

110<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1814

To provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health related information, promote the use of non-identifiable information for health research, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States' rights.

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## IN THE SENATE OF THE UNITED STATES

JULY 18 (legislative day, JULY 17), 2007

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

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## A BILL

To provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health related information, promote the use of non-identifiable information for health research, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States' rights.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 (a) **SHORT TITLE.**—This Act may be cited as the  
 3 “Health Information Privacy and Security Act”.

4 (b) **TABLE OF CONTENTS.**—The table of contents for  
 5 this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Purposes.
- Sec. 3. Definitions.

**TITLE I—INDIVIDUALS’ RIGHTS**

Subtitle A—Rights of the Subjects of Protected Health Information

- Sec. 101. Right to privacy and security.
- Sec. 102. Inspection and copying of protected health information.
- Sec. 103. Modifications to protected health information.
- Sec. 104. Notice of privacy practices.
- Sec. 105. Demonstration grant.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Transparency.
- Sec. 113. Risk management.
- Sec. 114. Accounting for disclosures and use.

**TITLE II—RESTRICTIONS ON USE AND DISCLOSURE**

Subtitle A—General Restrictions on Use and Disclosure

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Informed consent for disclosure of protected health information for treatment and payment.
- Sec. 203. Authorizations for disclosure of protected health information other than for treatment or payment.
- Sec. 204. Notification in the case of breach.

Subtitle B—Disclosure Under Special Circumstances

- Sec. 211. Emergency circumstances.
- Sec. 212. Public health.
- Sec. 213. Protection and advocacy agencies.
- Sec. 214. Oversight.
- Sec. 215. Disclosure for law enforcement, national security, and intelligence purposes.
- Sec. 216. Next of kin and directory information.
- Sec. 217. Health research.
- Sec. 218. Judicial and administrative purposes.
- Sec. 219. Individual representatives.

**TITLE III—OFFICE OF HEALTH INFORMATION PRIVACY OF THE  
 DEPARTMENT OF HEALTH AND HUMAN SERVICES**

## Subtitle A—Designation

Sec. 301. Designation.

## Subtitle B—Enforcement

## CHAPTER 1—CRIMINAL PROVISIONS

Sec. 311. Wrongful disclosure of protected health information.

Sec. 312. Debarment for crimes and civil violations.

## CHAPTER 2—CIVIL SANCTIONS

Sec. 321. Civil penalty.

Sec. 322. Procedures for imposition of penalties.

Sec. 323. Civil action by individuals.

Sec. 324. Enforcement by State attorneys general.

Sec. 325. Protection for whistleblower.

## TITLE IV—MISCELLANEOUS

Sec. 401. Relationship to other laws.

Sec. 402. Effective date.

1 **SEC. 2. PURPOSES.**

2 The purposes of this Act are as follows:

3 (1) To recognize that individuals have a right  
4 to privacy, confidentiality, and security with respect  
5 to health information, including genetic information,  
6 and that those rights must be protected.

7 (2) To create incentives to turn protected  
8 health information into de-identified health informa-  
9 tion, where appropriate.

10 (3) To designate an Office of Health Informa-  
11 tion Privacy within the Department of Health and  
12 Human Services to protect that right of privacy.

13 (4) To provide individuals with—

14 (A) access to health information of which  
15 they are the subject; and

1 (B) the opportunity to challenge the accu-  
2 racy and completeness of such information by  
3 being able to file modifications to or request the  
4 deletion of such information.

5 (5) To provide individuals with the right to  
6 limit the use and disclosure of protected health in-  
7 formation.

8 (6) To establish strong and effective mecha-  
9 nisms to protect against the unauthorized and inap-  
10 propriate use of protected health information.

11 (7) To invoke the sweep of congressional pow-  
12 ers, including the power to enforce the 14th amend-  
13 ment to the Constitution, to regulate commerce, and  
14 to abrogate the immunity of the States under the  
15 11th amendment to the Constitution, in order to ad-  
16 dress violations of the rights of individuals to pri-  
17 vacy, to provide individuals with access to their  
18 health information, and to prevent the unauthorized  
19 use of protected health information that is genetic  
20 information.

21 (8) To establish strong and effective remedies  
22 for violations of this Act.

23 (9) To protect the rights of States.

24 **SEC. 3. DEFINITIONS.**

25 In this Act:

1           (1) ADMINISTRATIVE BILLING INFORMATION.—

2           The term “administrative billing information”  
3           means any of the following forms of protected health  
4           information:

5                   (A) Date of service, policy, patient identi-  
6                   fiers, and practitioner or facility identifiers.

7                   (B) Diagnostic codes, in accordance with  
8                   medicare billing codes, for which treatment is  
9                   being rendered or requested.

10                   (C) Complexity of service codes, indicating  
11                   duration of treatment.

12                   (D) Total billed charges.

13           (2) AGENT.—The term “agent” means a person  
14           that represents or acts for another person (a prin-  
15           cipal) under a contract or relationship of agency, or  
16           that functions to bring about, modify, affect, accept  
17           performance of, or terminate, contractual obligations  
18           between the principal and a third person. With re-  
19           spect to an employer, the term includes the employ-  
20           ees of the employer.

21           (3) AUTHORIZATION.—The term “authoriza-  
22           tion” means the authority granted by an individual  
23           that is the subject of protected health information,  
24           in accordance with title II, for the disclosure of the  
25           individual’s protected health information.

1           (4) AUTHORIZED RECIPIENT.—The term “au-  
2           thorized recipient” means a person granted the au-  
3           thority by an individual, in accordance with title II,  
4           to access, maintain, retain, modify, record, store, de-  
5           stroy, or otherwise use the individual’s protected  
6           health information through an authorized disclosure.

7           (5) BREACH.—The term “breach” means the  
8           unauthorized acquisition, disclosure, or loss of pro-  
9           tected health information which compromises the se-  
10          curity, privacy, or integrity of protected health infor-  
11          mation maintained by or on behalf of a person.

12          (6) CONFIDENTIALITY.—The term “confiden-  
13          tiality” means the obligations of those who receive  
14          information to respect the privacy interests of those  
15          to whom the data relate.

16          (7) DATA BROKER.—The term “data broker”  
17          means a data bank, data warehouse, information  
18          clearinghouse, record locator system, or other busi-  
19          ness entity, which for monetary fees, dues, or on a  
20          cooperative nonprofit basis, engages in the practice  
21          of accessing, collecting, maintaining, modifying, stor-  
22          ing, recording, transmitting, destroying, or otherwise  
23          using or disclosing the protected health information  
24          of individuals. Any person maintaining protected  
25          health information for the purposes of making such

1 information available to the individual or the health  
2 care provider, including persons furnishing free or  
3 paid personal health records, electronic health  
4 records, electronic medical records, and related prod-  
5 ucts and services, shall be deemed to be a data  
6 broker subject to the requirements of this Act.

7 (8) DE-IDENTIFIED HEALTH INFORMATION.—

8 (A) IN GENERAL.—The term “de-identified  
9 health information” means any protected health  
10 information, with respect to which—

11 (i) all personal identifiers, or other in-  
12 formation that may be used by itself or in  
13 combination with other information which  
14 may be available to re-identify the subject  
15 of the information, have been removed;

16 (ii) a good faith effort has been made  
17 to evaluate, minimize, and mitigate the  
18 risks of re-identification of the subject of  
19 such information, using commonly accept-  
20 ed scientific and statistical standards and  
21 methods for minimizing risk of disclosure;  
22 and

23 (iii) there is no reasonable basis to be-  
24 lieve that the information can be used to  
25 identify an individual.

1           (B) **EXAMPLES.**—Such term includes ag-  
2           gregate statistics, redacted health information,  
3           information in which random or fictitious alter-  
4           natives have been substituted for personally  
5           identifiable information, and information in  
6           which personally identifiable information has  
7           been encrypted and the decryption key is main-  
8           tained only by persons otherwise authorized to  
9           have access to such protected health informa-  
10          tion in an identifiable format.

11          (9) **DISCLOSE.**—The term “disclose” means to  
12          release, publish, share, transfer, transmit, dissemi-  
13          nate, show, permit access to, communicate (orally or  
14          otherwise), re-identify, or otherwise divulge protected  
15          health information to any person other than the in-  
16          dividual who is the subject of such information.  
17          Such term includes the initial disclosure and any  
18          subsequent redisclosure of protected health informa-  
19          tion.

20          (10) **DECRYPTION KEY.**—The term “decryption  
21          key” means the variable information used in or pro-  
22          duced by a mathematical formula, code, or algo-  
23          rithm, or any component thereof, used for  
24          encryption or decryption of wire, electronic, or other  
25          communications or stored information.



1           (11) EMPLOYER.—The term “employer” means  
2 a person that is engaged in business affecting com-  
3 merce and that has employees.

4           (12) ENCRYPTION.—The term “encryption”—

5           (A) means the protection of data in elec-  
6 tronic form, in storage or in transit, using an  
7 encryption technology that has been adopted by  
8 an established standards setting body which  
9 renders such data indecipherable in the absence  
10 of associated cryptographic keys necessary to  
11 enable decryption of such data; and

12           (B) includes appropriate management and  
13 safeguards of such cryptographic keys so as to  
14 protect the integrity of the encryption.

15           (13) HEALTH CARE.—The term “health care”  
16 means—

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

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

24           (ii) affecting the structure or function  
25 of the human body or any part of the

1 human body, including the banking of  
2 blood, sperm, organs, or any other tissue.

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 (14) HEALTH CARE PROVIDER.—The term  
8 “health care provider” means a person that, with re-  
9 spect to a specific item of protected health informa-  
10 tion, receives, accesses, maintains, retains, modifies,  
11 records, stores, destroys, or otherwise uses or dis-  
12 closes the information while acting in whole or in  
13 part in the capacity of—

14 (A) an entity that is, or holds itself out to  
15 be, licensed, certified, registered, or otherwise  
16 authorized by Federal or State law to provide  
17 an item or service that constitutes health care  
18 in the ordinary course of business, or practice  
19 of a profession;

20 (B) contractors and other health care pro-  
21 viders or facilities authorized to provide items  
22 or services related to diagnosis or treatment of  
23 a health concern, including hospitals, nursing  
24 facilities, allied health professionals, and facili-

1           ties used or maintained by allied health profes-  
2           sionals;

3           (C) a Federal or State program that di-  
4           rectly provides items or services that constitute  
5           health care to beneficiaries;

6           (D) an officer or employee or agent of a  
7           person described in subparagraph (A) or (C)  
8           who is engaged in the provision of health care  
9           or who uses health information; or

10          (E) medical personnel in an emergency sit-  
11          uation, including while communicating pro-  
12          tected health information by radio transmission  
13          or other means.

14          (15) HEALTH OR LIFE INSURER.—The term  
15          “health or life insurer” means a health insurance  
16          issuer (as defined in section 9805(b)(2) of the Inter-  
17          nal Revenue Code of 1986) or a life insurance com-  
18          pany (as defined in section 816 of such Code) and  
19          includes the employees and agents of such a person.

20          (16) HEALTH OVERSIGHT AGENCY.—The term  
21          “health oversight agency”—

22                 (A) means a person that—

23                         (i) performs or oversees the perform-  
24                         ance of an assessment, investigation, or  
25                         prosecution relating to compliance with

1 legal or fiscal standards relating to health  
2 care fraud or fraudulent claims regarding  
3 health care, health services or equipment,  
4 or related activities and items; and

5 (ii) is a public executive branch agen-  
6 cy, acting on behalf of a public executive  
7 branch agency, acting pursuant to a re-  
8 quirement of a public executive branch  
9 agency, or carrying out activities under a  
10 Federal or State law governing an assess-  
11 ment, evaluation, determination, investiga-  
12 tion, or prosecution described in clause (i);  
13 and

14 (B) includes the employees and agents of  
15 such a person.

16 (17) HEALTH PLAN.—The term “health plan”  
17 has the meaning given such term for purposes of the  
18 regulations promulgated under section 264(c) of the  
19 Health Insurance Portability and Accountability Act  
20 of 1996.

21 (18) HEALTH RECORD SET.—The term “health  
22 record set” means any item, collection, or grouping  
23 of information that includes protected health infor-  
24 mation, such as an electronic health record, elec-  
25 tronic medical record, personal health record, or ac-

1 count of disclosure, use or access, that is created,  
2 accessed, received, maintained, retained, modified,  
3 recorded, stored, destroyed, or otherwise used or dis-  
4 closed by a health care provider, employer, insurer,  
5 health plan, health researcher, school or university,  
6 data broker, or other person.

7 (19) HEALTH RESEARCHER.—The term “health  
8 researcher” means a person that, with respect to a  
9 specific item of protected health information, re-  
10 ceives the information—

11 (A) pursuant to section 217 (relating to  
12 health research); or

13 (B) while acting in whole or in part in the  
14 capacity of an officer, employee, or agent of a  
15 person that receives the information pursuant  
16 to such section.

17 (20) INFORMED CONSENT.—The term “in-  
18 formed consent” means the authorization for use or  
19 disclosure of protected health information by the in-  
20 dividual who is the subject of such information, con-  
21 ditioned upon that individual’s having been informed  
22 of the nature and probability of harm to the indi-  
23 vidual resulting from such authorization.

24 (21) LAW ENFORCEMENT INQUIRY.—The term  
25 “law enforcement inquiry” means a lawful executive

1 branch investigation or official proceeding inquiring  
2 into a violation of, or failure to comply with, any  
3 criminal or civil statute or any regulation, rule, or  
4 order issued pursuant to such a statute.

5 (22) OFFICE OF HEALTH INFORMATION PRI-  
6 VACY.—The term “Office of Health Information Pri-  
7 vacy” means the Office of Health Information Pri-  
8 vacy designated under section 301.

9 (23) PERSON.—The term “person” means an  
10 entity that is a government, governmental subdivi-  
11 sion of an executive branch agency or authority, cor-  
12 poration, company, association, firm, partnership,  
13 society, estate, trust, joint venture, individual, indi-  
14 vidual representative, tribal government, and any  
15 other legal entity. Such term also includes the em-  
16 ployees, contractors, agents, and affiliates of all legal  
17 entities described in the preceding sentence, whether  
18 or not they are acting in the capacity of their em-  
19 ployment, contract, agency, or affiliation.

20 (24) PRIVACY.—The term “privacy” means an  
21 individual’s right to control the acquisition, uses, or  
22 disclosures of his or her identifiable health data.

23 (25) PROTECTED HEALTH INFORMATION.—

24 (A) IN GENERAL.—The term “protected  
25 health information” means any information, in-

1 including genetic information, biometric informa-  
2 tion, demographic information, and tissue sam-  
3 ples collected from an individual, whether oral  
4 or recorded in any form or medium, that—

5 (i) is created or received by a health  
6 care provider, health researcher, health  
7 plan, health or life insurer, medical or  
8 health savings plan administrator, school  
9 or university, health care clearinghouse,  
10 health oversight agency, public health au-  
11 thority, employer, data broker, or other  
12 person or such person's agent, officer, or  
13 employee; and

14 (ii)(I) relates to the past, present, or  
15 future physical or mental health or condi-  
16 tion of an individual (including individual  
17 cells and their components), the provision  
18 of health care to an individual, or the past,  
19 present, or future payment for the provi-  
20 sion of health care to an individual; and

21 (II)(aa) identifies an individual; or

22 (bb) with respect to which there is a  
23 reasonable basis to believe that the infor-  
24 mation can be used to identify an indi-  
25 vidual.

1           (B) DECRYPTION KEY.—The term “pro-  
2           tected health information” includes any infor-  
3           mation described in paragraph (8).

4           (26) PUBLIC HEALTH AUTHORITY.—The term  
5           “public health authority” means an authority or in-  
6           strumentality of the United States, a tribal govern-  
7           ment, a State, or a political subdivision of a State  
8           that is—

9                   (A) primarily responsible for public health  
10                  matters; and

11                   (B) primarily engaged in activities such as  
12                  injury reporting, public health surveillance, and  
13                  public health investigation or intervention.

14           (27) RE-IDENTIFY.—The term “re-identify”,  
15           when used with respect to de-identified health infor-  
16           mation, means an attempt, successful or otherwise,  
17           to ascertain—

18                   (A) the identity of the individual who is  
19                  the subject of such information; or

20                   (B) the decryption key with respect to the  
21                  information (when undertaken with knowledge  
22                  that such key would allow for the identification  
23                  of the individual who is the subject of such in-  
24                  formation).



1           (28) SCHOOL OR UNIVERSITY.—The term  
2           “school or university” means an institution or place  
3           for instruction or education, including an elementary  
4           school, secondary school, or institution of higher  
5           education, a college, or an assemblage of colleges  
6           united under one corporate organization or govern-  
7           ment.

8           (29) SECRETARY.—The term “Secretary”  
9           means the Secretary of Health and Human Services.

10          (30) SECURITY.—The term “security” means  
11          physical, technological, or administrative safeguards  
12          or tools used to protect identifiable health data from  
13          unwarranted access or disclosure.

14          (31) SECURITY BREACH.—The term “security  
15          breach” means the physical, structural, or sub-  
16          stantive compromise of the security of protected  
17          health information, through unauthorized disclosure,  
18          use, or access, whether actual or attempted, result-  
19          ing in the acquisition, access, or use of such infor-  
20          mation by an unauthorized person. Such term does  
21          not apply to good faith or accidental acquisition, or  
22          disclosure of protected health information by an un-  
23          authorized person, so long as no further use or dis-  
24          closure is made by such person.

1           (32) STATE.—The term “State” includes the  
2           District of Columbia, Puerto Rico, the Virgin Is-  
3           lands, Guam, American Samoa, and the Northern  
4           Mariana Islands.

5           (33) TO THE MAXIMUM EXTENT PRAC-  
6           TICABLE.—The term “to the maximum extent prac-  
7           ticable” means the level of compliance that a reason-  
8           able person would deem technologically feasible so  
9           long as such feasibility is periodically evaluated in  
10          light of scientific advances.

11          (34) USE.—The term “use” means to create,  
12          record, collect, access, obtain, store, maintain,  
13          amend, correct, restore, modify, supplement, iden-  
14          tify, re-identify, employ, apply, utilize, examine, ana-  
15          lyze, detect, remove, destroy, dispose of, account for,  
16          or monitor the flow of protected health information.

17          (35) WRITING.—The term “writing” means  
18          writing in either a paper-based or computer-based  
19          form, including electronic and digital signatures.

20       **TITLE I—INDIVIDUALS’ RIGHTS**  
21       **Subtitle A—Rights of the Subjects**  
22       **of Protected Health Information**

23       **SEC. 101. RIGHT TO PRIVACY AND SECURITY.**

24          (a) IN GENERAL.—Individuals who are the subject  
25       of protected health information have the right to—

1           (1) privacy and security with respect to the use  
2           and disclosure of such information;

3           (2) control and withhold protected health infor-  
4           mation of which they are the subject; and

5           (3) exercise nondisclosure and nonuse rights  
6           (referred to in this Act as “opt-out”) with respect to  
7           their protected health information, including the  
8           right to opt out of any local, regional, or nationwide  
9           health information network or system that is used  
10          by the person.

11          (b) OBLIGATIONS.—A person that discloses, uses, or  
12          receives an individual’s protected health information shall  
13          expressly recognize the right to privacy and security of  
14          such individual with respect to the use and disclosure of  
15          such information.

16       **SEC. 102. INSPECTION AND COPYING OF PROTECTED**  
17                                   **HEALTH INFORMATION.**

18          (a) RIGHT OF INDIVIDUAL.—

19           (1) IN GENERAL.—A person, including a health  
20           care provider, health researcher, health plan, health  
21           or life insurer, medical or health savings plan admin-  
22           istrator, school or university, health care clearing-  
23           house, health oversight agency, public health author-  
24           ity, employer, or data broker, or such person’s  
25           agent, officer, employee, or affiliate, that accesses,

1 maintains, retains, modifies, records, stores, or oth-  
2 erwise holds, uses, or discloses protected health in-  
3 formation, shall permit an individual who is the sub-  
4 ject of such protected health information, or the in-  
5 dividual's designee, to inspect and copy the protected  
6 health information concerning the individual, includ-  
7 ing records created under sections 102, 112, 202,  
8 203, and 211.

9 (2) PROCEDURES AND FEES.—A person de-  
10 scribed in paragraph (1) may establish appropriate  
11 procedures to be followed for inspection and copying  
12 under such paragraph and may require an individual  
13 to pay reasonable fees associated with such inspec-  
14 tion and copying in an amount that is not in excess  
15 of the actual costs of providing such copying. Such  
16 fees may not be assessed where such an assessment  
17 would have the effect of inhibiting an individual  
18 from gaining access to the information described in  
19 paragraph (1).

20 (b) DEADLINE.—A person described in subsection  
21 (a)(1) shall comply with a request for inspection or copy-  
22 ing of protected health information under this section not  
23 later than—

24 (1) 15 business days after the date on which  
25 the person receives the request, if such request re-

1       quires the inspection, copying, or sending of printed  
2       materials; or

3               (2) 5 business days after the date on which the  
4       person receives the request, or sooner if the Sec-  
5       retary determines appropriate, if such request re-  
6       quires only the inspection, copying, or sending of  
7       electronic or other digital materials.

8       (c) RULES GOVERNING AGENTS.—A person that is  
9       the agent, officer, or employee of a person described in  
10      subsection (a) shall provide for the inspection and copying  
11      of protected health information if—

12              (1) the protected health information is retained  
13      by the person; and

14              (2) the person has been asked by the person de-  
15      scribed in subsection (a)(1) to fulfill the require-  
16      ments of this section.

17      (d) SPECIAL RULE RELATING TO ONGOING CLINICAL  
18      TRIALS.—With respect to protected health information  
19      that is created as part of an individual’s participation in  
20      an ongoing clinical trial, access to the information shall  
21      be provided consistent with the individual’s agreement to  
22      participate in the clinical trial.

1 **SEC. 103. MODIFICATIONS TO PROTECTED HEALTH INFOR-**  
2 **MATION.**

3 (a) IN GENERAL.—Not later than 15 business days,  
4 or earlier if the Secretary determines appropriate, after  
5 the date on which a person described in section 102(a)(1)  
6 receives from an individual a request in writing to supple-  
7 ment, correct, amend, segregate, or remove protected  
8 health information concerning the individual, such per-  
9 son—

10 (1) shall, subject to subsections (b) and (c),  
11 modify the information, by adding the requested  
12 supplement, correction, or amendment to the infor-  
13 mation, or by removing any information that has  
14 been requested to be destroyed;

15 (2) shall inform the individual that the modi-  
16 fication has been made; and

17 (3) shall make reasonable efforts to inform any  
18 person to which the portion of the unmodified infor-  
19 mation was previously disclosed, of any substantive  
20 modification that has been made.

21 (b) REFUSAL TO MODIFY.—If a person described in  
22 subsection (a) declines to make the modification requested  
23 under such subsection within 15 business days after re-  
24 ceipt of such request, such person shall inform the indi-  
25 vidual in writing of—

1           (1) the reasons for declining to make the modi-  
2           fication;

3           (2) any procedures for further review of the de-  
4           clining of such modification; and

5           (3) the individual's right to file with the person  
6           a concise statement setting forth the requested  
7           modification and the individual's reasons for dis-  
8           agreeing with the declining person and the individ-  
9           ual's right to include a copy of this refusal in the  
10          health record set concerning the individual.

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

15               (1) shall include, at the individual's request, a  
16               copy of the individual's statement in the individual's  
17               health record set; and

18               (2) may include a concise statement of the rea-  
19               sons for not making the requested modification.

20          (d) RULES GOVERNING AGENTS.—A person that is  
21          the agent of a person described in subsection (a) shall only  
22          be required to make a modification to protected health in-  
23          formation where—

24               (1) the protected health information is retained,  
25               distributed, used, or maintained by the agent; and

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

3           (e) NOTIFICATION OF LOSS OR CORRUPTION.—Not  
4           later than 15 business days, or earlier if the Secretary de-  
5           termines appropriate, after the date on which a person de-  
6           scribed in subsection (a) discovers loss or corruption of  
7           health record sets or protected health information under  
8           its management, or if such person has reason to believe  
9           that its database has been compromised, such person  
10          shall—

11           (1) notify individuals whose records have been  
12          affected;

13           (2) notify persons and the agents of persons  
14          that receive, access, maintain, retain, modify, record,  
15          store, destroy, or otherwise use or disclose such  
16          data; and

17           (3) repair or restore corrupted data to the ex-  
18          tent practicable.

19          **SEC. 104. NOTICE OF PRIVACY PRACTICES.**

20           (a) PREPARATION OF WRITTEN NOTICE.—A person  
21          described in section 102(a)(1) shall prepare a written no-  
22          tice of the privacy practices of such person, including in-  
23          formation with respect to the following:

24           (1) The express right of an individual to pri-  
25          vacy, security, and confidentiality with respect to the



1 electronic disclosure of such individual's protected  
2 health information;

3 (2) The procedures for an individual to author-  
4 ize disclosures of protected health information, and  
5 to object to, modify, and revoke such authorizations.

6 (3) The right of an individual to inspect, copy,  
7 and modify that individual's protected health infor-  
8 mation.

9 (4) The right of an individual not to have em-  
10 ployment or the receipt of services or choice of  
11 health plan conditioned upon the execution by the  
12 individual of an authorization for disclosure.

13 (5) A description of the categories or types of  
14 employees, by general category or by general job de-  
15 scription, who have access to or use of protected  
16 health information regarding the individual.

17 (6) A simple, concise description of any infor-  
18 mation systems used to store or transmit protected  
19 health information, including a description of any  
20 linkages made with other networks, systems, or  
21 databases outside the person's direct control.

22 (7) The right of and procedures for an indi-  
23 vidual to request segregation of protected health in-  
24 formation, and to restrict the use of such informa-

1       tion by employees, agents, and contractors of a per-  
2       son.

3           (8) The circumstances under which the infor-  
4       mation will be, lawfully and actually, used or dis-  
5       closed without an authorization executed by the indi-  
6       vidual.

7           (9) A statement that, if an individual elects to  
8       pay for health care from the individual's own funds,  
9       that individual may elect for identifying information  
10      not to be disclosed to anyone other than designated  
11      health care providers, unless such disclosure is re-  
12      quired by mandatory reporting requirements or  
13      other similar information collection duties required  
14      by law.

15          (10) The right of the individual to have contin-  
16      ued maintenance, distribution, or storage of that in-  
17      dividual's personal health information not condi-  
18      tioned upon whether that individual amends or re-  
19      vokes an authorization for disclosure, or requests a  
20      modification of protected health information.

21          (11) The right of and procedures for an indi-  
22      vidual to request that protected health information  
23      be transferred to a third party person without un-  
24      reasonable delay.

1           (12) The right to prompt notification of an ac-  
2           tual or suspected security breach of protected health  
3           information, and how such breaches will be remedied  
4           by the person.

5           (13) The right of an individual to inspect and  
6           obtain a copy of records of authorized and unauthor-  
7           ized disclosures as well as attempted and actual ac-  
8           cess and use by an authorized or unauthorized per-  
9           son.

10          (14) The right of an individual to exercise non-  
11          disclosure and nonuse rights (referred to in this Act  
12          as “opt-out”) with respect to their protected health  
13          information, including the right to opt out of any  
14          local, regional, or nationwide health information net-  
15          work or system that is used by the person.

16          (b) PROVISION AND POSTING OF WRITTEN NO-  
17          TICE.—

18               (1) PROVISION.—A person described in sub-  
19               section (a) shall provide a copy of the written notice  
20               of privacy practices required under such sub-  
21               section—

22                       (A) at the time an authorization is sought  
23                       for the disclosure of protected health informa-  
24                       tion; and

25                       (B) upon the request of an individual.

1           (2) POSTING.—A person described in subsection  
2           (a) shall post, in a clear and conspicuous manner, a  
3           brief summary of the privacy practices of the person.

4           (c) MODEL NOTICE.—The Secretary, in consultation  
5 with the Director of the Office of Health Information Pri-  
6 vacy appointed under section 301, after notice and oppor-  
7 tunity for public comment, shall develop and disseminate  
8 model notices of privacy practices, and model summary  
9 notices for posting for use under this section. Use of such  
10 model notice shall be deemed to satisfy the requirements  
11 of this section.

12          (d) REQUIREMENT FOR OPT-OUT.—A person shall  
13 not access, maintain, retain, modify, record, store, destroy,  
14 or otherwise use or disclose an individual’s protected  
15 health information for other than treatment or payment  
16 purposes until that individual has been given an oppor-  
17 tunity, before the time that such information is initially  
18 used or disclosed, to direct that such information not be  
19 used or disclosed. The individual must be given adequate  
20 time to exercise the nondisclosure and nonuse option (re-  
21 ferred to as the “opt-out”) through the method that is  
22 most convenient to the individual, along with an expla-  
23 nation of how the individual can exercise such option.

1 **SEC. 105. DEMONSTRATION GRANT.**

2 (a) IN GENERAL.—The Secretary shall award con-  
3 tracts or competitive grants to eligible entities to support  
4 demonstration projects that are designed to improve the  
5 communication of information pertaining to health privacy  
6 rights with individuals with limited English language pro-  
7 ficiency and limited health literacy.

8 (b) PURPOSE.—It is the purpose of this section, to  
9 promote the cultural competency of persons that access,  
10 maintain, retain, modify, record, store, destroy, or other-  
11 wise use or disclose protected health information, and to  
12 enable such persons to better communicate privacy proce-  
13 dures to non-English speakers, those with limited English  
14 proficiency, and those with limited health literacy.

15 (c) ELIGIBLE ENTITIES.—In this section, the term  
16 “eligible entity” means an organization or community-  
17 based consortium that includes—

18 (1) individuals who are representatives of orga-  
19 nizations serving or advocating for ethnic and racial  
20 minorities, low income immigrant populations, and  
21 others with limited English language proficiency and  
22 limited health literacy;

23 (2) health care providers that provide care for  
24 ethnic and racial minorities, low income immigrant  
25 populations, and others with limited English lan-  
26 guage proficiency and limited health literacy;

1           (3) community leaders and leaders of commu-  
2           nity-based organizations; and

3           (4) experts and researchers in the areas of so-  
4           cial and behavioral sciences, who have knowledge,  
5           training, or practical experience in health policy, ad-  
6           vocacy, cultural and linguistic competency, or other  
7           relevant areas as determined by the Secretary.

8           (d) APPLICATION.—An eligible entity seeking a con-  
9           tract or grant under this section shall submit an applica-  
10          tion to the Secretary at such time, in such manner, and  
11          containing such information as the Secretary may require.

12          (e) USE OF FUNDS.—An eligible entity shall use  
13          amounts received under this section to carry out programs  
14          and studies designed to help identify best practices in the  
15          communication of privacy rights and procedures to ensure  
16          comprehension by individuals with limited English pro-  
17          ficiency and limited health literacy.

## 18                   **Subtitle B—Establishment of** 19                   **Safeguards**

### 20   **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

21          (a) IN GENERAL.—A person described in section  
22          102(a)(1) shall establish and maintain appropriate admin-  
23          istrative, organizational, technical, and physical safe-  
24          guards and procedures to ensure the privacy, confiden-  
25          tiality, security, accuracy, and integrity of protected health

1 information that is accessed, maintained, retained, modi-  
2 fied, recorded, stored, destroyed, or otherwise used or dis-  
3 closed by such person.

4 (b) FACTORS TO BE CONSIDERED.—The policies and  
5 safeguards established under subsection (a) shall ensure  
6 that—

7 (1) protected health information is used or dis-  
8 closed only with informed consent;

9 (2) the categories of personnel who will have ac-  
10 cess to protected health information are identified;

11 (3) the feasibility of limiting access to protected  
12 health information is considered;

13 (4) the privacy, security and confidentiality of  
14 protected health information is maintained;

15 (5) protected health information is protected  
16 against any anticipated vulnerabilities to the privacy,  
17 security, or integrity of such information; and

18 (6) protected health information is protected  
19 against unauthorized access, use, or misuse of such  
20 information.

21 (c) MODEL GUIDELINES.—The Secretary, in con-  
22 sultation with the Director of the Office of Health Infor-  
23 mation Privacy appointed under section 301, after notice  
24 and opportunity for public comment, shall develop and dis-  
25 seminate model guidelines for the establishment of safe-

1 guards and procedures for use under this section, such  
2 as, where appropriate, individual authentication of uses of  
3 computer systems, access controls, audit trails, encryption,  
4 physical security, protection of remote access points and  
5 protection of external electronic communications, periodic  
6 security assessments, incident reports, and sanctions. The  
7 Director shall update and disseminate the guidelines, as  
8 appropriate, to take advantage of new technologies.

9 (d) REVIEW AND UPDATING OF SAFEGUARDS.—Per-  
10 sons subject to this Act shall monitor, evaluate, and ad-  
11 just, as appropriate, all safeguards and procedures, con-  
12 comitant with relevant changes in technology, the sensi-  
13 tivity of personally identifiable information, internal or ex-  
14 ternal threats to personally identifiable information, and  
15 any changes in the contracts or business of the person.  
16 For the purpose of reviewing and updating safeguards, the  
17 Secretary may provide technical assistance to persons de-  
18 scribed in subsection (a), as appropriate.

19 **SEC. 112. TRANSPARENCY.**

20 (a) PUBLIC LIST OF DATA BROKERS.—A person de-  
21 scribed in section 102(a)(1) shall establish a list of data  
22 brokers with which such person has entered into a con-  
23 tract or relationship for the purposes of providing services  
24 involving any protected health information. Such list and



1 the contact information for each broker shall be made pub-  
2 licly accessible on the Internet.

3 (b) SUBCONTRACTING AND OUTSOURCING OVER-  
4 SEAS.—In the event a person subject to this Act contracts  
5 with service providers not subject to this Act, including  
6 service providers operating in a foreign country, such per-  
7 son shall—

8 (1) take reasonable steps to select and retain  
9 third party service providers capable of maintaining  
10 appropriate safeguards for the security, privacy, and  
11 integrity of protected health information;

12 (2) require by contract that such service pro-  
13 viders implement and maintain appropriate meas-  
14 ures designed to meet the requirements of persons  
15 subject to this Act;

16 (3) be held liable for any violation of this Act  
17 by an overseas service provider or other provider not  
18 subject to this law; and

19 (4) in the case of a service provider operating  
20 in a foreign country, obtain the informed consent of  
21 the individual involved prior to outsourcing such in-  
22 dividual's protected health information to such pro-  
23 vider.

24 (c) LIST OF PERSONS.—The Secretary shall maintain  
25 a public list identifying persons described in section

1 102(a)(1) that have lost, stolen, disclosed or used in an  
2 unauthorized manner or for an unauthorized purpose the  
3 protected health information of a significant number of  
4 individuals. The list shall include how many individuals  
5 were affected by such action.

6 **SEC. 113. RISK MANAGEMENT.**

7 (a) IN GENERAL.—Persons described in section  
8 102(a)(1) that have access to protected health information  
9 shall establish risk management and control processes to  
10 protect against anticipated vulnerabilities to the privacy,  
11 security, and integrity of protected health information.

12 (b) RISK ASSESSMENT.—A person described in sub-  
13 section (a) shall perform annual risk assessments of proce-  
14 dures, systems, or networks involved in the creation, ac-  
15 ccessing, maintenance, retention, modification, recording,  
16 storage, distribution, destruction, or other use or disclo-  
17 sure of personal health information. Such risk assessment  
18 may include—

19 (1) identifying reasonably foreseeable internal  
20 and external vulnerabilities that could result in inac-  
21 curacy or in unauthorized access, disclosure, use, or  
22 modification of protected health information, or of  
23 systems containing protected health information;

24 (2) assessing the likelihood of and potential  
25 damage from inaccuracy or from unauthorized ac-

1       cess, disclosure, use, or modification of protected  
2       health information;

3           (3) assessing the sufficiency of policies, tech-  
4       nologies, and safeguards in place to minimize and  
5       control risks from unauthorized access, disclosure,  
6       use, or modification of protected health information;  
7       and

8           (4) assessing the vulnerability of protected  
9       health information during destruction and disposal  
10      of such information, including through the disposal  
11      or retirement of hardware.

12      (c) RISK MANAGEMENT.—A person described in sub-  
13      section (a) shall establish risk management and control  
14      procedures designed to control risks such as those identi-  
15      fied in subsection (b). Such procedures shall include—

16           (1) a means for the detection and recording of  
17      actual or attempted, unauthorized, fraudulent, or  
18      otherwise unlawful access, disclosure, transmission,  
19      modification, use, or loss of personal health informa-  
20      tion;

21           (2) procedures for ensuring the secure disposal  
22      of personal health information;

23           (3) a means for limiting physical access to  
24      hardware, software, data storage technology, servers,  
25      systems, or networks by unauthorized persons in

1 order to minimize the risk of information disclosure,  
2 modification, transmission, access, use, or loss;

3 (4) providing appropriate risk management and  
4 control training for employees; and

5 (5) carrying out annual testing of such risk  
6 management and control procedures.

7 **SEC. 114. ACCOUNTING FOR DISCLOSURES AND USE.**

8 (a) IN GENERAL.—A person described in section  
9 102(a)(1) shall establish and maintain, with respect to any  
10 protected health information disclosure, a record of each  
11 disclosure in accordance with regulations promulgated by  
12 the Secretary in consultation with the Director of the Of-  
13 fice of Health Information Privacy. Such record shall in-  
14 clude the purpose of any disclosure and the identity of  
15 the specific individual executing the disclosure, as well as  
16 the person to which such information is disclosed.

17 (b) MAINTENANCE OF RECORD.—A record estab-  
18 lished under subsection (a) shall be maintained for not less  
19 than 7 years.

20 (c) ELECTRONIC RECORDS.—A person described in  
21 subsection (a) shall, to the maximum extent practicable,  
22 maintain an accessible electronic record concerning each  
23 access, use, or disclosure, whether authorized or unauthor-  
24 ized and whether successful or unsuccessful, of protected  
25 health information maintained by such person in electronic

1 form. The record shall include the identities of the specific  
 2 individuals (or a way to identify such individuals, or infor-  
 3 mation helpful in determining the identities of such indi-  
 4 viduals) who access or seek to gain access to, use or seek  
 5 to use, or disclose or seek to disclose, information suffi-  
 6 cient to identify the protected health information sought  
 7 or accessed, and other appropriate information.

8 (d) ACCESS TO RECORDS.—A person described in  
 9 subsection (a) shall permit an individual who is the subject  
 10 of protected health information, or the individual’s des-  
 11 ignee, to inspect and copy the records created in para-  
 12 graphs (a) and (c) of this section.

13 **TITLE II—RESTRICTIONS ON**  
 14 **USE AND DISCLOSURE**  
 15 **Subtitle A—General Restrictions**  
 16 **on Use and Disclosure**

17 **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-**  
 18 **SURE.**

19 (a) PROHIBITION.—

20 (1) GENERAL RULE.—A person may not dis-  
 21 close, access, or use protected health information ex-  
 22 cept as authorized under this Act.

23 (2) RULE OF CONSTRUCTION.—Disclosure or  
 24 use of health information that meets the standards  
 25 of being de-identified health information shall not be

1 construed as a disclosure or use of protected health  
2 information.

3 (b) SCOPE OF DISCLOSURE OR USE.—

4 (1) IN GENERAL.—A disclosure or use of pro-  
5 tected health information under this title shall be  
6 limited to the minimum amount of information nec-  
7 essary to accomplish the purpose for which the dis-  
8 closure or use is made.

9 (2) DETERMINATION.—The determination as to  
10 what constitutes the minimum disclosure or use pos-  
11 sible for purposes of paragraph (1) shall be made by  
12 a health care provider to the extent required by law.  
13 The minimum necessary standard is intended to be  
14 consistent with, and not override, professional judg-  
15 ment and standards.

16 (c) USE OR DISCLOSURE FOR PURPOSE ONLY.—An  
17 authorized recipient of information pursuant to this title  
18 may use or disclose such information solely to carry out  
19 the purpose for which the information was disclosed, ex-  
20 cept as provided in section 214.

21 (d) NO GENERAL REQUIREMENT TO DISCLOSE.—  
22 Nothing in this title permitting the disclosure of protected  
23 health information shall be construed to require such dis-  
24 closure.

1 (e) IDENTIFICATION OF DISCLOSED INFORMATION AS  
2 PROTECTED HEALTH INFORMATION.—Protected health  
3 information disclosed or used pursuant to this title shall  
4 be clearly identified and labeled as protected health infor-  
5 mation that is subject to this Act.

6 (f) DISCLOSURE OR USE BY AGENTS.—An agent,  
7 employee, or affiliate of a person described in section  
8 102(a)(1) that accesses, seeks to access, obtains, discloses,  
9 uses, or receives protected health information from such  
10 person, shall be subject to this title to the same extent  
11 as the person.

12 (g) DISCLOSURE OR USE BY OTHERS.—A person re-  
13 ceiving protected health information initially held by a per-  
14 son described in subsection (f) shall be subject to this title  
15 to the same extent as the person described in subsection  
16 (f).

17 (h) CREATION OF DE-IDENTIFIED INFORMATION.—  
18 Notwithstanding subsection (c), but subject to the other  
19 provisions of this section, a person described in subsection  
20 (f) may disclose protected health information to an em-  
21 ployee or other agent of the person for purposes of cre-  
22 ating de-identified information.

23 (i) UNAUTHORIZED USE OR DISCLOSURE OF THE  
24 DECRYPTION KEY.—The unauthorized disclosure of a  
25 decryption key or other secondary or tertiary means for

1 accessing protected health information shall be deemed to  
2 be a disclosure of protected health information. The unau-  
3 thorized use of a decryption key (or other secondary or  
4 tertiary means for accessing protected health information)  
5 or de-identified health information in order to identify an  
6 individual is deemed to be disclosure of protected health  
7 information.

8 (j) NO WAIVER.—Except as provided in this Act, an  
9 authorization to disclose or use personally identifiable  
10 health information executed by an individual pursuant to  
11 section 202 or 203 shall not be construed as a waiver of  
12 any rights that the individual has under other Federal or  
13 State laws, the rules of evidence, or common law.

14 (k) OPT-OUT.—A person may not disclose, access, or  
15 use an individual's protected health information until that  
16 individual has been given the opportunity to opt out of  
17 any local, regional, or nationwide health information net-  
18 work or system that is used by the person.

19 (l) DISPOSAL OF DATA.—To prevent the unauthor-  
20 ized disclosure or use of protected health information,  
21 such information, when disposed of, shall be fully de-iden-  
22 tified, destroyed, and expunged from any electronic, paper,  
23 or other files and documents maintained by authorized  
24 persons.



1 (m) OBLIGATIONS OF UNAUTHORIZED RECIPI-  
2 ENTS.—A person that obtains, accesses, or receives pro-  
3 tected health information and that is an unauthorized re-  
4 cipient of such information may not access, maintain, re-  
5 tain, modify, record, store, destroy, or otherwise use or  
6 disclose such information for any purposes, and use or dis-  
7 closure of protected health information under such cir-  
8 cumstances shall be deemed an unauthorized disclosure of  
9 protected health information.

10 (n) DEFINITIONS.—In this title:

11 (1) INVESTIGATIVE OR LAW ENFORCEMENT OF-  
12 FICER.—The term “investigative or law enforcement  
13 officer” means any officer of the United States or of  
14 a State or political subdivision thereof, who is em-  
15 powered by law to conduct investigations of, or to  
16 make arrests for, civil or criminal offenses, and any  
17 attorney authorized by law to prosecute or partici-  
18 pate in the prosecution of such offenses.

19 (2) SEGREGATE.—The term “segregate” means  
20 to hide, mask, or mark separate a designated subset  
21 of an individual’s protected health information, or to  
22 place such a subset in a location that is securely sep-  
23 arated from the location used to store other pro-  
24 tected health information, such that access to or use  
25 of any information so segregated may be effectively

1 limited to those persons that are authorized by the  
2 individual to access or use that segregated informa-  
3 tion.

4 (3) SIGNED.—The term “signed” refers to both  
5 signatures in ink and electronic signatures, and the  
6 term “written” refers to both paper and computer-  
7 ized formats.

8 **SEC. 202. INFORMED CONSENT FOR DISCLOSURE OF PRO-**  
9 **TECTED HEALTH INFORMATION FOR TREAT-**  
10 **MENT AND PAYMENT.**

11 (a) REQUIREMENTS RELATING TO EMPLOYERS,  
12 HEALTH PLANS, HEALTH OR LIFE INSURERS, UNIN-  
13 SURED AND SELF-PAY INDIVIDUALS, AND PROVIDERS.—

14 (1) IN GENERAL.—To satisfy the requirement  
15 under section 201(b)(1), an employer, health plan,  
16 health or life insurer, or health care provider that  
17 seeks to disclose protected health information in con-  
18 nection with treatment or payment shall obtain an  
19 authorization from the subject of such protected  
20 health information that satisfies the requirements of  
21 this section. A single authorization may authorize  
22 multiple disclosures.

23 (2) EMPLOYERS.—Every employer offering a  
24 health plan to its employees shall, at the time of an  
25 employee’s enrollment in the health plan, obtain a

1 signed, written authorization that is an authoriza-  
2 tion based on informed consent that satisfies the re-  
3 quirements of subsection (b) concerning the use and  
4 disclosure of protected health information for treat-  
5 ment or payment with respect to each individual who  
6 is eligible to receive care under the health plan.

7 (3) HEALTH PLANS, HEALTH OR LIFE INSUR-  
8 ERS.—Every health plan or health or life insurer of-  
9 fering enrollment to individual or nonemployer  
10 groups shall, at the time of enrollment in the plan  
11 or insurance, obtain a signed, written authorization  
12 that is a legal, informed authorization that satisfies  
13 the requirements of subsection (b) concerning the  
14 use and disclosure of protected health information  
15 with respect to each individual who is eligible to re-  
16 ceive care or benefits under the plan or insurance.

17 (4) UNINSURED AND SELF-PAY.—An origi-  
18 nating provider that provides health care in other  
19 than a network plan setting, or provides health care  
20 to an uninsured individual, shall obtain a signed,  
21 written authorization that satisfies the requirements  
22 of subsection (b) to access or use protected health  
23 information in providing health care or arranging for  
24 health care from other providers or seeking payment  
25 for the provision of health care services.

## 1 (5) PROVIDERS.—

2 (A) IN GENERAL.—Every health care pro-  
3 vider that provides health care to an individual  
4 that has not been given the appropriate prior  
5 authorization under this section, shall at the  
6 time of providing such care obtain a signed,  
7 written authorization that is a legal, informed  
8 authorization, that satisfies the requirements of  
9 subsection (b), concerning the use and disclo-  
10 sure of protected health information with re-  
11 spect to such individual.

12 (B) RULE OF CONSTRUCTION.—Subpara-  
13 graph (A) shall not be construed to preclude  
14 the provision of health care to an individual  
15 who has not given appropriate authorization  
16 prior to receipt of such care if—

17 (i) the health care provider involved  
18 determines that such care is essential; and

19 (ii) the individual can reasonably be  
20 expected to sign an authorization for such  
21 care when appropriate.

22 (b) REQUIREMENTS FOR INDIVIDUAL INFORMED  
23 CONSENT.—To satisfy the requirements of this sub-  
24 section, an authorization from an individual to disclose the  
25 individual's protected health information shall—

1           (1) identify, by general job description or other  
2 functional description and by geographic location,  
3 those persons that are authorized to disclose the in-  
4 formation, including entities employed by, or oper-  
5 ating within, a person authorized to disclose the in-  
6 formation;

7           (2) describe the nature of the information to be  
8 disclosed;

9           (3) identify, by general job description or other  
10 functional description and by geographic location,  
11 those persons to which the information will be dis-  
12 closed, including entities employed by, or operating  
13 within, a person to which information is authorized  
14 to be disclosed;

15           (4) describe the purpose of the disclosures;

16           (5) permit the executing individual to indicate  
17 that a particular person or class of persons (a group  
18 of persons with similar roles or functions) listed on  
19 the authorization is not authorized to receive pro-  
20 tected health information concerning the individual,  
21 except as provided for in subsection (c)(3);

22           (6) provide the means by which an individual  
23 may indicate that some of the individual's protected  
24 health information should be segregated and to what

1 persons or classes of persons such segregated infor-  
2 mation may be disclosed;

3 (7) be subject to revocation by the individual  
4 and indicate that the authorization is valid until rev-  
5 ocation by the individual or until an event or date  
6 specified;

7 (8)(A) be—

8 (i) in writing, dated, and signed by the in-  
9 dividual; or

10 (ii) in electronic form, dated and authenti-  
11 cated by the individual using an authentication  
12 method approved by the Secretary; and

13 (B) not have been revoked under subparagraph  
14 (A);

15 (9) describe the procedure by which an indi-  
16 vidual can amend an authorization previously ob-  
17 tained by a person;

18 (10) include a concise description of any sys-  
19 tems or services used for access, maintenance, reten-  
20 tion, modification, recording, storage, destruction, or  
21 other use of protected health information by the au-  
22 thorized person, including—

23 (A) a description of any linkages made  
24 with other systems, databases, networks, or  
25 services external to the authorized person; and

1           (B) how the linkages made with other sys-  
2           tems, databases, networks, or services external  
3           to the authorized person meet the privacy and  
4           security standards of the authorized person;

5           (11) describe the extent to which the authorized  
6           person will share information with sub-contracted  
7           persons, and the geographic location of sub-con-  
8           tracted persons, including those operating or located  
9           overseas, except that the authorized person shall ob-  
10          tain the informed consent of the individual involved  
11          prior to outsourcing such individual's protected  
12          health information to a sub-contracted person oper-  
13          ating or located overseas; and

14          (12) describe the nature and probability of  
15          harm to the individual resulting from authorization  
16          for use or disclosure, consistent with the principle of  
17          informed consent.

18          (c) LIMITATION ON AUTHORIZATIONS.—

19           (1) IN GENERAL.—Subject to paragraphs (2)  
20           and (3), a person described in section 102(a)(1) that  
21           seeks an authorization under this title may not con-  
22           dition the delivery of treatment or payment for serv-  
23           ices on the receipt of such an authorization.

24           (2) RIGHT TO REQUIRE SELF-PAYMENT.—If an  
25           individual has refused to provide an authorization

1 for disclosure of administrative billing information to  
2 a person and such authorization is necessary for a  
3 health care provider to receive payment for services  
4 delivered, the health care provider may require the  
5 individual to pay from their own funds for the serv-  
6 ices.

7 (3) RIGHT OF HEALTH CARE PROVIDER TO RE-  
8 QUIRE AUTHORIZATION FOR TREATMENT PUR-  
9 POSES.—If a health care provider that is seeking an  
10 authorization for disclosure of an individual’s pro-  
11 tected health information believes that the disclosure  
12 of such information is necessary so as not to endan-  
13 ger the health or treatment of the individual, and if  
14 the withholding of services will not endanger the life  
15 of the individual, the health care provider may con-  
16 dition the provision of services upon the individual’s  
17 execution of an authorization to disclose personal  
18 health information to the minimum extent necessary.

19 (4) AUTHORIZATIONS FOR PAYMENT UNDER  
20 CERTAIN CIRCUMSTANCES.—If an individual is in a  
21 physical or mental condition such that the individual  
22 is not capable of authorizing the disclosure of pro-  
23 tected health information and no other arrange-  
24 ments have been made to pay for the health care  
25 services being rendered to the patient, such informa-



1       tion may be disclosed to a governmental authority to  
2       the extent necessary to determine the individual's  
3       eligibility for, and to obtain, payment under a gov-  
4       ernmental program for health care services provided  
5       to the patient. The information may also be dis-  
6       closed to another provider of health care or health  
7       care service plan as necessary to assist the other  
8       provider or health care service plan in obtaining pay-  
9       ment for health care services rendered by that pro-  
10      vider of health care or health care service plan to the  
11      patient.

12      (d) MODEL AUTHORIZATIONS.—The Secretary, in  
13      consultation with the Director of the Office of Health In-  
14      formation Privacy, after notice and opportunity for public  
15      comment, shall develop and disseminate model written au-  
16      thorizations of the type described in this section and model  
17      statements of the limitations on authorizations. Any au-  
18      thorization obtained on a model authorization form under  
19      section 202 developed by the Secretary pursuant to the  
20      preceding sentence shall be deemed to satisfy the require-  
21      ments of this section.

22      (e) SEGREGATION OF FILES.—A person described in  
23      section 102(a)(1) shall comply with the request of an indi-  
24      vidual who is the subject of protected health information—

1           (1) to hide, mask, or mark separate any type or  
2 amount of protected health information held by the  
3 person; and

4           (2) to limit the use or disclosure of the seg-  
5 regated health information within the person to  
6 those specifically designated by the subject of the  
7 protected health information.

8 (f) REVOCATION OF AUTHORIZATION.—

9           (1) IN GENERAL.—An individual may, electroni-  
10 cally or in writing, revoke or amend an authorization  
11 under this section at any time, unless the disclosure  
12 that is the subject of the authorization is required  
13 to effectuate payment for health care that has been  
14 provided to the individual and for which the indi-  
15 vidual has declined or refused to pay from the indi-  
16 vidual's own funds.

17           (2) HEALTH PLANS.—With respect to a health  
18 plan, the authorization of an individual is deemed to  
19 be revoked at the time of the cancellation or non-re-  
20 newal of enrollment in the health plan, except as  
21 may be necessary to complete plan administration  
22 and payment requirements related to the individual's  
23 period of enrollment.

1           (3) ACTIONS.—An individual may not maintain  
2           an action against a person for disclosure of person-  
3           ally identifiable health information—

4                   (A) if the disclosure was made based on a  
5                   good faith reliance on the individual’s author-  
6                   ization under this section at the time such dis-  
7                   closure was made;

8                   (B) in a case in which the authorization is  
9                   revoked, if the disclosing person had no actual  
10                  or constructive notice of the revocation; or

11                  (C) if the disclosure was for the purpose of  
12                  protecting another individual from imminent  
13                  physical harm, and is authorized under section  
14                  204.

15           (g) RECORD OF INDIVIDUAL’S AUTHORIZATIONS AND  
16           REVOCATIONS.—Each person accessing, maintaining, re-  
17           taining, modifying, recording, storing, destroying, or oth-  
18           erwise using personally identifiable or protected health in-  
19           formation shall maintain a record for a period of 7 years  
20           of each authorization by an individual and any revocation  
21           thereof, and such record shall become part of the individ-  
22           ual’s health record set.

23           (h) RULE OF CONSTRUCTION.—Authorizations for  
24           the disclosure of protected health information for treat-  
25           ment or payment shall not authorize the disclosure of such

1 information where the intent is to sell, market, transfer,  
2 or use the protected health information for a commercial  
3 advantage other than for the revenues directly derived  
4 from the provision of health care to that individual. With  
5 respect to such a disclosure for a use other than for treat-  
6 ment or payment, a separate authorization that satisfies  
7 the requirements of section 203 is required.

8 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**  
9 **TECTED HEALTH INFORMATION OTHER THAN**  
10 **FOR TREATMENT OR PAYMENT.**

11 (a) IN GENERAL.—To satisfy the requirement under  
12 section 201(b)(1), a health care provider, health plan,  
13 health oversight agency, public health authority, employer,  
14 health researcher, law enforcement official, health or life  
15 insurer, school or university, or other person described  
16 under section 102(a)(1) that seeks to disclose protected  
17 health information for a purpose other than treatment or  
18 payment shall obtain an authorization that satisfies the  
19 requirements of subsections (b), (e), (f), and (g) of section  
20 202. Such an authorization under this section shall be sep-  
21 arate from an authorization provided under section 202.

22 (b) LIMITATION ON AUTHORIZATIONS.—

23 (1) IN GENERAL.—A person subject to section  
24 202 may not condition the delivery of treatment, or

1 payment for services, on the receipt of an authoriza-  
2 tion described in this section.

3 (2) REQUIREMENT FOR SEPARATE AUTHORIZA-  
4 TION.—A person subject to section 202 may not dis-  
5 close protected health information to any employees  
6 or agents who are responsible for making employ-  
7 ment, work assignment, or other personnel decisions  
8 with respect to the subject of the information with-  
9 out a separate authorization permitting such a dis-  
10 closure.

11 (c) MODEL AUTHORIZATIONS.—The Secretary, in  
12 consultation with the Director of the Office of Health In-  
13 formation Privacy, after notice and opportunity for public  
14 comment, shall develop and disseminate model written au-  
15 thorizations of the type described in subsection (a). Any  
16 authorization obtained on a model authorization form  
17 under this section shall be deemed to meet the authoriza-  
18 tion requirements of this section.

19 (d) REQUIREMENT TO RELEASE PROTECTED  
20 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-  
21 AMINERS.—

22 (1) IN GENERAL.—When a coroner or medical  
23 examiner or their duly appointed deputies seek pro-  
24 tected health information for the purpose of inquiry  
25 into and determination of, the cause, manner, and

1 circumstances of an individual's death, the health  
2 care provider, health plan, health oversight agency,  
3 public health authority, employer, health researcher,  
4 law enforcement officer, health or life insurer, school  
5 or university, or other person involved shall provide  
6 that individual's protected health information to the  
7 coroner or medical examiner or to the duly ap-  
8 pointed deputies without undue delay.

9 (2) PRODUCTION OF ADDITIONAL INFORMA-  
10 TION.—If a coroner or medical examiner or their  
11 duly appointed deputies receives health information  
12 from a person referred to in paragraph (1), such  
13 health information shall remain as protected health  
14 information unless the health information is at-  
15 tached to or otherwise made a part of a coroner's or  
16 medical examiner's official report, in which case it  
17 shall no longer be protected.

18 (3) EXEMPTION.—Health information attached  
19 to or otherwise made a part of a coroner's or med-  
20 ical examiner's official report shall be exempt from  
21 the provisions of this Act except as provided for in  
22 this subsection.

23 (4) REIMBURSEMENT.—A person referred to  
24 paragraph (1) may request reimbursement from a  
25 coroner or medical examiner for the reasonable costs

1 associated with inspection or copying of protected  
2 health information maintained, retained, or stored  
3 by such person.

4 (e) REVOCATION OR AMENDMENT OF AUTHORIZA-  
5 TION.—An individual may, in writing, revoke or amend an  
6 authorization under this section at any time.

7 (f) ACTIONS.—An individual may not maintain an ac-  
8 tion against a person described in section 102(a)(1) for  
9 the disclosure of protected health information—

10 (1) if the disclosure was made based on a good  
11 faith reliance on the individual's authorization under  
12 this section at the time disclosure was made;

13 (2) in a case in which the authorization is re-  
14 voked, if the disclosing person had no actual or con-  
15 structive notice of the revocation; or

16 (3) if the disclosure was for the purpose of pro-  
17 tecting another individual from imminent physical  
18 harm, and is authorized under section 204.

19 (g) RECORD OF AUTHORIZATIONS AND REVOCA-  
20 TIONS.—Each person accessing, maintaining, retaining,  
21 modifying, recording, storing, destroying, or otherwise  
22 using personally identifiable or protected health informa-  
23 tion for purposes other than treatment or payment shall  
24 maintain a record for a period of 7 years of each author-  
25 ization by an individual and any revocation thereof, and

1 such record shall become part of the individual's health  
2 record set.

3 **SEC. 204. NOTIFICATION IN THE CASE OF BREACH.**

4 (a) IN GENERAL.—A person described in section  
5 102(a)(1) that accesses, maintains, retains, modifies,  
6 records, stores, destroys, or otherwise uses or discloses  
7 protected health information shall, following the discovery  
8 of a security breach of such information, notify each indi-  
9 vidual whose protected health information has been, or is  
10 reasonably believed to have been, accessed, or acquired  
11 during such breach.

12 (b) OBLIGATION OF OWNER OR LICENSEE.—

13 (1) NOTICE TO OWNER OR LICENSEE.—Any  
14 person engaged in interstate commerce, that uses,  
15 accesses, transmits, stores, disposes of, or collects  
16 protected health information that the person does  
17 not own or license shall notify the owner or licensee  
18 of the information following the discovery of a secu-  
19 rity breach involving such information.

20 (2) NOTICE BY OWNER, LICENSEE, OR OTHER  
21 DESIGNATED THIRD PARTY.—Nothing in this sub-  
22 title shall be construed to prevent or abrogate an  
23 agreement between a person required to give notice  
24 under this section and a designated third party, in-  
25 cluding an owner or licensee of the protected health



1 information subject to the security breach, to pro-  
2 vide the notifications required under subsection (a).

3 (3) PERSON RELIEVED FROM GIVING NOTICE.—

4 A person obligated to give notice under subsection  
5 (a) shall be relieved of such obligation if an owner  
6 or licensee of the protected health information sub-  
7 ject to the security breach, or other designated third  
8 party, provides such notification.

9 (c) TIMELINESS OF NOTIFICATION.—

10 (1) IN GENERAL.—All notifications required  
11 under this section shall be made within 15 business  
12 days, or earlier if the Secretary determines appro-  
13 priate, following the discovery by the person of a se-  
14 curity breach.

15 (2) BURDEN OF PROOF.—The person required  
16 to provide notification under this section shall have  
17 the burden of demonstrating that all notifications  
18 were made as required under this subtitle, including  
19 evidence demonstrating the necessity of any delay.

20 (d) METHODS OF NOTICE.—A person described in  
21 subsection (a) shall provide to an individual the following  
22 forms of notice in the case of a security breach:

23 (1) INDIVIDUAL NOTICE.—Notice required  
24 under this section shall be provided in such form as  
25 the individual selects, including—

1 (A) written notification to the last known  
2 home mailing address of the individual in the  
3 records of the person;

4 (B) telephone notice to the individual per-  
5 sonally; or

6 (C) e-mail notice, if the individual has con-  
7 sented to receive such notice and the notice is  
8 consistent with the provisions permitting elec-  
9 tronic transmission of notices under section 101  
10 of the Electronic Signatures in Global and Na-  
11 tional Commerce Act (15 U.S.C. 7001).

12 (2) MEDIA NOTICE.—Notice shall be provided  
13 to prominent media outlets serving a State or juris-  
14 diction, if the protected health information of more  
15 than 1,000 residents of such State or jurisdiction is,  
16 or is reasonably believed to have been, acquired by  
17 an unauthorized person.

18 (3) NOTICE TO SECRETARY.—Notice shall be  
19 provided to the Secretary for persons described in  
20 section 102 (a)(1) that have lost, stolen, disclosed,  
21 or used in an unauthorized manner or for an unau-  
22 thorized purpose the protected health information of  
23 a significant number of individuals.

24 (e) CONTENT OF NOTIFICATION.—Regardless of the  
25 method by which notice is provided to individuals under

1 section 104, notice of a security breach shall include, to  
2 the extent possible—

3 (1) a description of the protected health infor-  
4 mation that has been, or is reasonably believed to  
5 have been, accessed, disclosed, or otherwise used by  
6 an unauthorized person;

7 (2) a toll-free number that the individual may  
8 use to contact the person described in subsection (a)  
9 to learn what types of protected health information  
10 the person maintained about that individual; and

11 (3) toll-free contact telephone numbers and ad-  
12 dresses for major credit reporting agencies.

13 (f) DELAY OF NOTIFICATION AUTHORIZED FOR LAW  
14 ENFORCEMENT PURPOSES.—

15 (1) IN GENERAL.—If a Federal law enforce-  
16 ment agency determines that the notification re-  
17 quired under this section would impede a criminal  
18 investigation or cause damage to national security,  
19 such notification shall be delayed upon written no-  
20 tice from the Federal law enforcement agency to the  
21 person that experienced the breach.

22 (2) EXTENDED DELAY OF NOTIFICATION.—If  
23 the notification required under subsection (a) is de-  
24 layed pursuant to paragraph (1), a person shall give  
25 notice not later than 30 days after such law enforce-

1       ment delay was invoked unless a Federal law en-  
2       forcement agency provides written notification that  
3       further delay is necessary.

4               (3) LAW ENFORCEMENT IMMUNITY.—No cause  
5       of action shall arise in any court against any Fed-  
6       eral law enforcement agency for acts relating to the  
7       delay of notification for law enforcement purposes  
8       under this subtitle.

9               **Subtitle B—Disclosure Under**  
10              **Special Circumstances**

11       **SEC. 211. EMERGENCY CIRCUMSTANCES.**

12           (a) GENERAL RULE.—In the event of a threat of im-  
13       minent physical or mental harm to the subject of protected  
14       health information, any person may, in order to allay or  
15       remedy such threat, disclose protected health information  
16       about such subject to a health care provider, health care  
17       facility, law enforcement authority, or emergency medical  
18       personnel, to the minimum extent necessary and only if  
19       determined appropriate by a health care provider.

20           (b) HARM TO OTHERS.—Any person may disclose  
21       protected health information about the subject of the in-  
22       formation where—

23               (1) such subject has made an identifiable threat  
24       of serious injury or death with respect to an identifi-  
25       able individual or group of individuals;

1           (2) the subject has the ability to carry out such  
2           threat; and

3           (3) the release of such information is necessary  
4           to prevent or significantly reduce the possibility of  
5           such threat being carried out.

6 **SEC. 212. PUBLIC HEALTH.**

7           (a) IN GENERAL.—A health care provider, health  
8           plan, public health authority, employer, health or life in-  
9           surer, law enforcement official, school or university, or  
10          other person described in section 102(a)(1) may disclose  
11          protected health information to a public health authority  
12          or other entity authorized by public health law, when re-  
13          ceipt of such information by the authority or other enti-  
14          ty—

15                 (1) relates directly to a specified public health  
16                 purpose;

17                 (2) is reasonably likely to achieve such purpose;  
18                 and

19                 (3) is intended for a purpose that cannot be  
20                 achieved through the receipt or use of de-identified  
21                 health information.

22           (b) PUBLIC HEALTH PROTECTION DEFINED.—For  
23           purposes of subsection (a), the term “public health protec-  
24           tion” means a population-based activity or individual ef-  
25           fort, authorized by law, the purpose of which is the preven-

1 tion of injury, disease, or premature mortality, or the pro-  
2 motion of health, in a community, including—

3 (1) assessing the health needs and status of the  
4 community through public health surveillance and  
5 epidemiological research;

6 (2) implementing public health policy;

7 (3) responding to public health needs and emer-  
8 gencies; and

9 (4) any other activities or efforts authorized by  
10 law.

11 (c) LIMITATIONS.—The purpose of the disclosure de-  
12 scribed in subsection (a) should be of sufficient importance  
13 to warrant the potential effect on, or risk to, the privacy  
14 of individuals that the additional exposure of protected  
15 health information might bring. Any infringement on the  
16 right to privacy under this section should use the least  
17 intrusive means that are tailored to minimize intrusion on  
18 the right to privacy.

19 **SEC. 213. PROTECTION AND ADVOCACY AGENCIES.**

20 Any person described in section 102(a)(1) that cre-  
21 ates, accesses, maintains, retains, modifies, records,  
22 stores, destroys, or otherwise uses or discloses protected  
23 health information under this title may disclose such infor-  
24 mation to a protection and advocacy agency established  
25 under part C of title I of the Developmental Disabilities

1 Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.)  
2 or under the Protection and Advocacy for Mentally Ill In-  
3 dividuals Act of 1986 (42 U.S.C. 10801 et seq.) when  
4 such person can establish that there is probable cause to  
5 believe that an individual who is the subject of the pro-  
6 tected health information is vulnerable to abuse and ne-  
7 glect by an entity providing health or social services to  
8 the individual.

9 **SEC. 214. OVERSIGHT.**

10 (a) IN GENERAL.—A health care provider, health  
11 plan, employer, law enforcement official, health or life in-  
12 surer, public health authority, health researcher, school or  
13 university, or other person described in section 102(a)(1)  
14 may disclose protected health information to a health over-  
15 sight agency to enable the agency to perform a health  
16 oversight function authorized by law, if—

17 (1) the purpose for which the disclosure is to be  
18 made cannot reasonably be accomplished without  
19 protected health information;

20 (2) the purpose for which the disclosure is to be  
21 made is of sufficient importance to warrant the ef-  
22 fect on, or the risk to, the privacy of the individuals  
23 that additional exposure of the information might  
24 bring; and

1           (3) there is a reasonable probability that the  
2           purpose of the disclosure will be accomplished.

3           (b) USE AND MAINTENANCE OF PROTECTED  
4 HEALTH INFORMATION.—A health oversight agency that  
5 receives protected health information under this section—

6           (1) shall secure protected health information in  
7           all work papers and all documents summarizing the  
8           health oversight activity through technological, ad-  
9           ministrative, and physical safeguards including cryp-  
10          tographic-key based encryption;

11          (2) shall maintain in its records only such infor-  
12          mation about an individual as is relevant and nec-  
13          essary to accomplish the purpose for which the pro-  
14          tected health information was obtained;

15          (3) using appropriate encryption measures.  
16          shall maintain such information securely and limit  
17          access to such information to those persons with a  
18          legitimate need for access to carry out the purpose  
19          for which the records were obtained; and

20          (4) shall remove or destroy the information that  
21          allows subjects of protected health information to be  
22          identified at the earliest time at which removal or  
23          destruction can be accomplished, consistent with the  
24          purpose of the health oversight activity.



1 (c) USE OF PROTECTED HEALTH INFORMATION IN  
2 JUDICIAL PROCEEDINGS.—

3 (1) IN GENERAL.—The disclosure and use of  
4 protected health information in any judicial, admin-  
5 istrative, court, or other public proceeding or inves-  
6 tigation relating to a health oversight activity shall  
7 be undertaken in such a manner as to preserve the  
8 confidentiality and privacy of individuals who are the  
9 subject of the information, unless disclosure is re-  
10 quired by the nature of the proceedings.

11 (2) LIMITING DISCLOSURE.—Whenever disclo-  
12 sure of the identity of the subject of protected health  
13 information is required by the nature of the pro-  
14 ceedings, or it is impracticable to redact the identity  
15 of such individual, the agency shall request that the  
16 presiding judicial or administrative officer enter an  
17 order limiting the disclosure of the identity of the  
18 subject to the extent possible, including the redact-  
19 ing of the protected health information from publicly  
20 disclosed or filed pleadings or records.

21 (d) AUTHORIZATION BY A SUPERVISOR.—For pur-  
22 poses of this section, the individual with authority to au-  
23 thorize the oversight function involved shall provide to the  
24 disclosing person described in subsection (a) a statement

1 that the protected health information is being sought for  
2 a legally authorized oversight function.

3 (e) USE IN ACTION AGAINST INDIVIDUALS.—Pro-  
4 tected health information about an individual that is dis-  
5 closed under this section may not be used in, or disclosed  
6 to any person for use in, an administrative, civil, or crimi-  
7 nal action or investigation directed against the individual,  
8 unless the action or investigation arises out of and is di-  
9 rectly related to—

10 (1) the receipt of health care or payment for  
11 health care;

12 (2) a fraudulent claim related to health; or

13 (3) oversight of a public health authority or a  
14 health researcher.

15 **SEC. 215. DISCLOSURE FOR LAW ENFORCEMENT, NA-**  
16 **TIONAL SECURITY, AND INTELLIGENCE PUR-**  
17 **POSES.**

18 (a) ACCESS TO PROTECTED HEALTH INFORMATION  
19 FOR LAW ENFORCEMENT, NATIONAL SECURITY, AND IN-  
20 TELLIGENCE ACTIVITIES.—A person described in section  
21 102(a)(1), or a person who receives protected health infor-  
22 mation pursuant to section 211, may disclose protected  
23 health information to—

24 (1) an investigative or law enforcement officer  
25 pursuant to a warrant issued under the Federal

1 Rules of Criminal Procedure, an equivalent State  
2 warrant, a grand jury subpoena, civil subpoena, civil  
3 investigative demand, or a court order under limita-  
4 tions set forth in subsection (b); and

5 (2) an authorized Federal official for the con-  
6 duct of lawful intelligence, counter-intelligence, and  
7 other national security activities authorized by the  
8 National Security Act (50 U.S.C. 401 et seq.) and  
9 implementing authority (Executive Order 12333), or  
10 otherwise by law.

11 (b) REQUIREMENTS FOR COURT ORDERS FOR AC-  
12 CESS TO PROTECTED HEALTH INFORMATION.—A court  
13 order for the disclosure of protected health information  
14 under subsection (a)(1) may be issued by any court that  
15 is a court of competent jurisdiction and shall issue only  
16 if the investigative or law enforcement officer submits a  
17 written application upon oath or equivalent affirmation  
18 demonstrating that there is probable cause to believe  
19 that—

20 (1) the protected health information sought is  
21 relevant and material to an ongoing criminal inves-  
22 tigation, except in the case of a State government  
23 authority, such a court order shall not issue if pro-  
24 hibited by the law of such State;

1           (2) the investigative or evidentiary needs of the  
2           investigative or law enforcement officer cannot rea-  
3           sonably be satisfied by de-identified health informa-  
4           tion or by any other information; and

5           (3) the law enforcement need for the informa-  
6           tion outweighs the privacy interest of the individual  
7           to whom the information pertains.

8           (c) MOTIONS TO QUASH OR MODIFY.—A court  
9           issuing an order pursuant to this section, on a motion  
10          made promptly by a person described in subsection (a)(1)  
11          may quash or modify such order if the court finds that  
12          information or records requested are unreasonably volumi-  
13          nous or if compliance with such order otherwise would  
14          cause an unreasonable burden on such entities.

15          (d) NOTICE.—

16                (1) IN GENERAL.—Except as provided in para-  
17                graph (2), no order for the disclosure of protected  
18                health information about an individual may be  
19                issued by a court under this section unless prior no-  
20                tice of the application for the order has been served  
21                on the individual and the individual has been af-  
22                forded an opportunity to oppose the issuance of the  
23                order.

24                (2) NOTICE NOT REQUIRED.—An order for the  
25                disclosure of protected health information about an

1 individual may be issued without prior notice to the  
2 individual if the court finds that notice would be im-  
3 practical because—

4 (A) the name and address of the individual  
5 are unknown; or

6 (B) notice would risk destruction or un-  
7 availability of the evidence, intelligence,  
8 counter-intelligence, or other national security  
9 information.

10 (e) CONDITIONS.—Upon the granting of an order for  
11 disclosure of protected health information under this sec-  
12 tion, the court shall impose appropriate safeguards to en-  
13 sure the confidentiality of such information and to protect  
14 against unauthorized or improper use or disclosure.

15 (f) LIMITATION ON USE AND DISCLOSURE FOR NA-  
16 TIONAL SECURITY, INTELLIGENCE, AND OTHER LAW EN-  
17 FORCEMENT INQUIRIES.—Protected health information  
18 about an individual that is disclosed under this section  
19 may not be used in, or disclosed to any entity for use in,  
20 any administrative, civil, or criminal action or investiga-  
21 tion directed against the individual, unless the action or  
22 investigation arises out of, or is directly related to, the  
23 law enforcement, national security, or intelligence inquiry  
24 for which the information was obtained.

1           (g) DESTRUCTION OR RETURN OF INFORMATION.—  
2 When the matter or need for which protected health infor-  
3 mation was disclosed to an investigative or law enforce-  
4 ment officer, a Federal official authorized for the conduct  
5 of lawful intelligence, counter-intelligence, and other na-  
6 tional security activities, or authorized Federal official, or  
7 grand jury has concluded, including any derivative matters  
8 arising from such matter or need, the law enforcement  
9 agency, authorized Federal official, or grand jury shall ei-  
10 ther destroy the protected health information, or return  
11 it to the entity from which it was obtained.

12           (h) REDACTIONS.—To the extent practicable, and  
13 consistent with the requirements of due process, a law en-  
14 forcement agency shall redact personally identifying infor-  
15 mation from protected health information prior to the  
16 public disclosure of such protected information in a judi-  
17 cial or administrative proceeding.

18           (i) EXCEPTION.—This section shall not be construed  
19 to limit or restrict the ability of law enforcement authori-  
20 ties to gain information while in hot pursuit of a suspect  
21 or if other exigent circumstances exist.

22 **SEC. 216. NEXT OF KIN AND DIRECTORY INFORMATION.**

23           (a) NEXT OF KIN.—A health care provider, or a per-  
24 son that receives protected health information under sec-  
25 tion 211, may disclose protected health information about

1 health care services provided to an individual to the indi-  
2 vidual's next of kin, or to another entity that the indi-  
3 vidual has identified, if at the time of the treatment of  
4 the individual—

5 (1) the individual—

6 (A) has been notified of the individual's  
7 right to object to such disclosure and the indi-  
8 vidual has not objected to the disclosure; or

9 (B) is in a physical or mental condition  
10 such that the individual is not capable of object-  
11 ing, and there are no prior indications that the  
12 individual would object; and

13 (2) the information disclosed is relevant to  
14 health care services currently being provided to that  
15 individual.

16 (b) DIRECTORY INFORMATION.—

17 (1) DISCLOSURE.—

18 (A) IN GENERAL.—Except as provided in  
19 paragraph (2), with respect to an individual  
20 who is admitted as an inpatient to a health care  
21 facility, a person described in subsection (a)  
22 may disclose information described in subpara-  
23 graph (B) about the individual to any entity if,  
24 at the time of the admission, the individual—

1 (i) has been notified of the individ-  
2 ual's right to object and has not objected  
3 to the disclosure; or

4 (ii) is in a physical or mental condi-  
5 tion such that the individual is not capable  
6 of objecting and there are no prior indica-  
7 tions that the individual would object.

8 (B) INFORMATION.—Information described  
9 in this subparagraph is information that con-  
10 sists only of 1 or more of the following items:

11 (i) The name of the individual who is  
12 the subject of the information.

13 (ii) The general health status of the  
14 individual, described as critical, poor, fair,  
15 stable, or satisfactory or in terms denoting  
16 similar conditions.

17 (iii) The location of the individual  
18 within the health care facility to which the  
19 individual is admitted.

20 (2) EXCEPTION.—Paragraph (1)(B)(iii) shall  
21 not apply if disclosure of the location of the indi-  
22 vidual would reveal specific information about the  
23 physical or mental condition of the individual, unless  
24 the individual expressly authorizes such disclosure.



1 (c) DIRECTORY OR NEXT-OF-KIN INFORMATION.—A  
2 disclosure may not be made under this section if the dis-  
3 closing person described in subsection (a) has reason to  
4 believe that the disclosure of directory or next-of-kin infor-  
5 mation could lead to the physical or mental harm of the  
6 individual, unless the individual expressly authorizes such  
7 disclosure.

8 **SEC. 217. HEALTH RESEARCH.**

9 (a) REGULATIONS.—

10 (1) IN GENERAL.—The requirements and pro-  
11 tections provided for under part 46 of title 45, Code  
12 of Federal Regulations (as in effect on the date of  
13 enactment of this Act), shall apply to all health re-  
14 search.

15 (2) EFFECTIVE DATE.—Paragraph (1) shall not  
16 take effect until the Secretary has promulgated final  
17 regulations to implement such paragraph.

18 (b) EVALUATION.—Not later than 24 months after  
19 the date of enactment of this Act, the Secretary shall pre-  
20 pare and submit to Congress detailed recommendations on  
21 whether written informed consent should be required, and  
22 if so, under what circumstances, before protected health  
23 information can be used for health research.

1 (c) RECOMMENDATIONS.—The recommendations re-  
2 quired to be submitted under subsection (b) shall in-  
3 clude—

4 (1) a detailed explanation of current institu-  
5 tional review board practices, including the extent to  
6 which the privacy of individuals is taken into ac-  
7 count as a factor before allowing waivers and under  
8 what circumstances informed consent is being  
9 waived;

10 (2) a summary of how technology could be used  
11 to strip identifying data for the purposes of re-  
12 search;

13 (3) an analysis of the risks and benefits of re-  
14 quiring informed consent versus the waiver of in-  
15 formed consent;

16 (4) an analysis of the risks and benefits of  
17 using protected health information for research pur-  
18 poses other than the health research project for  
19 which such information was obtained; and

20 (5) an analysis of the risks and benefits of al-  
21 lowing individuals to consent or to refuse to consent,  
22 at the time of receiving medical treatment, to the  
23 possible future use of records of medical treatments  
24 for research studies.

1           (d) CONSULTATION.—In carrying out this section,  
2 the Secretary shall consult with individuals who have dis-  
3 tinguished themselves in the fields of health research, pri-  
4 vacy, related technology, consumer interests in health in-  
5 formation, health data standards, and the provision of  
6 health services.

7           (e) CONGRESSIONAL NOTICE.—Not later than 6  
8 months after the date on which the Secretary submits to  
9 Congress the recommendations required under subsection  
10 (b), the Secretary shall propose to implement such rec-  
11 ommendations through regulations promulgated on the  
12 record after opportunity for a hearing, and shall advise  
13 the Congress of such proposal.

14           (f) OTHER REQUIREMENTS.—

15               (1) OBLIGATIONS OF THE RECIPIENT.—A per-  
16 son who receives protected health information pursu-  
17 ant to this section shall remove or destroy, at the  
18 earliest opportunity consistent with the purposes of  
19 the project involved, information that would enable  
20 an individual to be identified, unless—

21                       (A) an institutional review board has de-  
22 termined that there is a health or research jus-  
23 tification for the retention of such identifiers;  
24                       and

1           (B) there is an adequate plan to protect  
2           the identifiers from disclosure consistent with  
3           this section.

4           (2) PERIODIC REVIEW AND TECHNICAL ASSIST-  
5           ANCE.—

6           (A) INSTITUTIONAL REVIEW BOARD.—Any  
7           institutional review board that authorizes re-  
8           search under this section shall provide the Sec-  
9           retary with the names and addresses of the in-  
10          stitutional review board members.

11          (B) TECHNICAL ASSISTANCE.—The Sec-  
12          retary shall provide technical assistance to insti-  
13          tutional review boards described in this sub-  
14          section.

15          (C) MONITORING.—The Secretary shall pe-  
16          riodically monitor institutional review boards  
17          described in this subsection.

18          (D) REPORTS.—Not later than 3 years  
19          after the date of enactment of this Act, the Sec-  
20          retary shall report to Congress regarding the  
21          activities of institutional review boards de-  
22          scribed in this subsection.

23          (g) LIMITATION.—Nothing in this section shall be  
24          construed to permit protected health information that is  
25          received by a researcher under this section to be accessed

1 for purposes other than research or as authorized by the  
2 individual that is the subject of such protected health in-  
3 formation.

4 **SEC. 218. JUDICIAL AND ADMINISTRATIVE PURPOSES.**

5 (a) IN GENERAL.—A person described in section  
6 102(a)(1), or a person who receives protected health infor-  
7 mation under section 211, may disclose protected health  
8 information—

9 (1) pursuant to the standards and procedures  
10 established in the Federal Rules of Civil Procedure  
11 or comparable rules of other courts or administrative  
12 agencies, in connection with litigation or proceedings  
13 to which an individual who is the subject of the in-  
14 formation is a party and in which the individual has  
15 placed his or her physical or mental condition at  
16 issue;

17 (2) to a court, and to others ordered by the  
18 court, if in response to a court order issued by a  
19 court of competent jurisdiction in accordance with  
20 subsections (b) and (c); or

21 (3) if necessary to present to a court an appli-  
22 cation regarding the provision of treatment of an in-  
23 dividual or the appointment of a guardian.

24 (b) COURT ORDERS FOR ACCESS TO PROTECTED  
25 HEALTH INFORMATION.—A court order for the disclosure

1 of protected health information under subsection (a) may  
2 be issued only if the person seeking disclosure submits a  
3 written application upon oath or equivalent affirmation  
4 demonstrating by clear and convincing evidence that—

5           (1) the protected health information sought is  
6           necessary for the adjudication of a material fact in  
7           dispute in a civil proceeding;

8           (2) the adjudicative need cannot be reasonably  
9           satisfied by de-identified health information or by  
10          any other information; and

11          (3) the need for the information outweighs the  
12          privacy interest of the individual to whom the infor-  
13          mation pertains.

14          (c) NOTICE.—

15           (1) IN GENERAL.—Except as provided in para-  
16           graph (2), no order for the disclosure of protected  
17           health information about an individual may be  
18           issued by a court unless notice of the application for  
19           the order has been served on the individual and the  
20           individual has been afforded an opportunity to op-  
21           pose the issuance of the order.

22           (2) NOTICE NOT REQUIRED.—An order for the  
23           disclosure of protected health information about an  
24           individual may be issued without notice to the indi-

1       vidual if the court finds, by clear and convincing evi-  
2       dence, that notice would be impractical because—

3               (A) the name and address of the individual  
4       are unknown; or

5               (B) notice would risk destruction or un-  
6       availability of the evidence.

7       (d) OBLIGATIONS OF RECIPIENT.—A person seeking  
8       protected health information pursuant to subsection  
9       (a)(1)—

10           (1) shall notify the individual or the individual’s  
11       attorney of the request for the information;

12           (2) shall provide the health care provider,  
13       health plan, health oversight agency, employer, in-  
14       surer, health or life insurer, school or university,  
15       agent, or other person involved with a signed docu-  
16       ment attesting—

17               (A) that the individual has placed his or  
18       her physical or mental condition at issue in liti-  
19       gation or proceedings in which the individual is  
20       a party; and

21               (B) the date on which the individual or the  
22       individual’s attorney was notified under para-  
23       graph (1); and

24           (3) shall not accept any requested protected  
25       health information from the health care provider,

1 health plan, health oversight agency, employer, in-  
2 surer, health or life insurer, school or university,  
3 agent, or other person until the termination of the  
4 10-day period beginning on the date notice was  
5 given under paragraph (1).

6 **SEC. 219. INDIVIDUAL REPRESENTATIVES.**

7 (a) IN GENERAL.—Except as provided in subsections  
8 (b) and (c), a person who is authorized by law (based on  
9 grounds other than an individual’s status as a minor), or  
10 by an instrument recognized under law, to act as an agent,  
11 attorney, proxy, or other legal representative of an indi-  
12 vidual, may, to the extent so authorized, exercise and dis-  
13 charge the rights of the individual under this Act.

14 (b) HEALTH CARE POWER OF ATTORNEY.—A person  
15 who is authorized by law (based on grounds other than  
16 being a minor), or by an instrument recognized under law,  
17 to make decisions about the provision of health care to  
18 an individual who is incapacitated, may exercise and dis-  
19 charge the rights of the individual under this Act to the  
20 extent necessary to effectuate the terms or purposes of  
21 the grant of authority.

22 (c) NO COURT DECLARATION.—If a physician or  
23 other health care provider determines that an individual,  
24 who has not been declared to be legally incompetent, suf-  
25 fers from a medical condition that prevents the individual



1 from acting knowingly or effectively on the individual's  
2 own behalf, the right of the individual to access or amend  
3 the health information and to authorize disclosure under  
4 this Act may be exercised and discharged in the best inter-  
5 est of the individual by—

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

8 (2) a person described in subsection (a) with re-  
9 spect to the individual, but only if a person de-  
10 scribed in paragraph (1) cannot be contacted after  
11 a reasonable effort or if there is no individual who  
12 fits the description in paragraph (1);

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

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

19 (d) RIGHTS OF MINORS.—

20 (1) INDIVIDUALS WHO ARE 18 OR LEGALLY CA-  
21 PABLE.—In the case of an individual—

22 (A) who is 18 years of age or older, all  
23 rights of the individual under this Act shall be  
24 exercised by the individual; or

1 (B) who, acting alone, can consent to  
2 health care without violating any applicable law,  
3 and who has sought such care, the individual  
4 shall exercise all rights of an individual under  
5 this Act with respect to protected health infor-  
6 mation relating to such health care.

7 (2) INDIVIDUALS UNDER 18.—Except as pro-  
8 vided in paragraph (1)(B), in the case of an indi-  
9 vidual who is—

10 (A) under 14 years of age, all of the indi-  
11 vidual's rights under this Act shall be exercised  
12 through the parent or legal guardian; or

13 (B) 14 through 17 years of age, the rights  
14 of inspection, supplementation, and modifica-  
15 tion, and the right to authorize use and diselo-  
16 sure of protected health information of the indi-  
17 vidual shall be exercised by—

18 (i) the individual where no parent or  
19 legal guardian exists;

20 (ii) the parent or legal guardian of the  
21 individual; or

22 (iii) the individual if the parent or  
23 legal guardian determined that the indi-  
24 vidual has the sole right the control their  
25 health information.

1 (e) DECEASED INDIVIDUALS.—

2 (1) APPLICATION OF ACT.—The provisions of  
3 this Act shall continue to apply to protected health  
4 information concerning a deceased individual.

5 (2) EXERCISE OF RIGHTS ON BEHALF OF A DE-  
6 CEASED INDIVIDUAL.—A person who is authorized  
7 by law or by an instrument recognized under law, to  
8 act as an executor or administrator of the estate of  
9 a deceased individual, or otherwise to exercise the  
10 rights of the deceased individual, may, to the extent  
11 so authorized, exercise and discharge the rights of  
12 such deceased individual under this Act. If no such  
13 designee has been authorized, the rights of the de-  
14 ceased individual may be exercised as provided for in  
15 subsection (c).

16 (3) IDENTIFICATION OF DECEASED INDI-  
17 VIDUAL.—A person described in section 216(a) may  
18 disclose protected health information if such dislo-  
19 sure is necessary to assist in the identification of a  
20 deceased individual.

1 **TITLE III—OFFICE OF HEALTH**  
2 **INFORMATION PRIVACY OF**  
3 **THE DEPARTMENT OF**  
4 **HEALTH AND HUMAN SERV-**  
5 **ICES**

6 **Subtitle A—Designation**

7 **SEC. 301. DESIGNATION.**

8 (a) IN GENERAL.—The Secretary shall designate an  
9 office within the Department of Health and Human Serv-  
10 ices to be known as the Office of Health Information Pri-  
11 vacy (referred to in this section as the “Office”). The Of-  
12 fice shall be headed by a Director, who shall be appointed  
13 by the Secretary.

14 (b) DUTIES.—The Director of the Office shall—

15 (1) receive and investigate complaints of alleged  
16 violations of this Act;

17 (2) provide for the conduct of audits where ap-  
18 propriate;

19 (3) provide guidance to the Secretary on the  
20 implementation of this Act;

21 (4) provide guidance to health care providers  
22 and other relevant individuals concerning the man-  
23 ner in which to interpret and implement the privacy  
24 protections under this Act (and the regulations pro-  
25 mulgated under this Act);

1           (5) prepare and submit the report described in  
2 subsection (c);

3           (6) consult with, and provide recommendation  
4 to, the Secretary concerning improvements in the  
5 privacy and security of protected health information  
6 and concerning medical privacy research needs; and

7           (7) carry out any other activities determined  
8 appropriate by the Secretary.

9 (c) STANDARDS FOR CERTIFICATION.—

10           (1) ESTABLISHMENT.—Not later than 12  
11 months after the date of enactment of this Act, the  
12 Secretary, in consultation with the Director of the  
13 Office and the Director of the Office of Civil Rights,  
14 shall establish and implement standards for health  
15 information technology products used to access, dis-  
16 close, maintain, store, distribute, transmit, amend,  
17 or dispose of protected health information in a man-  
18 ner that protects the individual’s right to privacy,  
19 confidentiality, and security relating to that informa-  
20 tion.

21           (2) STAKEHOLDER PARTICIPATION.—In estab-  
22 lishing the standards under paragraph (1), the Sec-  
23 retary shall ensure the participation of various  
24 stakeholders, including patients and consumer advo-  
25 cates, privacy advocates, experts in information tech-

1 nology and information systems, and experts in  
2 health care.

3 (d) REPORT ON COMPLIANCE.—Not later than Janu-  
4 ary 1 of the first calendar year beginning more than 1  
5 year after the establishment of the Office under subsection  
6 (a), and every January 1 thereafter, the Secretary, in con-  
7 sultation with the Director of the Office, shall prepare and  
8 submit to Congress a report concerning the number of  
9 complaints of alleged violations of this Act that are re-  
10 ceived during the year for which the report is being pre-  
11 pared. Such report shall describe the complaints and any  
12 remedial action taken concerning such complaints and  
13 shall be made available to the public on the Internet  
14 website of the Department of Health and Human Services.

## 15 **Subtitle B—Enforcement**

### 16 **CHAPTER 1—CRIMINAL PROVISIONS**

#### 17 **SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED** 18 **HEALTH INFORMATION.**

19 (a) IN GENERAL.—Part I of title 18, United States  
20 Code, is amended by adding at the end the following:

1 **“CHAPTER 124—WRONGFUL DISCLOSURE**  
2 **OF PROTECTED HEALTH INFORMATION**

3 **“SEC. 2801. WRONGFUL DISCLOSURE OF PROTECTED**  
4 **HEALTH INFORMATION.**

5 “(a) OFFENSE.—The penalties described in sub-  
6 section (b) shall apply to a person that knowingly and in-  
7 tentiously—

8 “(1) obtains, uses, or attempts to obtain or use  
9 protected health information relating to an indi-  
10 vidual in violation of title II of the Health Informa-  
11 tion Privacy and Security Act; or

12 “(2) discloses or attempts to disclose protected  
13 health information to another person in violation of  
14 title II of the Health Information Privacy and Secu-  
15 rity Act.

16 “(b) PENALTIES.—A person described in subsection  
17 (a) shall—

18 “(1) be fined not more than \$50,000, impris-  
19 oned not more than 1 year, or both;

20 “(2) if the offense is committed under false pre-  
21 tenses, be fined not more than \$250,000 or impris-  
22 oned not more than 5 years, or both; or

23 “(3) if the offense is committed with the intent  
24 to sell, transfer, or use protected health information  
25 for commercial advantage, personal gain, or mali-

1 cious harm, be fined not more than \$500,000, im-  
2 prisoned not more than 10 years, or any combina-  
3 tion of such penalties.

4 “(c) SUBSEQUENT OFFENSES.—In the case of a per-  
5 son described in subsection (a), the maximum penalties  
6 described in subsection (b) shall be doubled for every sub-  
7 sequent conviction for an offense arising out of a violation  
8 or violations related to a set of circumstances that are dif-  
9 ferent from those involved in the previous violation or set  
10 of related violations described in such subsection (a).”.

11 (b) CLERICAL AMENDMENT.—The table of chapters  
12 for part I of title 18, United States Code, is amended by  
13 inserting after the item relating to chapter 123 the fol-  
14 lowing new item:

“Sec. 2801. Wrongful disclosure of protected health information.”.

15 **SEC. 312. DEBARMENT FOR CRIMES AND CIVIL VIOLA-**  
16 **TIONS.**

17 (a) PURPOSE.—The purpose of this section is to pre-  
18 vent and deter instances of intentional criminal actions  
19 that violate criminal laws that are designed to protect the  
20 privacy of protected health information in a manner con-  
21 sistent with this Act.

22 (b) DEBARMENT.—Not later than 270 days after the  
23 date of enactment of this Act, the Attorney General, in  
24 consultation with the Secretary, shall promulgate regula-  
25 tions and establish procedures to permit the debarment



1 of health care providers, health researchers, health or life  
2 insurers, employers, or schools or universities from receiv-  
3 ing benefits under any Federal health program or other  
4 Federal procurement program if the managers or officers  
5 of such persons are found guilty of violating section 2801  
6 of title 18, United States Code, have civil penalties im-  
7 posed against such officers or managers under section 321  
8 in connection with the illegal disclosure of protected health  
9 information, or are found guilty of making a false state-  
10 ment or obstructing justice related to attempting to con-  
11 ceal or concealing such illegal disclosure. Such regulations  
12 shall take into account the need for continuity of medical  
13 care and may provide for a delay of any debarment im-  
14 posed under this section to take into account the medical  
15 needs of patients.

16 (c) CONSULTATION.—Prior to publishing a proposed  
17 rule to implement subsection (b), the Attorney General  
18 shall consult with State law enforcement officials, health  
19 care providers, patient privacy rights’ advocates, and other  
20 appropriate persons, to gain additional information re-  
21 garding the debarment of persons under subsection (b)  
22 and the best methods to ensure the continuity of medical  
23 care.

24 (d) REPORT.—The Attorney General shall annually  
25 prepare and submit to the Committee on the Judiciary of

1 the House of Representatives and the Committee on the  
 2 Judiciary of the Senate a report concerning the activities  
 3 and debarment actions taken by the Attorney General  
 4 under this section.

5 (e) ASSISTANCE TO PREVENT CRIMINAL VIOLA-  
 6 TIONS.—The Attorney General, in cooperation with any  
 7 other appropriate individual, organization, or agency, may  
 8 provide advice, training, technical assistance, and guid-  
 9 ance regarding ways to reduce the incidence of improper  
 10 disclosure of protected health information.

11 (f) RELATIONSHIP TO OTHER AUTHORITIES.—A de-  
 12 barment imposed under this section shall not reduce or  
 13 diminish the authority of a Federal, State, or local govern-  
 14 mental agency or court to penalize, imprison, fine, sus-  
 15 pend, debar, or take other adverse action against a person,  
 16 in a civil, criminal, or administrative proceeding.

## 17 **CHAPTER 2—CIVIL SANCTIONS**

### 18 **SEC. 321. CIVIL PENALTY.**

19 A health care provider, health researcher, health  
 20 plan, health oversight agency, public health agency, law  
 21 enforcement agency, employer, health or life insurer,  
 22 school or university, agent or other person described in  
 23 section 102(a)(1), who the Secretary, in consultation with  
 24 the Attorney General, determines has substantially and  
 25 materially failed to comply with this Act shall be subject,

1 in addition to any other penalties that may be prescribed  
2 by law—

3 (1) in a case in which the violation relates to  
4 title I, to a civil penalty of not more than \$500 for  
5 each such violation, but not to exceed \$5,000 in the  
6 aggregate for multiple violations;

7 (2) in a case in which the violation relates to  
8 title II, to a civil penalty of not more than \$10,000  
9 for each such violation, but not to exceed \$50,000  
10 in the aggregate for multiple violations; or

11 (3) in a case in which such violations have oc-  
12 curred with such frequency as to constitute a gen-  
13 eral business practice, to a civil penalty of not more  
14 than \$100,000.

15 **SEC. 322. PROCEDURES FOR IMPOSITION OF PENALTIES.**

16 (a) INITIATION OF PROCEEDINGS.—The Attorney  
17 General, in consultation with the Secretary, may initiate  
18 a proceeding in United States District Court to recover  
19 a civil money penalty under section 321. The Attorney  
20 General may not initiate an action under this section with  
21 respect to any violation described in section 321 after the  
22 expiration of the 6-year period beginning on the date on  
23 which such violation was alleged to have occurred. The At-  
24 torney General may initiate an action under this section

1 by filing a complaint pursuant to Rule 4 of the Federal  
2 Rules of Civil Procedure.

3 (b) SCOPE OF PENALTY.—In determining the  
4 amount or scope of any penalty sought pursuant to section  
5 321, the Attorney General shall take into account—

6 (1) the nature of claims and the circumstances  
7 under which they were presented;

8 (2) the degree of culpability, history of prior of-  
9 fenses, and financial condition of the person against  
10 whom the claim is brought; and

11 (3) such other matters as justice may require.

12 (c) RECOVERY OF PENALTIES.—

13 (1) IN GENERAL.—Civil money penalties im-  
14 posed under this section may be recovered in a civil  
15 action in the name of the United States brought in  
16 United States district court for the district where  
17 the claim was presented, or where the claimant re-  
18 sides, as determined by the Attorney General.  
19 Amounts recovered under this section shall be paid  
20 to the United States and deposited as miscellaneous  
21 receipts of the Treasury of the United States.

22 (2) DEDUCTION FROM AMOUNTS OWING.—The  
23 amount of any penalty may be deducted from any  
24 sum then or later owing by the United States or a

1 State to the person against whom the penalty has  
2 been assessed.

3 (d) INJUNCTIVE RELIEF.—Whenever the Attorney  
4 General in consultation with the Secretary has reason to  
5 believe that any person has engaged, is engaging, or is  
6 about to engage in any activity which makes the person  
7 subject to a civil monetary penalty under section 321, the  
8 Attorney General may bring an action in an appropriate  
9 district court of the United States (or, if applicable, a  
10 United States court of any territory) to enjoin such activ-  
11 ity, or to enjoin the person from concealing, removing, en-  
12 cumbering, or disposing of assets which may be required  
13 in order to pay a civil monetary penalty if any such pen-  
14 alty were to be imposed or to seek other appropriate relief.

15 (e) AGENCY.—A principal is jointly and severally lia-  
16 ble with the principal's agent for penalties under section  
17 321 for the actions of the principal's agent acting within  
18 the scope of the agency.

19 **SEC. 323. CIVIL ACTION BY INDIVIDUALS.**

20 (a) IN GENERAL.—Any individual whose rights under  
21 this Act have been knowingly or negligently violated may  
22 bring a civil action to recover—

23 (1) such preliminary and equitable relief as the  
24 court determines to be appropriate; and

1           (2) the greater of compensatory damages or liq-  
2           uidated damages of \$5,000.

3           (b) PUNITIVE DAMAGES.—In any action brought  
4 under this section in which the individual has prevailed  
5 because of a knowing violation of a provision of this Act,  
6 the court may, in addition to any relief awarded under  
7 subsection (a), award such punitive damages as may be  
8 warranted.

9           (c) ATTORNEY'S FEES.—In the case of a civil action  
10 brought under subsection (a) in which the individual has  
11 substantially prevailed, the court may assess against the  
12 respondent a reasonable attorney's fee and other litigation  
13 costs and expenses (including expert fees) reasonably in-  
14 curred.

15          (d) LIMITATION.—No action may be commenced  
16 under this section more than 3 years after the date on  
17 which the violation was or should reasonably have been  
18 discovered.

19          (e) AGENCY.—A principal is jointly and severally lia-  
20 ble with the principal's agent for damages under this sec-  
21 tion for the actions of the principal's agent acting within  
22 the scope of the agency.

23          (f) VENUE; SERVICE OF PROCESS.—

24           (1) VENUE.—An action shall be brought under  
25           subsection (a) in the district court of the United

1 States that meets applicable requirements relating to  
2 venue under section 1391 of title 28, United States  
3 Code.

4 (2) SERVICE OF PROCESS.—In an action  
5 brought under subsection (a), process may be served  
6 in any district in which the defendant—

7 (A) is an inhabitant; and

8 (B) may be found.

9 (g) ADDITIONAL REMEDIES.—The equitable relief or  
10 damages that may be available under this section shall be  
11 in addition to any other lawful remedy or award that may  
12 be available.

13 **SEC. 324. ENFORCEMENT BY STATE ATTORNEYS GENERAL.**

14 (a) IN GENERAL.—

15 (1) CIVIL ACTIONS.—In any case in which the  
16 attorney general of a State or any State or local law  
17 enforcement agency authorized by the State attorney  
18 general or by State law to prosecute violations of  
19 consumer protection laws, has reason to believe that  
20 an interest of the residents of that State has been  
21 or is threatened or adversely affected by the engage-  
22 ment of a person in a practice that is prohibited  
23 under this subtitle, the State or local law enforce-  
24 ment agency on behalf of the residents of the agen-  
25 cy's jurisdiction, may bring a civil action on behalf

1 of the residents of the State or jurisdiction in a dis-  
2 trict court of the United States of appropriate juris-  
3 diction to—

4 (A) enjoin that act or practice;

5 (B) enforce compliance with this subtitle;

6 or

7 (C) obtain civil penalties of not more than  
8 \$1,000 per day per individual whose personally  
9 identifiable information was, or is reasonably  
10 believed to have been, accessed or acquired by  
11 an unauthorized person, up to a maximum of  
12 \$50,000 per day.

13 (2) NOTICE.—

14 (A) IN GENERAL.—Prior to filing an ac-  
15 tion under paragraph (1), the attorney general  
16 of the State involved shall provide to the Attor-  
17 ney General and Secretary—

18 (i) written notice of the action; and

19 (ii) a copy of the complaint for the ac-  
20 tion.

21 (B) EXEMPTION.—Subparagraph (A) shall  
22 not apply with respect to the filing of an action  
23 by a State attorney general under this sub-  
24 section, if the attorney general of a State deter-  
25 mines that it is not feasible to provide the no-



1           tice described in this paragraph before the filing  
2           of the action.

3           (C) NOTIFICATION WHEN PRACTICABLE.—

4           In an action described under subparagraph (B),  
5           the attorney general of a State shall provide the  
6           written notice and a copy of the complaint to  
7           the Attorney General and Secretary as soon  
8           after the filing of the complaint as practicable.

9           (b) FEDERAL PROCEEDINGS.—Upon receiving notice  
10          under subsection (a)(2), the Attorney General in consulta-  
11          tion with the Secretary, shall, have the right to—

12           (1) move to stay the action, pending the final  
13          disposition of a pending Federal proceeding or ac-  
14          tion;

15           (2) intervene in an action brought under sub-  
16          section (a)(2); and

17           (3) file petitions for appeal.

18          (c) PENDING PROCEEDINGS.—If the Attorney Gen-  
19          eral has instituted a proceeding or action for a violation  
20          of this subtitle or any regulations thereunder, no attorney  
21          general of a State may, during the pendency of such pro-  
22          ceeding or action, bring an action under this subtitle  
23          against any defendant named in such criminal proceeding  
24          or civil action for any violation that is alleged in that pro-  
25          ceeding or action.

1 (d) RULE OF CONSTRUCTION.—For purposes of  
2 bringing any civil action under subsection (a), nothing in  
3 this subtitle regarding notification shall be construed to  
4 prevent an attorney general of a State from exercising the  
5 powers conferred on such attorney general by the laws of  
6 that State to—

- 7 (1) conduct investigations;
- 8 (2) administer oaths or affirmations; or
- 9 (3) compel the attendance of witnesses or the  
10 production of documentary and other evidence.

11 (e) VENUE; SERVICE OF PROCESS.—

12 (1) VENUE.—Any action brought under sub-  
13 section (a) may be brought in the district court of  
14 the United States that meets applicable require-  
15 ments relating to venue under section 1391 of title  
16 28, United States Code.

17 (2) SERVICE OF PROCESS.—In an action  
18 brought under subsection (a), process may be served  
19 in any district in which the defendant—

20 (A) is an inhabitant; or

21 (B) may be found.

22 **SEC. 325. PROTECTION FOR WHISTLEBLOWER.**

23 (a) PROHIBITION AGAINST DISCRIMINATION.—An  
24 employer may not discharge, demote, suspend, threaten,  
25 harass, retaliate against, or in any other manner discrimi-

1 nate or cause any employer to discriminate against an em-  
2 ployee in the terms and conditions of employment because  
3 of any lawful act committed by the employee to provide  
4 information or cause information to be provided to a State  
5 or Federal official relating to an actual or suspected viola-  
6 tion of this Act by an employer or an employee of an em-  
7 ployer.

8 (b) ENFORCEMENT ACTIONS.—

9 (1) IN GENERAL.—Any employee or former em-  
10 ployee who alleges discharge or discrimination by  
11 any person in violation of subsection (a) may seek  
12 relief under subsection (c), by—

13 (A) filing a complaint with the Secretary of  
14 Labor; or

15 (B) if the Secretary has not issued a final  
16 decision within 180 days of the filing of the  
17 complaint under subparagraph (A), and there is  
18 no showing that such delay is due to the bad  
19 faith of the claimant, bringing an action at law  
20 or equity for de novo review in the appropriate  
21 district court of the United States, which shall  
22 have jurisdiction over such an action without  
23 regard to the amount in controversy.

24 (2) PROCEDURES.—

1 (A) IN GENERAL.—Except as provided in  
2 this paragraph, the complaint procedures con-  
3 tained in section 42121(b) of title 49, United  
4 States Code, shall apply with respect to a com-  
5 plaint filed under paragraph (1)(A).

6 (B) EXCEPTION.—With respect to a com-  
7 plaint filed under paragraph (1)(A), the notifi-  
8 cation provided for under section 42121(b)(1)  
9 of title 49, United States Code, (as required  
10 under subparagraph (A)) shall be made to the  
11 person named in the complaint and to the em-  
12 ployer.

13 (C) BURDEN OF PROOF.—The legal bur-  
14 dens of proof contained in section 42121(b) of  
15 title 49, United States Code, shall apply to an  
16 action brought under paragraph (1)(B).

17 (D) STATUTE OF LIMITATIONS.—An action  
18 shall be filed under paragraph (1)(B), not later  
19 than 2 years after the date on which the alleged  
20 violation occurs.

21 (c) REMEDIES.—

22 (1) IN GENERAL.—If the district court deter-  
23 mines in an action under subsection (b)(1) that a  
24 violation of subsection (a) has occurred, the court

1 shall order any relief necessary to make the em-  
2 ployee whole.

3 (2) COMPENSATORY DAMAGES.—Relief in any  
4 action under subsection (b)(1) shall include—

5 (A) reinstatement of the employee to the  
6 employee’s former position with the same se-  
7 niority status that the employee would have had  
8 but for the discrimination;

9 (B) payment of the amount of back pay,  
10 with interest, to which the employee is entitled;  
11 and

12 (C) the payment of compensation for any  
13 special damages sustained by the employee as a  
14 result of the discrimination, including litigation  
15 costs, expert witness fees, and reasonable attor-  
16 ney fees.

17 (d) RIGHTS RETAINED BY THE EMPLOYEE.—Noth-  
18 ing in this section shall be construed to diminish or elimi-  
19 nate the rights, privileges, or remedies available to an em-  
20 ployee under any Federal or State law, or under any col-  
21 lective bargaining agreement.

22 (e) LIMITATION.—The protections of this section  
23 shall not apply to any employee who—

24 (1) deliberately causes or participates in the al-  
25 leged violation; or

1           (2) knowingly or recklessly provides materially  
2 false information to an individual or entity described  
3 in subsection (a).

4           (f) DEFINITIONS.—In this section:

5           (1) EMPLOY.—The term “employ” has the  
6 meaning given such term under section 3(g) of the  
7 Fair Labor Standards Act of 1938 (29 U.S.C.  
8 203(g)) for the purposes of implementing the re-  
9 quirements of that Act (29 U.S.C. 201, et seq.).

10           (2) EMPLOYEE.—The term “employee” means  
11 an individual who is employed by an employer.

12           (3) EMPLOYER.—The term “employer” means  
13 any person who employs employees, including any  
14 person acting directly or indirectly in the interest of  
15 any employer in relation to an employee and in-  
16 cludes a public agency.

17           (g) GENERAL PROHIBITION AGAINST RETALIA-  
18 TION.—A person described in section 102(a)(1), or any  
19 other person that receives protected health information  
20 under this title, may not adversely affect another person,  
21 directly or indirectly, because such person has exercised  
22 a right under this Act, disclosed information relating to  
23 a possible violation of this Act, or associated with, or as-  
24 sisted, an individual in the exercise of a right under this  
25 Act.

1       **TITLE IV—MISCELLANEOUS**

2       **SEC. 401. RELATIONSHIP TO OTHER LAWS.**

3       (a) FEDERAL AND STATE LAWS.—Nothing in this  
4 Act shall be construed as preempting, superseding, or re-  
5 pealing, explicitly or implicitly, other Federal or State laws  
6 or regulations relating to protected health information or  
7 relating to an individual’s access to protected health infor-  
8 mation or health care services, if such laws or regulations  
9 provide protections for the rights of individuals to the pri-  
10 vacy of, and access to, their health information that is  
11 greater than those provided for in this Act.

12       (b) PRIVILEGES.—Nothing in this Act shall be con-  
13 strued to preempt or modify any provisions of State statu-  
14 tory or common law to the extent that such law concerns  
15 a privilege of a witness or person in a court of that State.  
16 This Act shall not be construed to supersede or modify  
17 any provision of Federal statutory or common law to the  
18 extent such law concerns a privilege of a witness or entity  
19 in a court of the United States. Authorizations pursuant  
20 to section 202 shall not be construed as a waiver of any  
21 such privilege.

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

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

3           (2) requires the reporting of abuse or neglect  
4           information about any individual;

5           (3) regulates the disclosure or reporting of in-  
6           formation concerning an individual's mental health;  
7           or

8           (4) governs a minor's rights to access protected  
9           health information or health care services.

10          (d) FEDERAL PRIVACY ACT.—

11           (1) MEDICAL EXEMPTIONS.—Section 552a of  
12           title 5, United States Code, is amended by adding  
13           at the end the following:

14           “(w) CERTAIN PROTECTED HEALTH INFORMA-  
15           TION.—The head of an agency that is a health care pro-  
16           vider, health plan, health oversight agency, employer, in-  
17           surer, health or life insurer, school or university, or other  
18           entity who receives protected health information under  
19           section 218 of the Health Information Privacy and Secu-  
20           rity Act shall promulgate rules, in accordance with the re-  
21           quirements (including general notice) of subsections  
22           (b)(1), (b)(2), (b)(3), (c), (e) of section 553 of this title,  
23           to exempt a system of records within the agency, to the  
24           extent that the system of records contains protected health  
25           information (as defined in section 4 of such Act), from



1 all provisions of this section except subsections (b)(6), (d),  
2 (e)(1), (e)(2), subparagraphs (A) through (C) and (E)  
3 through (I) of subsection (e)(4), and subsections (e)(5),  
4 (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).”.

5 (2) TECHNICAL AMENDMENT.—Section  
6 552a(f)(3) of title 5, United States Code, is amend-  
7 ed by striking “pertaining to him,” and all that fol-  
8 lows through the semicolon and inserting “per-  
9 taining to the individual”.

10 (e) HEALTH INSURANCE PORTABILITY AND AC-  
11 COUNTABILITY ACT.—The standards governing the pri-  
12 vacy and security of individually identifiable health infor-  
13 mation promulgated by the Secretary of Health and  
14 Human Services under sections 262(a) and 264 of the  
15 Health Insurance Portability and Accountability Act of  
16 1996 shall remain in effect to the extent that they are  
17 consistent with this Act. The Secretary shall amend such  
18 Federal regulations as required to make such regulations  
19 consistent with this Act.

20 **SEC. 402. EFFECTIVE DATE.**

21 (a) EFFECTIVE DATE.—Unless specifically provided  
22 for otherwise, this Act shall take effect on the date that  
23 is 12 months after the date of the promulgation of the  
24 regulations required under subsection (b), or 30 months

1 after the date of enactment of this Act, whichever is ear-  
2 lier.

3 (b) REGULATIONS.—Not later than 12 months after  
4 the date of enactment of this Act, or as specifically pro-  
5 vided for otherwise, the Secretary shall promulgate regula-  
6 tions implementing this Act.

○