

106TH CONGRESS  
1ST SESSION

# H. R. 2455

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.

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## IN THE HOUSE OF REPRESENTATIVES

JULY 1, 1999

Mr. SHAYS (for himself, Mr. HILLIARD, Mr. LATOURETTE, and Mr. MCHUGH) 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, 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

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## 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 facili-  
5 tating 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 that satisfies the re-  
15 quirements of the policy set forth in  
16 45 C.F.R. § 46.107 (or any successor  
17 to such policy); or

18 (II) in accordance with section  
19 106(a); or

20 (vii) made to a party to, or potential  
21 party to, a merger or acquisition of a com-  
22 mercial enterprise, in anticipation of, or  
23 upon, the merger or acquisition.

1           (2) FAILURE TO PROVIDE FOR REASONABLE  
2 PROTECTIONS AGAINST PROHIBITED DISCLO-  
3 SURES.—

4           (A) IN GENERAL.—Subject to the excep-  
5 tion described in subparagraph (B), a negligent  
6 or intentional failure to provide for reasonable  
7 protections against disclosures of individually  
8 identifiable health information that are prohib-  
9 ited under this Act is prohibited, including—

10           (i) a failure to establish and enforce  
11 reasonable and appropriate administrative,  
12 technical, and physical safeguards—

13           (I) to ensure the confidentiality  
14 of individually identifiable health in-  
15 formation; and

16           (II) to protect against—

17           (aa) any reasonably antici-  
18 pated threats or hazards to the  
19 security or integrity of such in-  
20 formation; and

21           (bb) unauthorized uses or  
22 disclosures of the information;

23           (ii) a failure to establish procedures  
24 for determining a response to a subpoena,  
25 warrant, court order, or other request from

1 a government authority for disclosure of  
2 such information; and

3 (iii) a failure to provide for secure de-  
4 struction of such information, where de-  
5 struction of the information is desired.

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

12 (3) FAILURE TO IMPLEMENT WRITTEN POLI-  
13 CIES FOR COMPLIANCE.—

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

1 (i) a failure to establish procedures  
2 for monitoring access to individually identi-  
3 fiable health information;

4 (ii) a failure to establish rules limiting  
5 access to such information to persons  
6 whose duties require such access; and

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

9 (B) EXCEPTION.—A failure described in  
10 subparagraph (A) is not prohibited when it is  
11 by an individual whose health or health care is  
12 the subject of the information (or an authorized  
13 representative of such an individual, pursuant  
14 to section 402).

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



1       them of their responsibilities under this Act, is pro-  
2       hibited.

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

6               (A) a disclosure for health research pur-  
7       poses of individually identifiable health informa-  
8       tion that—

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

11              (ii) does not satisfy the requirements  
12       of section 106; or

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

15              (i) a research protocol approved by an  
16       institutional review board or any other re-  
17       quirement or condition concerning such use  
18       or disclosure established by such a review  
19       board; or

20              (ii) any requirement or condition con-  
21       cerning such use or disclosure established  
22       by a person making, or approving, a disclo-  
23       sure under section 106.

24              (6) ANONYMIZED INFORMATION.—A use of  
25       anonymized information, or an encryption key or

1 coding system used to anonymize information, in  
2 violation of section 102, is prohibited.

3 (7) CIVIL PROCEEDING.—A negligent or inten-  
4 tional disclosure of individually identifiable health in-  
5 formation pursuant to a subpoena or discovery re-  
6 quest related to a civil proceeding, in violation of  
7 section 104, is prohibited.

8 (8) CRIMINAL PROCEEDING.—A negligent or in-  
9 tentional disclosure of individually identifiable health  
10 information for a criminal law enforcement purpose,  
11 in violation of section 105, or a negligent or inten-  
12 tional use of information obtained pursuant to such  
13 section in violation of the section, is prohibited.

14 (9) SALE OR COMMERCIAL PUBLICATION.—

15 (A) IN GENERAL.—Subject to the excep-  
16 tions described in subparagraph (B), an inten-  
17 tional disclosure of individually identifiable  
18 health information that constitutes a sale or  
19 commercial publication of the information, is  
20 prohibited.

21 (B) EXCEPTIONS.—A disclosure otherwise  
22 prohibited under subparagraph (A) is not pro-  
23 hibited when—

24 (i) the disclosure is made by an indi-  
25 vidual whose health or health care is the

1 subject of the information (or an author-  
2 ized representative of such an individual,  
3 pursuant to section 402); or

4 (ii) the disclosure is made to a person  
5 having a written authorization permitting  
6 the disclosure that satisfies the require-  
7 ments of section 103.

8 (10) FRAUD OR MISREPRESENTATION.—Use of  
9 fraud, duress, deceit, or misrepresentation to obtain  
10 access to individually identifiable health information  
11 is prohibited.

12 **SEC. 102. SPECIAL RULES FOR ANONYMIZED INFORMA-**  
13 **TION.**

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

1 (b) USE.—

2 (1) IN GENERAL.—Subject to paragraph (2), a  
3 person may use anonymized information, or an  
4 encryption key or coding system described in sub-  
5 section (c)(2), for any lawful purpose, if the person,  
6 in such use, does not—

7 (A) attempt to identify any individual with  
8 respect to whom information has been removed,  
9 encrypted, or replaced with a code; or

10 (B) intentionally use the anonymized infor-  
11 mation, the key, or the coding system in any  
12 way that results in the identification of any  
13 such individual.

14 (2) EXCEPTIONS.—A use otherwise prohibited  
15 under paragraph (1) is not prohibited when any of  
16 the following circumstances apply:

17 (A) The use is by an individual whose  
18 health or health care is the subject of the infor-  
19 mation (or an authorized representative of such  
20 an individual, pursuant to section 402).

21 (B) The use is by a person having an au-  
22 thorization permitting the use that satisfies the  
23 requirements of section 103.

24 (C) The use is for the purpose of pro-  
25 viding, or facilitating the provision of, health

1 care to an individual described in subparagraph  
2 (A).

3 (D) The use is for the purpose of facili-  
4 tating payment activities related to health care  
5 provided to an individual described in subpara-  
6 graph (A).

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

10 (i) disease or injury reporting;

11 (ii) public health surveillance, such as  
12 birth and death reporting, and reporting  
13 incidents of abuse, domestic violence, or  
14 neglect;

15 (iii) public health investigation or  
16 intervention;

17 (iv) management audits, financial au-  
18 dits, or program monitoring and evalua-  
19 tion; or

20 (v) licensure, certification, accredita-  
21 tion, utilization review, quality assurance  
22 activities, benchmarking, or outcomes man-  
23 agement and assessment.

24 (F) The use is pursuant to an authoriza-  
25 tion granted in a contract providing health care

benefits for an individual described in subparagraph (A), for the purpose of licensure, certification, accreditation, utilization review, quality assurance activities, benchmarking, or outcomes management and assessment.

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

(i) in accordance with a research protocol approved by an institutional review board and any other requirement or condition concerning such use established by such a review board; or

(ii) in accordance with any requirement or condition concerning such use established by a person making, or approving, a disclosure under section 106.

(H) The use is by a party to, or potential party to, a merger or acquisition of a commercial enterprise, in anticipation of, or upon, the merger or acquisition.

(c) DISCLOSURE.—

(1) ANONYMIZED INFORMATION.—For purposes of this Act, disclosure of anonymized information shall not be considered disclosure of individually identifiable health information, unless it is disclosed

1 with an encryption key or coding system described in  
2 paragraph (2) in manner such that the combined in-  
3 formation satisfies the requirements of section  
4 406(8).

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

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

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

21 (C) a general description of the persons  
22 who are authorized to use such information;

23 (D) a valid signature of an individual  
24 whose health or health care is the subject of the  
25 information (or an authorized representative of  
26 such individual);



1 (E) the date of the signature;

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

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

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

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

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

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

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

23 (1) was made in good faith reliance on an au-  
24 thorization executed by the individual that satisfies  
25 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 demonstration, by clear and con-  
14       vincing evidence, that the need for the information  
15       of the person requesting the disclosure substantially  
16       outweighs the privacy interest of each individual  
17       whose health or health care is the subject of the in-  
18       formation.

19       (b) CONSTRUCTION.—This section shall not be con-  
20       strued to supersede any ground that may otherwise apply  
21       under Federal or State law for an objection to the dislo-  
22       sure of individually identifiable health information in any  
23       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 demonstration, by  
16 clear and convincing evidence, that the need for the  
17 information of the person requesting the disclosure  
18 substantially outweighs the privacy interest of each  
19 individual whose health or health care is the subject  
20 of the information.

21 (b) DESTRUCTION OR RETURN OF INFORMATION.—

22 When the proceeding for which individually identifiable  
23 health information was disclosed is concluded, including  
24 any derivative matters arising from such proceeding, the  
25 person to whom the disclosure was made shall either de-

1 destroy the individually identifiable health information, or  
 2 return it to the person from whom it was obtained.

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

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

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

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

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

23 (2) the disclosure has been reviewed and ap-  
 24 proved, by a board, committee, or other group for-  
 25 mally designated by the person to review requests

1 for such information, in accordance with written  
2 standards for confidentiality that specify permissible  
3 and impermissible uses of such information for  
4 health research;

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

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

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

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

21 (1) A health care provider.

22 (2) A health plan.

23 (3) A public health authority.

24 (4) An employer.

25 (5) A health or life insurer.

1 (6) A school or university.

2 **TITLE II—INDIVIDUALS’ RIGHTS**

3 **SEC. 201. INSPECTION AND COPYING OF HEALTH INFORMA-**  
4 **TION.**

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

20 (b) EFFECT OF OTHER LAW.—

21 (1) DISCLOSURE PROHIBITED BY OTHER  
22 LAW.—A person described in subsection (a) may not  
23 permit the inspection or copying of individually iden-  
24 tifiable health information under such subsection, if

1       such inspection or copying is prohibited by any pro-  
2       vision of law other than this Act.

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

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

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

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

1           (3) INFORMATION COMPILED IN ANTICIPATION  
2       OF LITIGATION.—The information is compiled  
3       principally—

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

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

7           (4) RESEARCH PURPOSES.—The information  
8       was collected for or during a clinical trial monitored  
9       by an institutional review board in which the indi-  
10      vidual was a participant.

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

16           (1) the reasons for the denial of the request for  
17      inspection or copying;

18           (2) any procedures for further review of the de-  
19      nial; and

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

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



1 information requested under subsection (a), shall  
2 include—

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

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

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

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

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

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

22      (h) RULE OF CONSTRUCTION.—This section shall not  
23      be construed to require a person described in subsection  
24      (a) to conduct a formal, informal, or other hearing or pro-

1 ceeding concerning a request for inspection or copying of  
2 individually identifiable health information.

3 **SEC. 202. AMENDMENT OF INDIVIDUALLY IDENTIFIABLE**  
4 **HEALTH INFORMATION.**

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

11 (1) shall make the amendment requested;

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

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

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

24 (1) the reasons for the refusal to make the  
25 amendment;

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

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

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

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

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

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

19           (1) the information is retained by the agent;  
20      and

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

23       (e) REPEATED REQUESTS FOR AMENDMENTS.—If a  
24      person described in subsection (a) receives a duplicative  
25      request for an amendment of information as provided for

1 in such subsection and a statement of disagreement with  
2 respect to the request has been filed pursuant to sub-  
3 section (c), the person shall inform the individual of such  
4 filing and shall not be required to carry out the procedures  
5 required under this section.

6 (f) RULE OF CONSTRUCTION.—This section shall not  
7 be construed—

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

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

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

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

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

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

4           (2) the uses and disclosures of individually  
 5       identifiable health information authorized under this  
 6       Act;

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

11          (4) the procedures established by the person for  
 12      the exercise of the individual’s rights; and

13          (5) the procedures established by the person for  
 14      providing copies of the notice.

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

## 22           **TITLE III—ENFORCEMENT**

### 23      **SEC. 301. CRIMINAL PENALTIES.**

24          (a) OFFENSE.—A person who knowingly and in viola-  
 25      tion of this Act obtains individually identifiable health in-

1 formation, uses such information, or discloses such infor-  
2 mation to another person, knowing that such obtaining,  
3 use, or disclosure is unlawful, shall be punished as pro-  
4 vided in subsection (b).

5 (b) PENALTIES.—A person described in subsection  
6 (a) shall—

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

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

12 (3) if the offense is committed with intent to  
13 sell, transfer, or use individually identifiable health  
14 information for commercial advantage, personal  
15 gain, or malicious harm, be fined not more than  
16 \$250,000, imprisoned not more than 10 years, or  
17 both.

18 **SEC. 302. CIVIL ACTION.**

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

23 (b) ATTORNEY'S FEES.—In the case of a civil action  
24 brought under subsection (a) in which the plaintiff has  
25 substantially prevailed, the court may assess against the

1 respondent a reasonable attorney’s fee and other litigation  
 2 costs and expenses (including expert fees) reasonably in-  
 3 curred.

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

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

13 **SEC. 303. PROGRAM EXCLUSIONS.**

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

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

24 (b) EXCLUSION OF PROVIDERS FROM PARTICIPA-  
 25 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 indi-  
22 vidual, otherwise to exercise the rights of the individual,  
23 may, to the extent so authorized, exercise and discharge  
24 the 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 indi-  
5 vidual who is incapacitated, may exercise and discharge  
6 the rights of the individual under this Act, to the extent  
7 necessary 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 “per-  
 12      taining 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) ARCHIVE.—The term “archive”—

10 (A) means a repository of collected infor-  
11 mation or material; and

12 (B) includes a tissue, blood, organ, or  
13 sperm bank.

14 (2) EMPLOYER.—The term “employer” has the  
15 meaning given such term under section 3(5) of the  
16 Employee Retirement Income Security Act of 1974  
17 (29 U.S.C. 1002(5)), except that such term shall in-  
18 clude only employers of two or more employees.

19 (3) HEALTH CARE.—The term “health care”  
20 means—

21 (A) preventive, diagnostic, therapeutic, re-  
22 habilitative, maintenance, or palliative care, in-  
23 cluding appropriate assistance with disease or  
24 symptom management and maintenance, coun-  
25 seling, service, or procedure—

1 (i) with respect to the physical or  
2 mental condition of an individual; or

3 (ii) affecting the structure or function  
4 of the human body or any part of the  
5 human body, including the banking of  
6 blood, sperm, organs, or any other tissue;  
7 and

8 (B) any sale or dispensing of a drug, de-  
9 vice, equipment, or other health care related  
10 item to an individual, or for the use of an indi-  
11 vidual, pursuant to a prescription.

12 (4) HEALTH CARE PROVIDER.—The term  
13 “health care provider” means a person, who with re-  
14 spect to a specific item of individually identifiable  
15 health information, receives, creates, uses, main-  
16 tains, or discloses the information while acting in  
17 whole or in part in the capacity of—

18 (A) a person who is licensed, certified, reg-  
19 istered, or otherwise authorized by Federal or  
20 State law to provide an item or service that  
21 constitutes health care in the ordinary course of  
22 business, or practice of a profession;

23 (B) a Federal, State, employer-sponsored  
24 or other privately sponsored program that di-

1           rectly provides items or services that constitute  
2           health care to beneficiaries; or

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

5           (5) HEALTH OR LIFE INSURER.—The term  
6           “health or life insurer” means a health insurance  
7           issuer as defined in section 9805(b)(2) of the Inter-  
8           nal Revenue Code of 1986 or a life insurance com-  
9           pany as defined in section 816 of such Code.

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

16                (A) a person who performs or oversees the  
17                performance of an assessment, evaluation, de-  
18                termination, or investigation, relating to the li-  
19                censing, accreditation, or credentialing of health  
20                care providers; or

21                (B) a person who—

22                      (i) performs or oversees the perform-  
23                      ance of an audit, assessment, evaluation,  
24                      determination, or investigation relating to  
25                      the effectiveness of, compliance with, or

1 applicability of, legal, fiscal, medical, or  
2 scientific standards or aspects of perform-  
3 ance related to the delivery of, or payment  
4 activities related to, health care; and

5 (ii) is a public agency, acting on be-  
6 half of a public agency, acting pursuant to  
7 a requirement of a public agency, or car-  
8 rying out activities under a Federal or  
9 State law governing the assessment, eval-  
10 uation, determination, investigation, or  
11 prosecution described in subparagraph (A).

12 (7) HEALTH PLAN.—The term “health plan”  
13 means any health insurance issuer, health insurance  
14 plan, including any hospital or medical service plan,  
15 dental or other health service plan or health mainte-  
16 nance organization plan, provider sponsored organi-  
17 zation, or other program providing or arranging for  
18 the provision of health benefits. Such term does not  
19 include any policy, plan or program to the extent  
20 that it provides, arranges or administers health ben-  
21 efits pursuant to a program of workers compensa-  
22 tion or automobile insurance.

23 (8) HEALTH RESEARCH AND HEALTH RE-  
24 SEARCHER.—

1           (A) HEALTH RESEARCH.—The term  
2           “health research” means a systematic investiga-  
3           tion of health (including basic biological proc-  
4           esses and structures), health care, or its deliv-  
5           ery and financing, including research develop-  
6           ment, testing and evaluation, designed to de-  
7           velop or contribute to generalizable knowledge  
8           concerning human health, health care, or health  
9           care delivery.

10          (B) HEALTH RESEARCHER.—The term  
11          “health researcher” means a person involved in  
12          health research, or an officer, employee, or  
13          agent of such person, who receives individually  
14          identifiable health information as part of a re-  
15          search project that involves data with respect to  
16          human subjects.

17          (9) INDIVIDUALLY IDENTIFIABLE HEALTH IN-  
18          FORMATION.—The term “individually identifiable  
19          health information” means any information, includ-  
20          ing demographic information, collected from an indi-  
21          vidual, whether oral or recorded in any form or me-  
22          dium, that—

23                (A) is created or received by a health care  
24                provider, health plan, health oversight agency,

1 public health authority, employer, health or life  
2 insurer, school or university; and

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

10 (ii)(I) identifies an individual;

11 (II) contains personal identifiers that pro-  
12 vide a direct means of identifying the indi-  
13 vidual; or

14 (III) has been provided in an encrypted  
15 format that does not directly identify an indi-  
16 vidual, but that provides a method for  
17 decrypting the information which might reason-  
18 ably be used by the recipient with the intent to  
19 identify an individual.

20 (10) INSTITUTIONAL REVIEW BOARD.—The  
21 term “institutional review board” means an entity—

22 (A) established to review proposed health  
23 research with respect to potential risks to  
24 human subjects pursuant to Federal regulations

1           adopted under section 1802(b) of the Public  
2           Health Service Act (42 U.S.C. 300v-1(b)); and

3           (B) that satisfies the requirements of the  
4           policy set forth in 45 C.F.R. § 46.107 (or any  
5           successor to such policy).

6           (11) PAYMENT ACTIVITIES.—The term “pay-  
7           ment activities”—

8           (A) means activities undertaken—

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

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

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

21               (i) Billing, claims management, med-  
22               ical data processing, practice management,  
23               or other administrative services and actual  
24               payment.

1 (ii) Determinations of coverage or ad-  
2 judication of health benefit claims and sub-  
3 rogation claims.

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

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

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

19 (A) primarily responsible for public health  
20 matters; and

21 (B) primarily engaged in activities such as  
22 injury reporting, public health surveillance, and  
23 public health investigation or intervention.

24 (14) QUALITY ASSURANCE ACTIVITIES.—The  
25 term “quality assurance activities” means a formal



1 methodology and set of activities designed to assess  
2 the quality of health care services provided to an in-  
3 dividual. The term includes formal review of care,  
4 problem identification, corrective actions taken to  
5 remedy any deficiencies, and evaluation of actions  
6 taken. The term also includes activities undertaken  
7 by a quality control and peer review organization (as  
8 defined in section 1152 of the Social Security Act  
9 (42 U.S.C. 1320c-1)).

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

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

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

1           (18) WRITING.—The term “writing” means  
2       writing in either a paper-based or computer-based  
3       form, including electronic signatures.

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