREEMENT.—If an individ-
6 ual has filed a statement of disagreement with a person
7 under subsection (b)(3), the person, in any subsequent dis-
8 closure of the disputed portion of the information—

9 (1) shall include a notation that such individual
10 has filed a statement of disagreement; and

11 (2) may include a concise statement of the rea-
12 sons for not making the requested amendment.

13 (d) RULES GOVERNING AGENTS.—The agent of a
14 person described in subsection (a) shall not be required
15 to make amendments to individually identifiable health in-
16 formation, except where—

17 (1) the information is retained by the agent;
18 and

19 (2) the agent has been asked by such person to
20 fulfill the requirements of this section.

21 (e) REPEATED REQUESTS FOR AMENDMENTS.—If a
22 person described in subsection (a) receives a duplicative
23 request for an amendment of information as provided for
24 in such subsection and a statement of disagreement with
25 respect to the request has been filed pursuant to sub-

1 section (c), the person shall inform the individual of such
2 filing and shall not be required to carry out the procedures
3 required under this section.

4 (f) RULE OF CONSTRUCTION.—This section shall not
5 be construed—

6 (1) to require a person described in subsection
7 (a) to conduct a formal, informal, or other hearing
8 or proceeding concerning a request for an amend-
9 ment to individually identifiable health information;

10 (2) to require a person described in subsection
11 (a) to make an amendment with which the person
12 disagrees; or

13 (3) to require the alteration of any arrange-
14 ment, written agreement, or obligation with respect
15 to the delivery of, or payment for, health care.

16 **SEC. 203. NOTICE OF CONFIDENTIALITY PRACTICES.**

17 (a) PREPARATION OF WRITTEN NOTICE.—A health
18 care provider, health plan, health oversight agency, public
19 health authority, employer, health or life insurer, health
20 researcher, school, or university shall post or provide, in
21 writing and in a clear and conspicuous manner, notice of
22 the person’s confidentiality practices, that shall include—

23 (1) a description of an individual’s rights with
24 respect to individually identifiable health informa-
25 tion;

1 (2) the uses and disclosures of individually
2 identifiable health information authorized under this
3 Act;

4 (3) the procedures established by the person for
5 authorizing disclosures of individually identifiable
6 health information and for revoking such authoriza-
7 tions;

8 (4) the procedures established by the person for
9 the exercise of the individual's rights; and

10 (5) the procedures established by the person for
11 providing copies of the notice.

12 (b) MODEL NOTICE.—The Secretary, after notice
13 and opportunity for public comment, shall develop and dis-
14 seminate model notices of confidentiality practices, for use
15 under this section. Use of the model notice developed by
16 the Secretary shall serve as a complete defense in any civil
17 action to an allegation that a violation of this section has
18 occurred.

19 **TITLE III—ENFORCEMENT**

20 **SEC. 301. CRIMINAL PENALTIES.**

21 (a) OFFENSE.—A person who knowingly and in viola-
22 tion of this Act obtains individually identifiable health in-
23 formation, uses such information, or discloses such infor-
24 mation to another person, knowing that such obtaining,

1 use, or disclosure is unlawful, shall be punished as pro-
2 vided in subsection (b).

3 (b) PENALTIES.—A person described in subsection
4 (a) shall—

5 (1) be fined not more than \$50,000, imprisoned
6 not more than 1 year, or both;

7 (2) if the offense is committed under false pre-
8 tenses, be fined not more than \$100,000, imprisoned
9 not more than 5 years, or both; and

10 (3) if the offense is committed with intent to
11 sell, transfer, or use individually identifiable health
12 information for commercial advantage, personal
13 gain, or malicious harm, be fined not more than
14 \$250,000, imprisoned not more than 10 years, or
15 both.

16 **SEC. 302. CIVIL ACTION.**

17 (a) IN GENERAL.—Any individual whose rights under
18 this Act have been knowingly or negligently violated may
19 bring a civil action to recover such preliminary and equi-
20 table relief as the court determines to be appropriate.

21 (b) ATTORNEY'S FEES.—In the case of a civil action
22 brought under subsection (a) in which the plaintiff has
23 substantially prevailed, the court may assess against the
24 respondent a reasonable attorney's fee and other litigation

1 costs and expenses (including expert fees) reasonably in-
2 curred.

3 (c) LIMITATION.—No action may be commenced
4 under this subsection by an individual more than 2 years
5 after the date on which the violation was, or should rea-
6 sonably have been, discovered by the individual.

7 (d) NO LIABILITY FOR PERMISSIBLE DISCLO-
8 SURES.—A person who makes a disclosure of individually
9 identifiable health information about an individual that is
10 permitted under this Act shall not be liable to the individ-
11 ual for such disclosure under common law.

12 **SEC. 303. PROGRAM EXCLUSIONS.**

13 (a) EXCLUSION FROM PARTICIPATION IN FEDERAL
14 AND STATE HEALTH CARE PROGRAMS.—Section 1128(b)
15 of the Social Security Act (42 U.S.C. 1320a–7(b)) is
16 amended by adding at the end the following:

17 “(16) FAILURE LAWFULLY TO TREAT INDIVID-
18 UALLY IDENTIFIABLE HEALTH INFORMATION.—Any
19 individual or entity that the Secretary determines
20 has failed substantially to comply with a provision of
21 the Consumer Health and Research Technology
22 (CHART) Protection Act.”.

23 (b) EXCLUSION OF PROVIDERS FROM PARTICIPA-
24 TION IN FEDERAL EMPLOYEES HEALTH BENEFITS PRO-

1 GRAM.—Section 8902a(b) of title 5, United States Code,
2 is amended by adding at the end the following:

3 “(6) Any provider that the Secretary of Health
4 and Human Services has determined has failed sub-
5 stantially to comply with a provision of the Con-
6 sumer Health and Research Technology (CHART)
7 Protection Act.”.

8 **TITLE IV—GENERAL** 9 **PROVISIONS**

10 **SEC. 401. STANDARDS FOR ELECTRONIC DISCLOSURES.**

11 The National Committee on Vital and Health Statis-
12 tics, in consultation with the National Science Foundation,
13 shall promulgate standards for disclosing, authorizing the
14 use and disclosure of, and authenticating, individually
15 identifiable health information in electronic form, in a
16 manner consistent with this Act.

17 **SEC. 402. AUTHORIZED REPRESENTATIVES.**

18 (a) IN GENERAL.—Except as provided in subsections
19 (b) and (c), a person who is authorized by law, or by an
20 instrument recognized under law, to act as an agent, at-
21 torney, proxy, or other legal representative for an individ-
22 ual, otherwise to exercise the rights of the individual, may,
23 to the extent so authorized, exercise and discharge the
24 rights of the individual under this Act.

1 (b) HEALTH CARE POWER OF ATTORNEY.—A person
2 who is not described in subsection (a), but is authorized
3 by law or by an instrument recognized under law to make
4 decisions about the provision of health care to an individ-
5 ual who is incapacitated, may exercise and discharge the
6 rights of the individual under this Act, to the extent nec-
7 essary to effectuate the terms or purposes of the grant
8 of authority.

9 (c) NO COURT DECLARATION.—If a health care pro-
10 vider determines that an individual, who has not been de-
11 clared to be legally incompetent, suffers from a medical
12 condition that prevents the individual from acting know-
13 ingly or effectively on the individual’s own behalf, the right
14 of the individual to authorize disclosure under this Act
15 may be exercised and discharged in the best interest of
16 the individual by—

17 (1) a person described in subsection (b) with re-
18 spect to the individual;

19 (2) a person described in subsection (a) with re-
20 spect to the individual, but only if a person de-
21 scribed in paragraph (1) cannot be contacted after
22 a reasonable effort;

23 (3) the next of kin of the individual, but only
24 if a person described in paragraph (1) or (2) cannot
25 be contacted after a reasonable effort; or

1 (4) the health care provider, but only if a per-
2 son described in paragraph (1), (2), or (3) cannot be
3 contacted after a reasonable effort.

4 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
5 provisions of this Act shall continue to apply to individ-
6 ually identifiable health information concerning a deceased
7 individual for a period of 2 years following the death of
8 that individual.

9 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
10 CEASED INDIVIDUAL.—A person who is authorized by law
11 or by an instrument recognized under law, to act as an
12 executor of the estate of a deceased individual, or other-
13 wise to exercise the rights of the deceased individual, may,
14 to the extent so authorized, exercise and discharge the
15 rights of such deceased individual under this Act for a pe-
16 riod of 2 years following the death of that individual. If
17 no such designee has been authorized, the rights of the
18 deceased individual may be exercised as provided for in
19 subsection (c).

20 **SEC. 403. RELATIONSHIP TO OTHER LAWS.**

21 (a) IN GENERAL.—

22 (1) STATE LAW.—Except as provided in sub-
23 sections (b) through (f), the provisions of this Act
24 shall preempt any State law that directly relates to
25 matters covered by this Act.

1 (2) FEDERAL LAW.—This Act shall not be con-
2 strued as repealing, explicitly or implicitly, other
3 Federal laws or regulations relating to individually
4 identifiable health information or relating to an indi-
5 vidual’s access to health care services.

6 (b) PRIVILEGES.—This Act does not preempt or mod-
7 ify State common or statutory law to the extent such law
8 concerns a privilege of a witness or person in a court of
9 the State. This Act does not supersede or modify Federal
10 common or statutory law to the extent such law concerns
11 a privilege of a witness or person in a court of the United
12 States. The execution of an authorization pursuant to sec-
13 tion 103 may not be construed as a waiver of any such
14 privilege.

15 (c) CERTAIN DUTIES UNDER LAW.—Nothing in this
16 Act shall be construed to preempt, supersede, or modify
17 the operation of any State law that—

18 (1) provides for the reporting of vital statistics
19 such as birth or death information;

20 (2) requires the reporting of abuse, domestic vi-
21 olence, or neglect information about any individual;

22 (3) regulates information concerning an individ-
23 ual’s mental health or communicable disease status;

24 or

1 (4) governs a minor’s rights to access individ-
2 ually identifiable health information or health care
3 services.

4 (d) RELATIONSHIP TO CLINICAL RESEARCH AND RE-
5 PORTS.—This Act shall not apply to individually identifi-
6 able health information that is created, received, main-
7 tained, used, disclosed, or transmitted by any person in
8 connection with—

9 (1) any activity conducted pursuant to an inves-
10 tigational new drug exemption, or for which approval
11 of an institutional review board is required by the
12 Food and Drug Administration; or

13 (2) any record required to be maintained or re-
14 port required to be filed by the Food and Drug Ad-
15 ministration.

16 (e) FEDERAL PRIVACY ACT.—

17 (1) MEDICAL EXEMPTIONS.—Sections 552a of
18 title 5, United States Code, is amended by adding
19 at the end the following:

20 “(w) MEDICAL EXEMPTIONS.—The head of an agen-
21 cy that is subject to the Consumer Health and Research
22 Technology (CHART) Protection Act shall promulgate
23 rules, in accordance with the requirements (including gen-
24 eral notice) of subsections (b)(1), (b)(2), (b)(3), (c), and
25 (e) of section 553 of this title, to exempt a system of

1 records within the agency, to the extent that the system
2 of records contains individually identifiable health infor-
3 mation (as defined in section 406 of such Act), from all
4 provisions of this section except subsections (b)(6), (d),
5 (e)(1), (e)(2), subparagraphs (A) and (C) and (E) through
6 (I) of subsection (e)(4), and subsections (e)(5), (e)(6),
7 (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).”.

8 (2) TECHNICAL AMENDMENT.—Section
9 552a(f)(3) of title 5, United States Code, is amend-
10 ed by striking “pertaining to him,” and all that fol-
11 lows through the semicolon and inserting “pertain-
12 ing to the individual;”.

13 (f) APPLICATION TO CERTAIN FEDERAL AGEN-
14 CIES.—

15 (1) DEPARTMENT OF DEFENSE.—

16 (A) EXCEPTIONS.—The Secretary of De-
17 fense may, by regulation, establish exceptions to
18 the requirements of this Act to the extent such
19 Secretary determines that disclosure of individ-
20 ually identifiable health information relating to
21 members of the Armed Forces from systems of
22 records operated by the Department of Defense
23 is necessary under circumstances different from
24 those permitted under this Act for the proper

1 conduct of national defense functions by mem-
2 bers of the Armed Forces.

3 (B) APPLICATION TO CIVILIAN EMPLOY-
4 EES.—The Secretary of Defense may, by regu-
5 lation, establish for civilian employees of the
6 Department of Defense and employees of De-
7 partment of Defense contractors, limitations on
8 the right of such persons to revoke or amend
9 authorizations for disclosures under section 103
10 when such authorizations were provided by such
11 employees as a condition of employment and
12 the disclosure is determined necessary by the
13 Secretary of Defense to the proper conduct of
14 national defense functions by such employees.

15 (2) DEPARTMENT OF TRANSPORTATION.—

16 (A) EXCEPTIONS.—The Secretary of
17 Transportation may, with respect to members
18 of the Coast Guard, exercise the same powers
19 as the Secretary of Defense may exercise under
20 paragraph (1)(A).

21 (B) APPLICATION TO CIVILIAN EMPLOY-
22 EES.—The Secretary of Transportation may,
23 with respect to civilian employees of the Coast
24 Guard and Coast Guard contractors, exercise

1 the same powers as the Secretary of Defense
2 may exercise under paragraph (1)(B).

3 (3) DEPARTMENT OF VETERANS AFFAIRS.—

4 The limitations on use and disclosure of individually
5 identifiable health information under this Act shall
6 not be construed to prevent any exchange of such in-
7 formation within and among components of the De-
8 partment of Veterans Affairs that determine eligi-
9 bility for or entitlement to, or that provide, benefits
10 under laws administered by the Secretary of Veteran
11 Affairs.

12 **SEC. 404. REPORTS ANALYZING IMPACT OF ACT.**

13 (a) EFFORTS TO COMBAT FRAUD AND ABUSE.—Be-
14 ginning not later than 12 months after the effective date
15 in section 405(a), the Inspector General of the Depart-
16 ment of Health and Human Services shall submit to the
17 Committee on Ways and Means and the Committee on
18 Government Reform and Oversight of the House of Rep-
19 resentatives and the Committee on Commerce, Science,
20 and Transportation and the Committee on Finance of the
21 Senate an annual report containing the results of an an-
22 nual study. The study shall analyze whether this Act has
23 had an adverse effect on efforts to combat fraud and abuse
24 undertaken under title XVIII, XIX, or XXI of the Social
25 Security Act.

1 (b) HEALTH RESEARCH.—Beginning not later than
2 12 months after the effective date in section 405(a), the
3 Secretary, in consultation with the National Research
4 Council of the National Academy of Sciences and the In-
5 stitute of Medicine, shall submit to the Congress an an-
6 nual report containing the results of an annual study. The
7 study shall analyze the effect of this Act on the quality
8 and efficacy of health research.

9 (c) ADMINISTRATIVE SIMPLIFICATION.—Not later
10 than 12 months after the effective date in section 405(a),
11 the Comptroller General of the United States shall submit
12 to the Congress a report containing the results of a study.
13 The study shall analyze the effect of this Act on the imple-
14 mentation of subtitle F of title II of the Health Insurance
15 Portability and Accountability Act of 1996 and part C of
16 title XI of the Social Security Act.

17 **SEC. 405. EFFECTIVE DATE.**

18 (a) IN GENERAL.—Except as provided in subsection
19 (b), this Act shall take effect on the date that is 18 months
20 after the date of the enactment of this Act.

21 (b) PROVISIONS EFFECTIVE IMMEDIATELY.—A pro-
22 vision of this Act shall take effect on the date of the enact-
23 ment of this Act if the provision authorizes or requires
24 the Secretary of Defense, the Secretary of Transportation,
25 or the Secretary of Health and Human Services to de-

1 velop, establish, or promulgate regulations or model no-
2 tices.

3 (c) DEADLINE FOR REGULATIONS.—The Secretary
4 shall promulgate regulations implementing this Act not
5 later than the date that is 12 months after the date of
6 the enactment of this Act.

7 **SEC. 406. DEFINITIONS.**

8 As used in this Act:

9 (1) EMPLOYER.—The term “employer” has the
10 meaning given such term under section 3(5) of the
11 Employee Retirement Income Security Act of 1974
12 (29 U.S.C. 1002(5)), except that such term shall in-
13 clude only employers of two or more employees.

14 (2) HEALTH CARE.—The term “health care”
15 means—

16 (A) preventive, diagnostic, therapeutic, re-
17 habilitative, maintenance, or palliative care, in-
18 cluding appropriate assistance with disease or
19 symptom management and maintenance, coun-
20 seling, service, or procedure—

21 (i) with respect to the physical or
22 mental condition of an individual; or

23 (ii) affecting the structure or function
24 of the human body or any part of the
25 human body, including the banking of

1 blood, sperm, organs, or any other tissue;
2 and

3 (B) any sale or dispensing of a drug, de-
4 vice, equipment, or other health care related
5 item to an individual, or for the use of an indi-
6 vidual, pursuant to a prescription.

7 (3) HEALTH CARE PROVIDER.—The term
8 “health care provider” means a person, who with re-
9 spect to a specific item of individually identifiable
10 health information, receives, creates, uses, main-
11 tains, or discloses the information while acting in
12 whole or in part in the capacity of—

13 (A) a person who is licensed, certified, reg-
14 istered, or otherwise authorized by Federal or
15 State law to provide an item or service that
16 constitutes health care in the ordinary course of
17 business, or practice of a profession;

18 (B) a Federal, State, employer-sponsored
19 or other privately sponsored program that di-
20 rectly provides items or services that constitute
21 health care to beneficiaries; or

22 (C) an officer or employee of a person de-
23 scribed in subparagraph (A) or (B).

24 (4) HEALTH OR LIFE INSURER.—The term
25 “health or life insurer” means a health insurance

1 issuer as defined in section 9805(b)(2) of the Inter-
2 nal Revenue Code of 1986 or a life insurance com-
3 pany as defined in section 816 of such Code.

4 (5) HEALTH OVERSIGHT AGENCY.—The term
5 “health oversight agency” means a person who, with
6 respect to a specific item of individually identifiable
7 health information, receives, creates, uses, main-
8 tains, or discloses the information while acting in
9 whole or in part in the capacity of—

10 (A) a person who performs or oversees the
11 performance of an assessment, evaluation, de-
12 termination, or investigation, relating to the li-
13 censing, accreditation, or credentialing of health
14 care providers; or

15 (B) a person who—

16 (i) performs or oversees the perform-
17 ance of an audit, assessment, evaluation,
18 determination, or investigation relating to
19 the effectiveness of, compliance with, or
20 applicability of, legal, fiscal, medical, or
21 scientific standards or aspects of perform-
22 ance related to the delivery of, or payment
23 activities related to, health care; and

24 (ii) is a public agency, acting on be-
25 half of a public agency, acting pursuant to

1 a requirement of a public agency, or carry-
2 ing out activities under a Federal or State
3 law governing the assessment, evaluation,
4 determination, investigation, or prosecution
5 described in subparagraph (A).

6 (6) HEALTH PLAN.—The term “health plan”
7 means any health insurance plan, including any hos-
8 pital or medical service plan, dental or other health
9 service plan, health maintenance organization plan,
10 plan offered by a provider-sponsored organization
11 (as defined in section 1855(d) of the Social Security
12 Act (42 U.S.C. 1395w–25(d))), or other program
13 providing or arranging for the provision of health
14 benefits, whether or not funded through the pur-
15 chase of insurance.

16 (7) HEALTH RESEARCHER.—The term “health
17 researcher” means a person, or an officer, employee,
18 or agent of a person, who receives individually iden-
19 tifiable health information as part of a research
20 project that involves data with respect to human
21 subjects.

22 (8) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
23 FORMATION.—The term “individually identifiable
24 health information” means any information, includ-
25 ing demographic information, collected from an indi-

1 vidual, whether oral or recorded in any form or me-
2 dium, that—

3 (A) is created or received by a health care
4 provider, health plan, health oversight agency,
5 public health authority, employer, health or life
6 insurer, school or university; and

7 (B)(i) relates to the past, present, or fu-
8 ture physical or mental health or condition of
9 an individual (including individual cells and
10 their components), the provision of health care
11 to an individual, or the past, present, or future
12 payment activities related to the provision of
13 health care to an individual; and

14 (ii)(I) identifies an individual;

15 (II) contains personal identifiers that pro-
16 vide a direct means of identifying the individ-
17 ual; or

18 (III) has been provided in an encrypted
19 format that does not directly identify an indi-
20 vidual, but that provides a method for
21 decrypting the information.

22 (9) INSTITUTIONAL REVIEW BOARD.—The term
23 “institutional review board” means an entity estab-
24 lished to review proposed health research with re-
25 spect to potential risks to human subjects pursuant

1 to Federal regulations adopted under section
2 1802(b) of the Public Health Service Act (42 U.S.C.
3 300v-1(b)).

4 (10) PAYMENT ACTIVITIES.—The term “pay-
5 ment activities”—

6 (A) means activities undertaken—

7 (i) by, or on behalf of, a health plan
8 to determine its responsibility for coverage
9 under the plan; or

10 (ii) by a health care provider to obtain
11 payment for items or services provided to
12 an individual, provided under a health plan
13 or provided based on a determination by
14 the health plan of responsibility for cov-
15 erage under the plan; and

16 (B) includes the following activities, when
17 performed in a manner consistent with subpara-
18 graph (A):

19 (i) Billing, claims management, medi-
20 cal data processing, practice management,
21 or other administrative services and actual
22 payment.

23 (ii) Determinations of coverage or ad-
24 judication of health benefit claims and sub-
25 rogation claims.

1 (iii) Review of health care services
2 with respect to medical necessity, coverage
3 under a health plan, appropriateness of
4 care, or justification of charges.

5 (11) PERSON.—The term “person” means a
6 natural person, a government, governmental subdivi-
7 sion, agency or authority, a company, corporation,
8 estate, firm, trust, partnership, association, joint
9 venture, society, joint stock company, or any other
10 legal entity.

11 (12) PUBLIC HEALTH AUTHORITY.—The term
12 “public health authority” means an authority or in-
13 strumentality of the United States, a tribal govern-
14 ment, a State, or a political subdivision of a State
15 that is—

16 (A) primarily responsible for public health
17 matters; and

18 (B) primarily engaged in activities such as
19 injury reporting, public health surveillance, and
20 public health investigation or intervention.

21 (13) QUALITY ASSURANCE ACTIVITIES.—The
22 term “quality assurance activities” means a formal
23 methodology and set of activities designed to assess
24 the quality of health care services provided to an in-
25 dividual. The term includes formal review of care,

1 problem identification, corrective actions taken to
2 remedy any deficiencies, and evaluation of actions
3 taken. The term also includes activities undertaken
4 by a quality control and peer review organization (as
5 defined in section 1152 of the Social Security Act
6 (42 U.S.C. 1320c-1)).

7 (14) SCHOOL OR UNIVERSITY.—The term
8 “school or university” means an institution or place
9 accredited or licensed for purposes of providing in-
10 struction or education, including an elementary
11 school, secondary school, or institution of higher
12 learning, a college, or an assemblage of colleges
13 united under one corporate organization or govern-
14 ment.

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

17 (16) STATE.—The term “State” includes the
18 District of Columbia, Puerto Rico, the Virgin Is-
19 lands, Guam, American Samoa, and the Northern
20 Mariana Islands.

21 (17) WRITING.—The term “writing” means
22 writing in either a paper-based or computer-based
23 form, including electronic signatures.

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