

106TH CONGRESS  
1ST SESSION

# H. R. 2404

To protect the privacy of individuals by ensuring the confidentiality of information contained in their medical records and health-care-related information, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 30, 1999

Mr. MURTHA introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To protect the privacy of individuals by ensuring the confidentiality of information contained in their medical records and health-care-related information, and for other purposes.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the  
5 “Personal Medical Information Protection Act of 1999”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—INDIVIDUAL’S RIGHTS

Subtitle A—Review of Protected Health Information by Subjects of the Information

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Amendment of protected health information.
- Sec. 103. Notice of confidentiality practices.

Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Procurement of authorizations for disclosure of protected health information for treatment, payment, and health care operations.
- Sec. 203. Authorizations for disclosure of protected health information other than for treatment, payment, or health care operations.
- Sec. 204. Next of kin and directory information.
- Sec. 205. Emergency circumstances.
- Sec. 206. Oversight.
- Sec. 207. Public health.
- Sec. 208. Health research.
- Sec. 209. Disclosure in civil, judicial, and administrative procedures.
- Sec. 210. Disclosure for law enforcement purposes.
- Sec. 211. Payment card and electronic payment transaction.
- Sec. 212. Standards for electronic disclosures.
- Sec. 213. Individual representatives.
- Sec. 214. Limited liability for law enforcement officers.
- Sec. 215. No liability for permissible disclosures.

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

- Sec. 301. Wrongful disclosure of protected health information.

Subtitle B—Civil Sanctions

- Sec. 311. Civil penalty.
- Sec. 312. Procedures for imposition of penalties.
- Sec. 313. Civil action by individuals.
- Sec. 314. Alternative dispute resolution.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. Notification of seniors
- Sec. 403. Effective date.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that—

3 (1) individuals have a right of confidentiality  
4 with respect to their personal health information and  
5 records;

6 (2) the personal and protected medical informa-  
7 tion of an individual is uniquely private and should  
8 only be disclosed with proper consent;

9 (4) an individual's protected medical informa-  
10 tion contains sensitive and personal details that  
11 could cause professional and personal embarrass-  
12 ment and stigmatization, even impermissible dis-  
13 crimination, if such information is released without  
14 authorization;

15 (5) with respect to information about medical  
16 care and health status, the traditional right of con-  
17 fidentiality is at risk;

18 (6) an erosion of the right of confidentiality  
19 may reduce the willingness of patients to confide in  
20 physicians and other practitioners, thus jeopardizing  
21 quality health care;

22 (7) an individual's confidentiality right means  
23 that an individual's consent is needed to disclose his  
24 or her protected health information, except in rare  
25 and limited circumstances required by the public in-  
26 terest;

1           (8) any disclosure of protected health informa-  
2           tion should be limited to that information or portion  
3           of the medical record necessary to fulfill the purpose  
4           of the disclosure;

5           (9) incentives need to be created to use non-  
6           identifiable health information where appropriate;

7           (10) the availability of timely and accurate per-  
8           sonal health data for the delivery of health care serv-  
9           ices throughout the Nation is needed;

10          (11) personal health care data may be essential  
11          for selected types of medical research;

12          (12) public health uses of personal health data  
13          are critical to both personal health as well as public  
14          health; and

15          (13) confidentiality of an individual's health in-  
16          formation must be assured without jeopardizing the  
17          pursuit of clinical and epidemiological research un-  
18          dertaken to improve health care and health outcomes  
19          and to assure the quality and efficiency of health  
20          care.

21 **SEC. 3. PURPOSES.**

22          The purposes of this Act are to—

23               (1) establish strong and effective mechanisms  
24               to protect against the unauthorized and inappro-  
25               priate use of protected health information that is

1 created or maintained as part of health care treat-  
2 ment, diagnosis, enrollment, payment, plan adminis-  
3 tration, testing, or research processes;

4 (2) promote the efficiency and security of the  
5 health information infrastructure so that members  
6 of the health care community may more effectively  
7 exchange and transfer health information in a man-  
8 ner that will ensure the confidentiality of protected  
9 health information without impeding the delivery of  
10 high quality health care;

11 (3) create incentives to turn personal health in-  
12 formation into nonidentifiable health information for  
13 oversight, health research, public health, law en-  
14 forcement, judicial, and administrative purposes,  
15 where appropriate;

16 (4) establish strong and effective remedies for  
17 violations of this Act; and

18 (5) establish a national board to oversee imple-  
19 mentation of this Act, promulgate rules and regula-  
20 tions, serve as an advisory body on the subject of  
21 protecting personal medical information and make  
22 recommendations to the President on improving the  
23 mechanisms for protecting the privacy of personal  
24 medical information, without stifling research and  
25 the free flow of scientific medical data.

1 **SEC. 4. DEFINITIONS.**

2 As used in this Act:

3 (1) ACCREDITING BODY.—The term “accred-  
4 iting body” means a national body, committee, orga-  
5 nization, or institution (such as the Joint Commis-  
6 sion on Accreditation of Health Care Organizations  
7 or the National Committee for Quality Assurance)  
8 that has been authorized by law or is recognized by  
9 a health care regulating authority as an accrediting  
10 entity or any other entity that has been similarly au-  
11 thorized or recognized by law to perform specific ac-  
12 creditation, licensing or credentialing activities.

13 (2) AGENT.—The term “agent” means a person  
14 who represents and acts for another under the con-  
15 tract or relation of agency, or whose function is to  
16 bring about, modify, affect, accept performance of,  
17 or terminate contractual obligations between the  
18 principal and a third person, including a contractor.

19 (3) ANONYMOUS LINK.—

20 (A) IN GENERAL.—The term “anonymous  
21 link” means a number assigned to nonidentifi-  
22 able health information which, by itself, con-  
23 tains no information about an individual, but  
24 which, under specific, controlled conditions, can  
25 be used to link to additional health information

1           about the same individual which may be used to  
2           identify that individual.

3           (B) DISCLOSURE.—Any subsequent disclo-  
4           sure of an anonymous link with any information  
5           which, together with information previously dis-  
6           closed with the same link might reasonably be  
7           used to identify an individual, shall be consid-  
8           ered to be a disclosure of protected health infor-  
9           mation. Such a disclosure shall convert any pre-  
10          viously disclosed, nonidentifiable information  
11          with the same link into protected health infor-  
12          mation.

13          (4) COMMON RULE.—The term “common rule”  
14          means the Federal policy for the protection of  
15          human subjects from research risks originally pub-  
16          lished as 56 Federal Register 28012 (et seq.) (June  
17          18, 1991) as adopted and implemented by a Federal  
18          department or agency.

19          (5) DISCLOSE.—The term “disclose” means to  
20          release, transfer, provide access to, or otherwise di-  
21          vulge protected health information to any person  
22          other than the individual who is the subject of such  
23          information. Such term includes the initial disclosure  
24          and any subsequent disclosures of protected health  
25          information.

1           (6) EMPLOYER.—The term “employer” has the  
2 meaning given such term under section 3(5) of the  
3 Employee Retirement Income Security Act of 1974  
4 (29 U.S.C. 1002(5)), except that such term shall in-  
5 clude only employers of two or more employees.

6           (7) HEALTH CARE.—The term “health care”  
7 means—

8           (A) preventive, diagnostic, therapeutic, re-  
9 habilitative, maintenance, or palliative care, in-  
10 cluding appropriate assistance with disease or  
11 symptom management and maintenance, coun-  
12 seling, service, or procedure—

13           (i) with respect to the physical or  
14 mental condition of an individual; or

15           (ii) affecting the structure or function  
16 of the human body or any part of the  
17 human body, including the banking of  
18 blood, sperm, organs, or any other tissue;  
19 or

20           (B) pursuant to a prescription or medical  
21 order any sale or dispensing of a drug, device,  
22 equipment, or other health care related item to  
23 an individual, or for the use of an individual.

24           (8) HEALTH CARE OPERATIONS.—The term  
25 ‘health care operations’ means services provided by



1 or on behalf of a health plan or health care provider  
2 for the purpose of carrying out the management  
3 functions of a health care provider or health plan, or  
4 implementing the terms of a contract for health plan  
5 benefits. Such term means—

6 (A) conducting quality assurance activities  
7 or outcomes assessments;

8 (B) reviewing the competence or qualifica-  
9 tions of health care professionals;

10 (C) performing accreditation, licensing, or  
11 credentialing activities;

12 (D) analysis of health plan claims or  
13 health care records data;

14 (E) evaluating health plan and provider  
15 performance;

16 (F) carrying out utilization review,  
17 precertification or preauthorization of services;

18 (G) underwriting or experience rating of  
19 health plans;

20 (H) conducting or arranging for auditing  
21 services; or

22 (I) such other services as the

23 Secretary determines appropriate.

24 (9) HEALTH CARE PROVIDER.—The term  
25 “health care provider” means a person, who with re-

1       spect to a specific item of protected health informa-  
2       tion, receives, creates, uses, maintains, or discloses  
3       the information while acting in whole or in part in  
4       the capacity of—

5               (A) a person who is licensed, certified, reg-  
6               istered, or otherwise authorized by Federal or  
7               State law to provide an item or service that  
8               constitutes health care in the ordinary course of  
9               business, or practice of a profession;

10              (B) a Federal, State, or employer spon-  
11              sored program that directly provides items or  
12              services that constitute health care to bene-  
13              ficiaries; or

14              (C) an officer, employee, or agent of a per-  
15              son described in subparagraph (A) or (B) that  
16              is engaged in the provision of health care.

17              (10) HEALTH OR LIFE INSURER.—The term  
18              “health or life insurer” means a health insurance  
19              issuer as defined in section 9805(b)(2) of the Inter-  
20              nal Revenue Code of 1986 or a life insurance com-  
21              pany as defined in section 816 of such Code.

22              (11) HEALTH OVERSIGHT AGENCY.—The term  
23              “health oversight agency” means a person who, with  
24              respect to a specific item of protected health infor-  
25              mation, receives, creates, uses, maintains, or dis-

1 closes the information while acting in whole or in  
2 part in the capacity of—

3 (A) a person who performs or oversees the  
4 performance of an assessment, evaluation, de-  
5 termination, or investigation, relating to the li-  
6 censing, accreditation, or credentialing of health  
7 care providers; or

8 (B) a person who—

9 (i) performs or oversees the perform-  
10 ance of an audit, assessment, evaluation,  
11 determination, or investigation relating to  
12 the effectiveness of, compliance with, or  
13 applicability of, legal, fiscal, medical, or  
14 scientific standards or aspects of perform-  
15 ance related to the delivery of, or payment  
16 for, health care; and

17 (ii) is a public agency, acting on be-  
18 half of a public agency, acting pursuant to  
19 a requirement of a public agency, or car-  
20 rying out activities under a Federal or  
21 State law governing the assessment, eval-  
22 uation, determination, investigation, or  
23 prosecution described in subparagraph (A).

24 (12) HEALTH PLAN.—The term “health plan”  
25 means any health insurance plan, including any hos-

1       pital or medical service plan, dental or other health  
2       service plan or health maintenance organization  
3       plan, provider sponsored organization, or other pro-  
4       gram providing or arranging for the provision of  
5       health benefits. Such term includes employee welfare  
6       benefits plans and group health plans as defined in  
7       sections 3 and 607 of the Employee Retirement In-  
8       come Security Act of 1974 (29 U.S.C. 1002 and  
9       1167).

10               (13) HEALTH RESEARCHER.—The term “health  
11       researcher” means a person, or an officer, employee  
12       or independent contractor of a person, who receives  
13       protected health information as part of a systematic  
14       investigation, testing or evaluation designed to de-  
15       velop or contribute to generalized scientific and clin-  
16       ical knowledge.

17               (14) INDIVIDUAL REPRESENTATIVE.—The term  
18       “individual representative” means a person who is  
19       authorized by law or by an instrument recognized  
20       under law, to act as an agent, attorney, proxy, or  
21       other legal representative of a protected individual.  
22       Such term includes a health care power of attorney.

23               (15) LAW ENFORCEMENT INQUIRY.—The term  
24       “law enforcement inquiry” means a lawful investiga-  
25       tion conducted by an appropriate government agency

1 or official inquiring into a violation of, or failure to  
2 comply with, any criminal or civil statute or any reg-  
3 ulation, rule, or order issued pursuant to such a  
4 statute.

5 (16) NETWORK PLAN.—The term “network  
6 plan” means health care coverage provided under a  
7 health plan under which the financing and delivery  
8 of health care are provided, in whole or in part,  
9 through a defined set of health care providers under  
10 contract with the health plan.

11 (17) NONIDENTIFIABLE HEALTH INFORMA-  
12 TION.—The term “nonidentifiable health informa-  
13 tion” means any information that would otherwise  
14 be protected health information except that such in-  
15 formation does not directly reveal the identity of the  
16 individual whose health or health care is the subject  
17 of the information and there is no reasonable basis  
18 to believe that such information could be used, either  
19 alone or with other information that is, or should  
20 reasonably be known to be, available to predictable  
21 recipients of such information, to reveal the identity  
22 of that individual.

23 (18) ORIGINATING PROVIDER.—The term “orig-  
24 inating provider” means a health care provider who

1 creates or originates medical information that is or  
2 that becomes protected health information.

3 (19) PAYMENT.—The term “payment”  
4 means—

5 (A) the activities undertaken by—

6 (i) or on behalf of a health plan to de-  
7 termine its responsibility for coverage  
8 under the plan and the actual payment  
9 under such plan; and

10 (ii) a health care provider to obtain  
11 payment for items or services provided  
12 under a health plan or provided based on  
13 a determination by the health plan of re-  
14 sponsibility for coverage under the plan;  
15 and

16 (B) activities undertaken as described in  
17 subparagraph (A) including—

18 (i) billing, claims management, med-  
19 ical data processing or other administrative  
20 services;

21 (ii) determinations of coverage or ad-  
22 judication of health benefit claims; and

23 (iii) review of health care services with  
24 respect to medical necessity, coverage

1 under a health plan, appropriateness of  
2 care, or justification of charges.

3 (20) PERSON.—The term “person” means a  
4 government, governmental subdivision, agency or au-  
5 thority, corporation, company, association, firm,  
6 partnership, society, estate, trust, joint venture, indi-  
7 vidual, individual representative, tribal government,  
8 and any other legal entity.

9 (21) PROTECTED HEALTH INFORMATION.—The  
10 term “protected health information” means any in-  
11 formation (including demographic information)  
12 whether or not recorded in any form or medium—

13 (A) that relates to the past, present or  
14 future—

15 (i) physical or mental health or condi-  
16 tion of an individual (including the condi-  
17 tion or other attributes of individual cells  
18 or their components, including genetic and  
19 pharmaceutical information);

20 (ii) provision of health care to an indi-  
21 vidual; or

22 (iii) payment for the provision of  
23 health care to an individual;

24 (B) that is created or received by a health  
25 care provider, health plan, health researcher,

1 health oversight agency, public health authority,  
2 employer, law enforcement official, health or life  
3 insurer, school or university; and

4 (C) that is not nonidentifiable health infor-  
5 mation.

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

11 (A) primarily responsible for public health  
12 matters; and

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

16 (23) SCHOOL OR UNIVERSITY.—The term  
17 “school or university” means an institution or place  
18 for instruction or education, including an elementary  
19 school, secondary school, or institution of higher  
20 learning, a college, or an assemblage of colleges  
21 united under one corporate organization or govern-  
22 ment.

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



1           (25) 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           (26) TREATMENT.—The term “treatment”  
6           means the provision of health care by, or the coordi-  
7           nation of health care among, health care providers,  
8           or the referral of a patient from one provider to an-  
9           other, or coordination of health care or other serv-  
10          ices among health care providers and third parties  
11          authorized by the health plan or the plan member.

12          (27) WRITING.—The term “writing” means  
13          writing in either a paper-based or computer-based  
14          form, including electronic signatures.

15       **TITLE I—INDIVIDUAL’S RIGHTS**  
16       **Subtitle A—Review of Protected**  
17       **Health Information by Subjects**  
18       **of the Information**

19       **SEC. 101. INSPECTION AND COPYING OF PROTECTED**  
20       **HEALTH INFORMATION.**

21       (a) RIGHT OF INDIVIDUAL.—

22           (1) IN GENERAL.—A health care provider,  
23           health plan, employer, health or life insurer, school,  
24           or university, or a person acting as the agent of any  
25           such person, shall permit an individual who is the

1 subject of protected health information, or the indi-  
2 vidual's designee, to inspect and copy protected  
3 health information concerning the individual, includ-  
4 ing records created under sections 102, 112, 202,  
5 203, 208, and 211, that such person maintains.

6 (2) PROCEDURES AND FEES.—A person de-  
7 scribed in paragraph (1) may set forth appropriate  
8 procedures to be followed for inspection and copying  
9 under such paragraph and may require an individual  
10 to pay fees associated with such inspection and copy-  
11 ing in an amount that is not in excess of the actual  
12 costs of providing such copying. Such procedures  
13 and fees shall not be inconsistent with current State  
14 law governing the inspection and copying of medical  
15 records.

16 (b) DEADLINE.—A person described in subsection  
17 (a)(1) shall comply with a request for inspection or copy-  
18 ing of protected health information under this section in  
19 good faith and within a reasonable timeframe after the  
20 date on which the person receives the request in writing.

21 (c) RULES GOVERNING AGENTS.—A person acting as  
22 the agent of a person described in subsection (a) shall pro-  
23 vide for the inspection and copying of protected health in-  
24 formation if—

1 (1) the protected health information is retained  
2 by the agency; and

3 (2) the agent has been asked by the person in-  
4 volved to fulfill the requirements of this section.

5 (d) SPECIAL RULE RELATING TO ONGOING CLINICAL  
6 TRIALS.—With respect to protected health information  
7 that is created as part of an individual’s participation in  
8 an ongoing clinical trial, access to the information shall  
9 be provided consistent with the individual’s agreement to  
10 participate in the clinical trial.

11 **SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-**  
12 **TION.**

13 (a) REQUIREMENTS.—

14 (1) IN GENERAL.—Except as provided in sub-  
15 sections (b) and (e), not later than 45 days after the  
16 date on which a health care provider, health plan,  
17 employer, health or life insurer, school, or university  
18 receives from an individual a request in writing to  
19 correct or amend information that meets the re-  
20 quirements of paragraph (2), such entity shall—

21 (A) make the correction or amendment re-  
22 quested;

23 (B) inform the individual of the amend-  
24 ment that has been made; and

1 (C) inform the individual of any other per-  
2 son to whom the unamended portion of the in-  
3 formation was previously disclosed.

4 (2) INFORMATION.—The requirements of this  
5 paragraph are that the information that is the sub-  
6 ject of the request is in fact inaccurate.

7 (b) REFUSAL TO AMEND.—If an entity described in  
8 subsection (a) refuses to make the correction or amend-  
9 ment requested under such subsection, the entity shall in-  
10 form the individual in writing of—

11 (1) the reasons for the refusal to make the  
12 amendment;

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

15 (3) the individual's right to file with the entity  
16 a concise statement setting forth the requested  
17 amendment and the individual's reasons for dis-  
18 agreeing with the refusal.

19 (c) STATEMENT OF DISAGREEMENT.—If an indi-  
20 vidual has filed a statement of disagreement under sub-  
21 section (b)(3), the entity involved—

22 (1) shall ensure such statement is retained as  
23 a permanent part of the file not to be separated  
24 from the disputed information;

1           (2) shall include a copy of the individual's  
2           statement in any subsequent disclosure of the dis-  
3           puted information; and

4           (3) may include a concise statement of the rea-  
5           sons for not making the requested amendment.

6           (d) RULES GOVERNING AGENTS.—The agent of an  
7           entity described in subsection (a) shall not be required to  
8           make amendments to protected health information, except  
9           where—

10           (1) the protected health information is retained  
11           by the agent; and

12           (2) the agent has been asked by such entity to  
13           fulfill the requirements of this section.

14           If the agent is required to comply with this section as pro-  
15           vided for in paragraph (2), such agent shall be subject  
16           to the 45-day deadline described in subsection (a).

17           (e) EXTENSION FOR PAPER RECORDS OFF PREM-  
18           ISES.—In the case of a request described in subsection (a),  
19           if the information involved is in paper form, located off  
20           the premises of the entity involved, and not readily avail-  
21           able, the entity shall have 60 days to comply with or deny  
22           such request.

23           (f) RULES OF CONSTRUCTION.—This section shall  
24           not be construed to—

1           (1) require that an entity described in sub-  
2           section (a) conduct a formal, informal, or other  
3           hearing or proceeding concerning a request for an  
4           amendment to protected health information.

5           (2) require a provider to amend an individual's  
6           record as to the type, duration, or quality of treat-  
7           ment the individual believes he or she should have  
8           been provided; or

9           (3) require any deletion or alteration of the  
10          original information.

11 **SEC. 103. NOTICE OF CONFIDENTIALITY PRACTICES.**

12          (a) PREPARATION OF WRITTEN NOTICE.—A health  
13          care provider, health plan, health oversight agency, public  
14          health authority, employer, health or life insurer, health  
15          researcher, school, or university shall post or provide, in  
16          writing and in a clear and conspicuous manner, notice of  
17          the entity's confidentiality practices, that shall include—

18               (1) a description of an individual's rights with  
19               respect to protected health information;

20               (2) the uses and disclosures of protected health  
21               information authorized under this Act;

22               (3) the procedures for authorizing disclosures of  
23               protected health information and for revoking such  
24               authorizations;

1 (4) the procedures established by the entity for  
2 the exercise of the individual's rights; and

3 (5) the right to obtain a copy of the notice of  
4 the confidentiality practices required under this Act.

5 (b) MODEL NOTICE.—The Secretary, after notice  
6 and opportunity for public comment, shall develop and dis-  
7 seminate model notices of confidentiality practices. Use of  
8 the model notice shall serve as an absolute defense against  
9 claims of receiving inappropriate notice.

## 10 **Subtitle B—Establishment of** 11 **Safeguards**

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

13 (a) IN GENERAL.—A health care provider, health  
14 plan, health oversight agency, public health authority, em-  
15 ployer, health or life insurer, health researcher, law en-  
16 forcement official, school, or university shall establish and  
17 maintain appropriate administrative, technical, and phys-  
18 ical safeguards to protect the confidentiality, security, ac-  
19 curacy, and integrity of protected health information cre-  
20 ated, received, obtained, maintained, used, transmitted, or  
21 disposed of by such entity.

22 (b) ENCRYPTION TECHNOLOGY.—Custodians that  
23 maintain medical records on a computer data base should  
24 implement encryption technology whenever possible to pro-  
25 tect the unauthorized disclosure of protected health infor-

1 mation. Custodians should also seek to anonymize medical  
2 records to the fullest extent practicable through the use  
3 of coding and the removal of personally identifiable infor-  
4 mation within an individual's medical records.

5 (c) REGULATIONS.—The Secretary shall have the au-  
6 thority to promulgate regulations for the implementation  
7 of subsections (a) and (b).

8 (d) RULE OF CONSTRUCTION.—Safeguards to pro-  
9 tect the security of protected health information under  
10 subsection (a) shall include the implementation of policies  
11 or procedures to consider whether protected health infor-  
12 mation is essential for a use of disclosure undertaken by  
13 an entity described in such subsection.

14 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

15 (a) IN GENERAL.—

16 (1) HEALTH RELATED ENTITIES.—Except as  
17 provided in paragraph (3), a health care provider,  
18 health plan, health oversight agency, public health  
19 authority, employer, health or life insurer, health re-  
20 searcher, law enforcement official, school, or univer-  
21 sity shall establish and maintain, with respect to any  
22 protected health information disclosure, a record of  
23 such disclosure in accordance with regulations issued  
24 by the Secretary.



1           (2) AGENT.—Except as provided in paragraph  
2           (3), an agent shall maintain a record of its disclo-  
3           sures made pursuant to sections 205 through 212.

4           (3) EXCEPTION.—A record of disclosures under  
5           this subsection is not required with respect to disclo-  
6           sures made to officers or employees of the entity  
7           that maintains the record involved who, in the per-  
8           formance of their duties, have a need for the pro-  
9           tected health information.

10          (b) RECORD OF DISCLOSURE.—A record established  
11          under subsection (a) shall be maintained for not less than  
12          7 years.

## 13           **TITLE II—RESTRICTIONS ON** 14           **USE AND DISCLOSURE**

### 15          **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-** 16           **SURE.**

17          (a) PROHIBITION.—

18           (1) GENERAL RULE.—A health care provider,  
19           health plan, health oversight agency, public health  
20           authority, employer, health or life insurer, health re-  
21           searcher, law enforcement official, school, or univer-  
22           sity may not disclose protected health information  
23           except as authorized under this title.

24           (2) RULE OF CONSTRUCTION.—Disclosure of  
25           health information in the form of nonidentifiable

1 health information shall not be construed as a dis-  
2 closure of protected health information.

3 (b) USE OR DISCLOSURE OF PROTECTED HEALTH  
4 INFORMATION WITHIN AN ENTITY.—

5 (1) IN GENERAL.—An entity described in sub-  
6 section (a) may use protected health information or  
7 disclose such information within the entity if such  
8 use or disclosure is made pursuant to an authoriza-  
9 tion under section 202 or 203 and consistent with  
10 the limitations under subsection (d) on the scope of  
11 disclosure.

12 (2) AGENTS.—Disclosure to agents of an entity  
13 described in subsection (a) shall be considered as a  
14 disclosure within an entity.

15 (c) DISCLOSURE BY AGENTS.—An agent who receives  
16 protected health information from an entity described in  
17 subsection (a) shall be subject to all rules of disclosure  
18 and safeguard requirements under this title.

19 (d) SCOPE OF DISCLOSURE.—Every disclosure of  
20 protected health information by an entity under this title  
21 shall be limited to the information necessary to accomplish  
22 the purpose for which the information is disclosed.

23 (e) NO GENERAL REQUIREMENT TO DISCLOSE.—  
24 Nothing in this title permitting the disclosure of protected

1 health information shall be construed to require such dis-  
2 closure.

3 (f) LABELING OF DISCLOSED INFORMATION AS PRO-  
4 TECTED INFORMATION.—Except as otherwise provided in  
5 this title, protected health information may not be dis-  
6 closed unless such information is clearly labeled as pro-  
7 tected health information that is subject to this Act.

8 (g) CREATION OF NONIDENTIFIABLE INFORMA-  
9 TION.—An entity described in subsection (a) may disclose  
10 protected health information to an employee or agent of  
11 the entity for purposes of creating nonidentifiable infor-  
12 mation, if the entity prohibits the employee or agent of  
13 the entity from using or disclosing the protected health  
14 information for purposes other than the sole purpose of  
15 creating nonidentifiable information as specified by the en-  
16 tity.

17 (h) REDISCLOSURE PROHIBITED.—Once authoriza-  
18 tion for disclosure of personal medical information has  
19 been granted, the recipient cannot release the information  
20 to another third party without the prior written consent  
21 of the individual that meets the requirements of section  
22 102(a).

1 **SEC. 202. PROCUREMENT OF AUTHORIZATIONS FOR DIS-**  
2 **CLOSURE OF PROTECTED HEALTH INFORMA-**  
3 **TION FOR TREATMENT, PAYMENT, AND**  
4 **HEALTH CARE OPERATIONS.**

5 (a) REQUIREMENTS RELATING TO EMPLOYERS,  
6 HEALTH PLANS, UNINSURED INDIVIDUALS, AND PRO-  
7 VIDERS.—

8 (1) IN GENERAL.—To meet the requirements  
9 relating to the authorized disclosure of protected  
10 health information under section 201, an authoriza-  
11 tion form must be secured for each individual in  
12 connection with treatment, payment and health care  
13 operations.

14 (2) CONSOLIDATED AUTHORIZATION.—A single  
15 authorization may be secured for each individual in  
16 connection with treatment, payment, and health care  
17 operations.

18 (3) EMPLOYERS.—Every employer offering a  
19 health plan to its employees shall, at the time of,  
20 and as a condition of enrollment in the health plan,  
21 obtain a signed, written authorization that is a legal,  
22 informed authorization concerning the use and dis-  
23 closure of protected health information for treat-  
24 ment, payment, and health care operations with re-  
25 spect to each individual who is eligible to receive  
26 care under the health plan.

1           (4) HEALTH PLANS.—Every health plan offer-  
2           ing enrollment to individual or non-employer groups  
3           shall, at the time of, and as a condition of enroll-  
4           ment in the health plan, obtain a signed, written au-  
5           thorization that is a legal, informed authorization  
6           concerning the use and disclosure of protected health  
7           information for treatment, payment, and health care  
8           operations with respect to each individual who is eli-  
9           gible to receive care under the plan.

10           (5) UNINSURED.—An originating provider pro-  
11           viding health care to an uninsured individual, shall  
12           obtain a signed, written authorization that is a legal,  
13           informed authorization concerning the use and dis-  
14           closure of protected health information, in providing  
15           health care or arranging for health care from other  
16           providers or seeking payment for the provision of  
17           health care services.

18           (b) REQUIREMENTS FOR INDIVIDUAL AUTHORIZA-  
19           TION.—To be valid, an authorization to disclose protected  
20           health information shall—

21           (1) identify the individual involved;

22           (2) describe the nature of the health care infor-  
23           mation to be disclosed;

24           (3) identify the type of person to whom the in-  
25           formation is to be disclosed;

1           (4) describe the purpose of the disclosure, in-  
2           cluding whether the information may be used for  
3           disease management or medication compliance;

4           (5) be subject to revocation by the individual  
5           and indicate that the authorization is valid until rev-  
6           ocation by the individual; and

7           (6)(A) be either—

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 a unique identi-  
12                fier; and

13           (B) not have been revoked under paragraph (c).

14           (c) REVOCATION OF AUTHORIZATION.—

15           (1) IN GENERAL.—An individual may revoke in  
16           writing an authorization under this section at any  
17           time, unless the disclosure that is the subject of the  
18           authorization is required to effectuate payment for  
19           health care that has been provided to the individual  
20           for which the individual has not agreed to assume  
21           personal financial responsibility.

22           (2) EXCEPTION FOR SELF-PAYMENT.—An indi-  
23           vidual may revoke a prior authorization for payment  
24           or health care operations described in paragraphs  
25           (1) through (6) of subsection (a) prior to a single or

1 series of encounters with a health care provider if  
2 such individual has agreed to assume personal finan-  
3 cial responsibility for the treatment.

4 (3) HEALTH PLANS.—With respect to a health  
5 plan, the authorization of an individual is deemed to  
6 be revoked at the time of the cancellation or non-re-  
7 newal of enrollment in the health plan, except as  
8 may be necessary to complete health care operations  
9 and payment requirements related to the individual’s  
10 period of enrollment.

11 (4) ACTIONS.—An individual may not maintain  
12 an action against a person for disclosure of pro-  
13 tected health information made in good faith reli-  
14 ance on the individual’s authorization at the time  
15 disclosure was made.

16 (d) RECORD OF INDIVIDUAL’S AUTHORIZATION AND  
17 REVOCATIONS.—

18 (1) IN GENERAL.—Each person collecting or  
19 storing protected health information shall maintain  
20 a record for a period of 7 years of each authoriza-  
21 tion of an individual and revocation thereof.

22 (2) RULE OF CONSTRUCTION.—Records of au-  
23 thORIZATIONS and revocations maintained under para-  
24 graph (1) shall not be construed to be protected  
25 health information under this Act.

1 (e) NO WAIVER.—Except as provided for in this Act,  
2 an authorization to disclose protected health information  
3 by an individual shall not be construed as a waiver of any  
4 rights that the individual has under other Federal or State  
5 laws, the rules of evidence, or common law.

6 (f) RULE OF CONSTRUCTION.—Authorizations for  
7 the disclosure of protected health information for treat-  
8 ment, payment, and health care operations shall not au-  
9 thorize the disclosure of such information by an individual  
10 with the intent to sell, transfer, or use protected health  
11 information for the purpose of marketing a product or  
12 service. For such disclosures a separate authorization is  
13 required under section 203.

14 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**  
15 **TECTED HEALTH INFORMATION OTHER THAN**  
16 **FOR TREATMENT, PAYMENT, OR HEALTH**  
17 **CARE OPERATIONS.**

18 (a) WRITTEN AUTHORIZATIONS.—A health care pro-  
19 vider, health plan, health oversight agency, health re-  
20 searcher, public health authority, law enforcement official,  
21 employer, health or life insurer, school, or university may  
22 disclose protected health information, for purposes other  
23 than those authorized under section 202, pursuant to an  
24 authorization executed by the individual who is the subject



1 of the information that meets the requirements of section  
2 202(b).

3 Such an authorization shall be separate from an au-  
4 thorization provided under section 202.

5 (b) LIMITATION ON AUTHORIZATIONS.—An entity  
6 described in section 202 may not condition the delivery  
7 of treatment or payment for services on the receipt of an  
8 authorization described in this section.

9 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-  
10 TION.—

11 (1) IN GENERAL.—An individual may in writing  
12 revoke or amend an authorization described in sub-  
13 section (a).

14 (2) NOTICE OF REVOCATION.—An entity de-  
15 scribed in subsection (a) that discloses protected  
16 health information pursuant to an authorization that  
17 has been revoked under paragraph (1) shall not be  
18 subject to any liability or penalty under this title if  
19 that entity had no actual or constructive notice of  
20 the revocation.

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

24 (1) IN GENERAL.—When a Coroner or Medical  
25 Examiner or their duly appointed deputies seek pro-

1        tected health information for the purpose of inquiry  
2        into and determination of, the cause, manner, and  
3        circumstances of a death, the health care provider,  
4        health plan, health oversight agency, public health  
5        authority, employer, health or life insurer, health re-  
6        searcher, law enforcement official, school, or univer-  
7        sity involved shall provide the protected health infor-  
8        mation to the Coroner or Medical Examiner or to  
9        the duly appointed deputies without undue delay.

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

19            (3) EXEMPTION.—Health information attached  
20        to or otherwise made a part of a Coroner’s or Med-  
21        ical Examiner’s official report, shall be exempt from  
22        the provisions of this Act except as provided for in  
23        this subsection.

24            (4) REIMBURSEMENT.—A Coroner or Medical  
25        Examiner may require a person to reimburse their

1 Office for the reasonable costs associated with such  
2 inspection or copying.

3 (e) DISCLOSURE FOR PURPOSE ONLY.—A recipient  
4 of information pursuant to an authorization under this  
5 section may use or disclose such information solely to  
6 carry out the purpose for which the information was au-  
7 thorized for release.

8 (f) MODEL AUTHORIZATIONS.—The Secretary, after  
9 notice and opportunity for public comment, shall develop  
10 and disseminate model written authorizations of the type  
11 described in subsection (a). Any authorization obtained on  
12 a model authorization form developed by the Secretary  
13 shall be deemed to meet the authorization requirements  
14 of this section.

15 **SEC. 204. NEXT OF KIN AND DIRECTORY INFORMATION.**

16 (a) NEXT OF KIN.—A health care provider, or a per-  
17 son who receives protected health information under sec-  
18 tion 205, may disclose protected health information re-  
19 garding an individual to the individual's spouse, parent,  
20 child, sister, brother, next of kin, or individual representa-  
21 tive if—

22 (1) the individual who is the subject of the pro-  
23 tected health information is physically or mentally  
24 incapacitated such that the individual is not capable

1 of authorizing the disclosure and there are no prior  
2 indications that the individual would object; and

3 (2) the disclosure of the protected health infor-  
4 mation to parties described in this subsection—

5 (A) is necessary for the purpose of aiding  
6 said parties in making a necessary decision re-  
7 garding the individual’s treatment that would  
8 be the prerogative of the individual if the indi-  
9 vidual were not incapacitated;

10 (B) is consistent with good medical or pro-  
11 fessional practice; and

12 (C) is not inconsistent with State laws in  
13 effect prior to the effective date of this Act gov-  
14 erning the release of medical records to parties  
15 described in this subsection.

16 (b) DIRECTORY INFORMATION.—

17 (1) DISCLOSURE.—

18 (A) IN GENERAL.—Except as provided in  
19 paragraph (2), a person described in subsection  
20 (a) may disclose the information described in  
21 subparagraph (B) to any person if the indi-  
22 vidual who is the subject of the information—

23 (i) has been notified of the individ-  
24 ual’s right to object and the individual has  
25 not objected to the disclosure; or

1                   (ii) is in a physical or mental condi-  
2                   tion such that the individual is not capable  
3                   of objecting, the individual's next of kin  
4                   has not objected, and there are no prior in-  
5                   dications that the individual would object.

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

9                   (i) The name of the individual who is  
10                  the subject of the information.

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

15                  (iii) The location of the individual on  
16                  premises controlled by a provider.

17                  (2) EXCEPTION.—

18                  (A) LOCATION.—Paragraph (1)(B)(iii)  
19                  shall not apply if disclosure of the location of  
20                  the individual would reveal specific information  
21                  about the physical or mental condition of the  
22                  individual, unless the individual expressly au-  
23                  thorizes such disclosure.

24                  (B) DIRECTORY OF NEXT OF KIN INFOR-  
25                  MATION.—A disclosure may not be made under

1           this section if the health care provider involved  
2           has reason to believe that the disclosure of di-  
3           rectory or next of kin information could lead to  
4           the physical or mental harm of the individual,  
5           unless the individual expressly authorizes such  
6           disclosure.

7 **SEC. 205. EMERGENCY CIRCUMSTANCES.**

8           Any person who creates or receives protected health  
9           information under this title may disclose protected health  
10          information in emergency circumstances when necessary  
11          to protect the health or safety of the individual who is  
12          the subject of such information from serious, imminent  
13          harm. No disclosure made in the good faith belief that  
14          the disclosure was necessary to protect the health or safety  
15          of an individual from serious, imminent harm shall be in  
16          violation of, or punishable under, this Act.

17 **SEC. 206. OVERSIGHT.**

18          (a) IN GENERAL.—Any person may disclose pro-  
19          tected health information to an accrediting body or public  
20          health authority, a health oversight agency, or a State in-  
21          surance department, for purposes of an oversight function  
22          authorized by law.

23          (b) PROTECTION FROM FURTHER DISCLOSURE.—  
24          Protected health information that is disclosed under this  
25          section shall not be further disclosed by an accrediting

1 body or public health authority, a health oversight agency,  
2 a State insurance department, or their agents for any pur-  
3 pose unrelated to the authorized oversight function. Not-  
4 withstanding any other provision of law, protected health  
5 information disclosed under this section shall be protected  
6 from further disclosure by an accrediting body or public  
7 health authority, a health oversight agency, a State insur-  
8 ance department, or their agents pursuant to a subpoena,  
9 discovery request, introduction as evidence, testimony, or  
10 otherwise.

11 (c) AUTHORIZATION BY A SUPERVISOR.—For pur-  
12 poses of this section, the individual with authority to au-  
13 thorize the oversight function involved shall provide to the  
14 person described in subsection (a) a statement that the  
15 protected health information is being sought for a legally  
16 authorized oversight function.

17 (d) USE IN ACTION AGAINST INDIVIDUALS.—Pro-  
18 tected health information about an individual that is dis-  
19 closed under this section may not be used by the recipient  
20 in, or disclosed by the recipient to any person for use in,  
21 an administrative, civil, or criminal action or investigation  
22 directed against the individual who is the subject of the  
23 protected health information unless the action or inves-  
24 tigation arises out of and is directly related to—

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

3           (2) a fraudulent claim related to health care, or  
4 a fraudulent or material misrepresentation of the  
5 health of the individual.

6 **SEC. 207. PUBLIC HEALTH.**

7           A health care provider, health plan, public health au-  
8 thority, employer, health or life insurer, law enforcement  
9 official, school, or university may disclose protected health  
10 information to a public health authority or other person  
11 authorized by law for use in a legally authorized—

12           (1) disease or injury report;

13           (2) public health surveillance; or

14           (3) public health investigation or intervention.

15 **SEC. 208. HEALTH RESEARCH.**

16           (a) IN GENERAL.—A health care provider, health  
17 plan, public health authority, employer, health or life in-  
18 surer, school, or university may disclose protected health  
19 information to a health researcher if—

20           (1) the research involves human subjects con-  
21 ducted or supported by any Federal department or  
22 agency and the researcher complies with the com-  
23 mon rule;

24           (2) the research is a clinical investigation in-  
25 volving human subjects and the researcher follows



1 the regulations of the Food and Drug Administra-  
2 tion governing confidentiality procedures; or

3 (3) the research is not subject to the Federal  
4 Policy for the Protection of Human Subjects.

5 (b) PERIODIC REVIEW AND TECHNICAL ASSISTANCE  
6 OF INSTITUTIONAL REVIEW BOARDS INVOLVED WITH  
7 THE FEDERAL POLICY FOR PROTECTION OF HUMAN  
8 SUBJECTS.—

9 (1) INSTITUTIONAL REVIEW BOARD.—Any in-  
10 stitutional review board that authorizes research  
11 under this section pursuant to the common rule shall  
12 keep records of the names and addresses of all mem-  
13 bers who participate in such authorizations for pos-  
14 sible review or audit.

15 (2) TECHNICAL ASSISTANCE.—The Secretary  
16 may provide technical assistance to institutional re-  
17 view boards described in this section.

18 (3) MONITORING.—The Secretary shall periodi-  
19 cally monitor institutional review boards described in  
20 this section.

21 (4) REPORTS.—Not later than 3 years after the  
22 date of enactment of this Act, the Secretary shall re-  
23 port to Congress regarding the activities of institu-  
24 tional review boards described in this section.

1           (c) REVIEW OF THE COMMON RULE BY THE SEC-  
2 RETARY.—The Secretary shall review the requirements of  
3 the common rule pertaining to the privacy of protected  
4 health information and shall promulgate any amendments  
5 to the common rule that may be necessary to ensure the  
6 confidentiality of such information.

7           (d) RECOMMENDATIONS WITH RESPECT TO PRI-  
8 VACY.—

9           (1) IN GENERAL.—Not later than the date that  
10 is 12 months after the date of the enactment of this  
11 Act, the Secretary shall submit to Congress detailed  
12 recommendations on standards with respect to the  
13 privacy of individually identifiable health information  
14 in research described in subsection (a)(3).

15           (2) RULE OF CONSTRUCTION.—In formulating  
16 the recommendations under paragraph (1), the Sec-  
17 retary shall consider the findings of the National  
18 Bioethics Advisory Commission and the results of  
19 the General Accounting Office report authorized by  
20 section 402.

21           (3) REGULATIONS.—If legislation governing  
22 standards with respect to the privacy of individually  
23 identifiable health information transmitted in con-  
24 nection with research described in subsection (a)(3)  
25 is not enacted by the date that is 24 months after

1 the date of the enactment of this Act, the Secretary  
2 shall promulgate final regulations containing such  
3 standards not later than the date that is 30 months  
4 after the date of the enactment of this Act.

5 **SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINIS-**  
6 **TRATIVE PROCEDURES.**

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 may  
10 disclose protected health information pursuant to a dis-  
11 covery request or subpoena in a civil action brought in  
12 a Federal or State court or a request or subpoena related  
13 to a Federal or State administrative proceeding, but only  
14 if the disclosure is made pursuant to a court order as pro-  
15 vided for in subsection (b).

16 (b) COURT ORDERS.—

17 (1) STANDARD FOR ISSUANCE.—In considering  
18 a request for a court order regarding the disclosure  
19 of protected health information under subsection (a),  
20 the court shall issue such order if the court deter-  
21 mines that without the disclosure of such informa-  
22 tion, the person requesting the order would be im-  
23 paired from establishing a claim or defense.

24 (2) REQUIREMENTS.—An order issued under  
25 paragraph (1) shall—

1 (A) provide that the protected health infor-  
2 mation involved is subject to court protection;

3 (B) specify to whom the information may  
4 be disclosed;

5 (C) specify that such information may not  
6 otherwise be disclosed or used; and

7 (D) meet any other requirements that the  
8 court determines are needed to protect the con-  
9 fidentiality of the information.

10 (c) APPLICABILITY.—This section shall not apply in  
11 a case in which the protected health information sought  
12 under such discovery request or subpoena—

13 (1) is nonidentifiable health information;

14 (2) is related to a party to the litigation whose  
15 medical condition is at issue; or

16 (3) could be disclosed under any of sections 202  
17 through 208, 210, and 212.

18 (d) EFFECT OF SECTION.—This section shall not be  
19 construed to supersede any grounds that may apply under  
20 Federal or State law for objecting to turning over the pro-  
21 tected health information.

22 **SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PUR-**  
23 **POSES.**

24 (a) IN GENERAL.—A health care provider, health  
25 plan, health oversight agency, employer, health or life in-

1 surer, school, university, or person who receives protected  
2 health information pursuant to sections 203 through 208,  
3 may disclose protected health information under this sec-  
4 tion, except to a health oversight agency governed by sec-  
5 tion 206, if the disclosure is pursuant to—

6 (1) a subpoena issued under the authority of a  
7 grand jury;

8 (2) an administrative subpoena or summons or  
9 judicial subpoena or warrant; or

10 (3) a Federal or State law requiring the report-  
11 ing of specific medical information to law enforce-  
12 ment authorities.

13 (b) PROBABLE CAUSE.—A subpoena or summons for  
14 a disclosure under paragraph (1) or (2) of subsection (a)  
15 shall only be issued if the law enforcement agency involved  
16 shows that there is probable cause to believe that the in-  
17 formation is relevant to a legitimate law enforcement in-  
18 quiry.

19 (c) DESTRUCTION OR RETURN OF INFORMATION.—  
20 When the matter or need for which protected health infor-  
21 mation was disclosed to a law enforcement agency or  
22 grand jury under subsection (a) has concluded, including  
23 any derivative matters arising from such matter or need,  
24 the law enforcement agency or grand jury shall either de-

1 stroy the protected health information, or return it to the  
2 person from whom it was obtained.

3 (d) REDACTIONS.—To the extent practicable, and  
4 consistent with the requirements of due process, a law en-  
5 forcement agency shall redact personally identifying infor-  
6 mation from protected health information prior to the  
7 public disclosure of such protected information in a judi-  
8 cial or administrative proceeding.

9 (e) USE OF INFORMATION.—Protected health infor-  
10 mation obtained by a law enforcement agency pursuant  
11 to this section may only be used for purposes of a legiti-  
12 mate law enforcement activity.

13 (f) EXCLUSION OF EVIDENCE.—If protected health  
14 information is obtained without meeting the requirements  
15 of paragraphs (1), (2), and (3) of subsection (a), any such  
16 information that is unlawfully obtained shall be excluded  
17 from court proceedings unless the defendant requests oth-  
18 erwise.

19 **SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT**  
20 **TRANSACTION.**

21 (a) PAYMENT FOR HEALTH CARE THROUGH CARD  
22 OR ELECTRONIC MEANS.—If an individual pays for health  
23 care by presenting a debit, credit, or other payment card  
24 or account number, or by any other electronic payment  
25 means, the entity receiving payment may disclose to a per-

1 son described in subsection (b) only such protected health  
2 information about the individual as is necessary for the  
3 processing of the payment transaction or the billing or col-  
4 lection of amounts charged to, debited from, or otherwise  
5 paid by, the individual using the card, number, or other  
6 electronic means.

7 (b) TRANSACTION PROCESSING.—A person who is a  
8 debit, credit, or other payment card issuer, or is otherwise  
9 directly involved in the processing of payment transactions  
10 involving such cards or other electronic payment trans-  
11 actions, or is otherwise directly involved in the billing or  
12 collection of amounts paid through such means, may use  
13 or disclose protected health information about an indi-  
14 vidual that has been disclosed in accordance with sub-  
15 section (a) only when necessary for—

16 (1) the authorization, settlement, billing or col-  
17 lection of amounts charged to, debited from, or oth-  
18 erwise paid the individual using a debit, credit, or  
19 other payment card or account number, or by other  
20 electronic payment means;

21 (2) the transfer of receivables, accounts, or in-  
22 terest therein;

23 (3) the audit of the debit, credit, or other pay-  
24 ment card account information;

1 (4) compliance with Federal, State, or local law;

2 or

3 (5) compliance with a properly authorized civil,  
4 criminal, or regulatory investigation by Federal,  
5 State, or local authorities as governed by the re-  
6 quirements of this section.

7 **SEC. 212. STANDARDS FOR ELECTRONIC DISCLOSURES.**

8 The Secretary shall promulgate standards for dis-  
9 closing, authorizing, and authenticating, protected health  
10 information in electronic form consistent with this title.

11 **SEC. 213. INDIVIDUAL REPRESENTATIVES.**

12 (a) IN GENERAL.—Except as provided in subsections  
13 (b) and (c), a person who is authorized by law (based on  
14 grounds other than the individual being a minor), or by  
15 an instrument recognized under law, to act as an agent,  
16 attorney, proxy, or other legal representative of a pro-  
17 tected individual, may, to the extent so authorized, exer-  
18 cise and discharge the rights of the individual under this  
19 Act.

20 (b) HEALTH CARE POWER OF ATTORNEY.—A person  
21 who is authorized by law (based on grounds other than  
22 being a minor), or by an instrument recognized under law,  
23 to make decisions about the provision of health care to  
24 an individual who is incapacitated, may exercise and dis-  
25 charge the rights of the individual under this Act to the



1 extent necessary to effectuate the terms or purposes of  
2 the grant of authority.

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

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

13 (2) a person described in subsection (a) with re-  
14 spect to the individual, but only if a person de-  
15 scribed in paragraph (1) cannot be contacted after  
16 a reasonable effort;

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

20 (4) the health care provider, but only if a per-  
21 son described in paragraph (1), (2); or

22 (5) cannot be contacted after a reasonable ef-  
23 fort.

24 (d) APPLICATION TO DECEASED INDIVIDUALS.—The  
25 provisions of this Act shall continue to apply to protected

1 health information concerning a deceased individual for a  
2 period of 2 years following the death of that individual.

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

14 **SEC. 214. LIMITED LIABILITY FOR LAW ENFORCEMENT OF-**  
15 **FICERS.**

16 Federal and State law enforcement officers shall not  
17 be personally liable for violations of this Act unless it is  
18 shown that the violation was a result of intentional con-  
19 duct committed with the intent to sell, transfer, or use  
20 protected health information for commercial advantage,  
21 personal gain, or malicious harm.

22 **SEC. 215. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

23 A health care provider, health plan, health oversight  
24 agency, health researcher, public health authority, law en-  
25 forcement official, employer, health or life insurer, school,

1 or university who makes a disclosure of protected health  
 2 information about an individual that is permitted by this  
 3 Act shall not be liable to the individual for such disclosure  
 4 under common law.

## 5 **TITLE III—SANCTIONS**

### 6 **Subtitle A—Criminal Provisions**

#### 7 **SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED** 8 **HEALTH INFORMATION.**

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

#### 11 **“CHAPTER 124—WRONGFUL DISCLOSURE** 12 **OF PROTECTED HEALTH INFORMATION**

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

#### 13 **“§ Sec. 2801. Wrongful disclosure of protected health** 14 **information**

15 “(a) OFFENSE.—The penalties described in sub-  
 16 section (b) shall apply to a person that knowingly and  
 17 intentionally—

18 “(1) obtains protected health information relat-  
 19 ing to an individual in violation of title II of the Per-  
 20 sonal Medical Information Protection Act of 1999;

21 “(2) discloses protected health information to  
 22 another person in violation of title II of the Personal  
 23 Medical Information Protection Act of 1999; or

1           “(3) uses protected health information in viola-  
2           tion of title II of the Personal Medical Information  
3           Protection Act of 1999.

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

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

8           “(2) if the offense is committed under false pre-  
9           tenses, be fined not more than \$250,000, imprisoned  
10          not more than 5 years, or any combination of such  
11          penalties;

12          “(3) if the offense is committed with the intent  
13          to sell, transfer, or use protected health information  
14          for commercial advantage, personal gain, or mali-  
15          cious harm, be fined not more than \$500,000, im-  
16          prisoned not more than 20 years, excluded from par-  
17          ticipation in any federally funded health care pro-  
18          grams, or any combination of such penalties.

19          “(c) SUBSEQUENT OFFENSES.—In the case of a per-  
20          son described in subsection (a), the maximum penalties  
21          described in subsection (b) shall be doubled for every sub-  
22          sequent conviction for an offense arising out of a violation  
23          or violations related to a set of circumstances that are dif-  
24          ferent from those involved in the previous violation or set  
25          of related violations described in such subsection (a).”.

1 (b) CLERICAL AMENDMENT.—The Table of chapters  
 2 for part I of title 18, United States Code, is amended by  
 3 inserting after the item relating to chapter 123 the fol-  
 4 lowing new item:

“124. **Wrongful disclosure of protected health informa-**  
**tion** ..... **2801”.**

## 5 **Subtitle B—Civil Sanctions**

### 6 **SEC. 311. CIVIL PENALTY.**

7 (a) VIOLATION.—A health care provider, health re-  
 8 searcher, health plan, health oversight agency, public  
 9 health agency, law enforcement agency, employer, health  
 10 or life insurer, school, or university, or the agent of any  
 11 such individual or entity, who the Secretary, in consulta-  
 12 tion with the Attorney General, determines has substan-  
 13 tially and materially failed to comply with this Act shall  
 14 be subject, in addition to any other penalties that may  
 15 be prescribed by law—

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

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

1           (3) in a case in which the Secretary finds that  
2           such violations have occurred with such frequency as  
3           to constitute a general business practice, to a civil  
4           penalty of not more than \$100,000.

5           (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—  
6           Section 1128A of the Social Security Act, other than sub-  
7           sections (a) and (b) and the second sentence of subsection  
8           (f) of that section, shall apply to the imposition of a civil,  
9           monetary, or exclusionary penalty under this section in the  
10          same manner as such provisions apply with respect to the  
11          imposition of a penalty under section 1128A of such Act.

12       **SEC. 312. PROCEDURES FOR IMPOSITION OF PENALTIES.**

13          (a) INITIATION OF PROCEEDINGS—

14               (1) IN GENERAL.—The Secretary, in consulta-  
15               tion with the Attorney general, may initiate a pro-  
16               ceeding to determine whether to impose a civil  
17               money penalty under section 311. The Secretary  
18               may not initiate an action under this section with re-  
19               spect to any violation described in section 311 after  
20               the expiration of the 6-year period beginning on the  
21               date on which such violation was alleged to have oc-  
22               curred. The Secretary may initiate an action under  
23               this section by serving notice of the action in any  
24               manner authorized by rule 4 of the Federal Rules of  
25               Civil Procedure.

1           (2) NOTICE AND OPPORTUNITY FOR HEAR-  
2           ING.—The Secretary shall not make a determination  
3           adverse to any person under paragraph (1) until the  
4           person has been given written notice and an oppor-  
5           tunity for the determination to be made on the  
6           record after a hearing at which the person is entitled  
7           to be represented by counsel, to present witnesses,  
8           and to cross-examine witnesses against the person.

9           (3) ESTOPPEL.—In a proceeding under para-  
10          graph (1) that—

11                 (A) is against a person who has been con-  
12                 victed (whether upon a verdict after trial or  
13                 upon a plea of guilty or nolo contendere) of a  
14                 crime under section 2801 of title 18, United  
15                 States Code; and

16                 (B) involves the same conduct as in the  
17                 criminal action; the person is estopped from de-  
18                 nying the essential elements of the criminal of-  
19                 fense.

20          (4) SANCTIONS FOR FAILURE TO COMPLY.—  
21          The official conducting a hearing under this section  
22          may sanction a person, including any party or attor-  
23          ney, for failing to comply with an order or proce-  
24          dure, failing to defend an action, or other mis-  
25          conduct as would interfere with the speedy, orderly,

1 or fair conduct of the hearing. Such sanction shall  
2 reasonably relate to the severity and nature of the  
3 failure or misconduct. Such sanction may include—

4 (A) in the case of refusal to provide or per-  
5 mit discovery, drawing negative factual infer-  
6 ences of treating such refusal as an admission  
7 by deeming the matter, or certain facts , to be  
8 established;

9 (B) prohibiting a party from introducing  
10 certain evidence or otherwise supporting a par-  
11 ticular claim or defense;

12 (C) striking pleadings, in whole or in part;

13 (D) staying the proceedings;

14 (E) dismissal of the action:

15 (F) entering a default judgment;

16 (G) ordering the party or attorney to pay  
17 attorneys' fees and other costs caused by the  
18 failure or misconduct; and

19 (H) refusing to consider any motion or  
20 other action which is not filed in a timely man-  
21 ner.

22 (b) SCOPE OF PENALTY.—In determining the  
23 amount or scope of any penalty imposed pursuant to sec-  
24 tion 311, the Secretary shall take into account—



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

3           (2) the degree of culpability, history of prior of-  
4           fenses, and financial condition of the person pre-  
5           senting the claims; and

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

7           (c) REVIEW OF DETERMINATION.—

8           (1) IN GENERAL.—Any person adversely af-  
9           fected by a determination of the Secretary under  
10          this section may obtain a review of such determination  
11          in the United States Court of Appeals for the circuit  
12          in which the person resides, or which the claim was  
13          presented, by filing in such court (within 60 days  
14          following the date the person is notified of the deter-  
15          mination of the Secretary) a written petition re-  
16          questing that the determination be modified or set  
17          aside.

18          (2) FILING OF RECORD.—A copy of the petition  
19          filed under paragraph (1) shall be forthwith trans-  
20          mitted by the clerk of the court to the Secretary,  
21          and thereupon the Secretary shall file in the court  
22          the record in the proceeding as provided in section  
23          2112 of title 28, United States Code. Upon such fil-  
24          ing, the court shall have jurisdiction of the pro-  
25          ceeding and of the question determined therein, and

1 shall have the power to make and enter upon the  
2 pleadings, testimony, and proceedings set forth in  
3 such record a decree affirming, modifying, remand-  
4 ing for further consideration, or setting aside, in  
5 whole or in part, the determination of the Secretary  
6 and enforcing the same to the extent that such order  
7 is affirmed or modified.

8 (3) CONSIDERATION OF OBJECTIONS.—No ob-  
9 jection that has not been raised before the Secretary  
10 with respect to a determination described in para-  
11 graph (1) shall be considered by the court, unless  
12 the failure or neglect to raise such objection shall be  
13 excused because of extraordinary circumstances.

14 (4) FINDINGS.—The findings of the Secretary  
15 with respect to questions of fact in an action under  
16 this subsection, if supported by substantial evidence  
17 on the record considered as a whole, shall be conclu-  
18 sive. If any party shall apply to the court for leave  
19 to adduce additional evidence and shall show to the  
20 satisfaction of the court that such additional evi-  
21 dence is material and that there were reasonable  
22 grounds for the failure to adduce such evidence in  
23 the hearing before, the Secretary, the court may  
24 order such additional evidence to be taken before the  
25 Secretary and to be made a part of the record. The

1 Secretary may modify findings as to facts, or make  
2 new findings, by reason of additional evidence so  
3 taken and filed, and shall file with the court such  
4 modified or new findings, and such findings with re-  
5 spect to questions of fact, if supported by substan-  
6 tial evidence on the record considered as a whole,  
7 and the recommendations of the Secretary, if any,  
8 for the modification or setting aside of the original  
9 order, shall be conclusive.

10 (5) EXCLUSIVE JURISDICTION.—Upon the filing  
11 of the record with the court under paragraph (2),  
12 the jurisdiction of the court shall be exclusive and its  
13 judgment and decree shall be final, except that the  
14 same shall be subject to review by the Supreme  
15 Court of the United States, as provided for in sec-  
16 tion 1254 of title 28, United States Code.

17 (d) RECOVERY OF PENALTIES.—

18 (1) IN GENERAL.—Civil money penalties im-  
19 posed under this subtitle may be compromised by  
20 the Secretary and may be recovered in a civil action  
21 in the name of the United States brought in United  
22 States district court for the district where the claim  
23 was presented, or where the claimant resides, as de-  
24 termined by the Secretary. Amounts recovered under  
25 this section shall be paid to the Secretary and depos-

1       ited as miscellaneous receipts of the Treasury of the  
2       United States.

3           (2) DEDUCTION FROM AMOUNTS OWING.—The  
4       amount of any penalty, when finally determined  
5       under this section, or the amount agreed upon in  
6       compromise under paragraph (1), may be deducted  
7       from any sum then or later owing by the United  
8       States or a State to the person against whom the  
9       penalty has been assessed.

10       (e) DETERMINATION FINAL.—A determination by  
11      the Secretary to impose a penalty under section 321 shall  
12      be final upon the expiration of the 60-day period referred  
13      to in subsection (c)(1). Matters that were raised or that  
14      could have been raised in a hearing before the Secretary  
15      or in an appeal pursuant to subsection (c) may not be  
16      raised as a defense to a civil action by the United States  
17      to collect a penalty under section 311.

18       (f) SUBPOENA AUTHORITY.—

19           (1) IN GENERAL.—For the purpose of any  
20      hearing, investigation, or other proceeding author-  
21      ized or directed under this section, or relative to any  
22      other matter within the jurisdiction of the Attorney  
23      General hereunder, the Attorney General, acting  
24      through the Secretary shall have the power to issue  
25      subpoenas requiring the attendance and testimony of

1 witnesses and the production of any evidence that  
2 relates to any matter under investigation or in ques-  
3 tion before the Secretary. Such attendance of wit-  
4 nesses and production of evidence at the designated  
5 place of such hearing, investigation, or other pro-  
6 ceeding may be required from any place in the  
7 United States or in any Territory or possession  
8 thereof.

9 (2) SERVICE.—Subpoenas of the Secretary  
10 under paragraph (1) shall be served by anyone au-  
11 thorized by the Secretary by delivering a copy there-  
12 of to the individual named therein.

13 (3) PROOF OF SERVICE.—A verified return by  
14 the individual serving the individual serving the sub-  
15 poena under this subsection setting forth the man-  
16 ner of service shall be proof of service.

17 (4) FEES.—Witnesses subpoenaed under this  
18 subsection shall be paid the same fees and mileage  
19 as are paid witnesses in the district court of the  
20 United States.

21 (5) REFUSAL TO OBEY.—In case of contumacy  
22 by, or refusal to obey a duly served upon, any per-  
23 son, any district court of the United States for the  
24 judicial district in which such person charged with  
25 contumacy or refusal to obey is found or resides or

1 transacts business, upon application by the Sec-  
2 retary, shall have jurisdiction to issue an order re-  
3 quiring such person to appear and give testimony, or  
4 to appear and produce evidence, or both. Any failure  
5 to obey such order of the court may be punished by  
6 the court as contempt thereof.

7 (g) INJUNCTIVE RELIEF.—Whenever the Secretary  
8 has reason to believe that any person has engaged, is en-  
9 gaging, or is about to engage in any activity which makes  
10 the person subject to a civil monetary penalty under sec-  
11 tion 311, the Secretary may bring an action in an appro-  
12 priate district court of the United States (or, if applicable,  
13 a United States court of any territory) to enjoin such ac-  
14 tivity, or to enjoin the person from concealing, removing,  
15 encumbering, or disposing of assets which may be required  
16 in order to pay a civil monetary penalty if any such pen-  
17 alty were to be imposed or to seek other appropriate relief.

18 (h) AGENCY.—A principal is liable for penalties  
19 under section 311 for the actions of the principal's agent  
20 acting within the scope of the agency.

21 **SEC. 313. CIVIL ACTION BY INDIVIDUALS.**

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

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

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

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

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

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

21       **SEC. 314. ALTERNATIVE DISPUTE RESOLUTION.**

22          (a) IN GENERAL.—The Secretary shall, within 2  
23          years following enactment of this Act, promulgate regula-  
24          tions to develop alternative dispute resolution procedures  
25          to resolve claims under section 314.

1           (b) METHODS OF ALTERNATIVE DISPUTE RESOLU-  
2 TION.—The regulations promulgated under subsection (a)  
3 may require that an individual, before filing a civil claim,  
4 pursue at least one avenue of alternative dispute resolu-  
5 tion, including—

6           (1) medication;

7           (2) arbitration; or

8           (3) the use of a process under which parties  
9 make early offers of settlements.

## 10           **TITLE IV—MISCELLANEOUS**

### 11           **SEC. 401. RELATIONSHIP TO OTHER LAWS.**

12           (a) FEDERAL AND STATE LAWS.—Nothing in this  
13 Act shall be construed as preempting, superseding, or re-  
14 pealing, explicitly or implicitly, other Federal or State laws  
15 or regulations relating to protected health information or  
16 relating to an individual’s access to protected health infor-  
17 mation or health care services, if such laws or regulations  
18 provide protections for the rights of individuals to the pri-  
19 vacy of, and access to, their health information that are  
20 greater than those provided for in this Act.

21           (b) PRIVILEGES.—Nothing in this Act shall be con-  
22 strued to preempt or modify any provisions of State statu-  
23 tory or common law to the extent that such law concerns  
24 a privilege of a witness or person in a court of that State.  
25 This Act shall not be constructed to supersede or modify



1 any provision of Federal statutory or common law to the  
2 extent such law concerns a privilege of a witness or person  
3 in a court of the United States. Authorizations pursuant  
4 to section 202 shall not be construed as a waiver of any  
5 such privilege.

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

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

11 (2) requires the reporting of abuse or neglect  
12 information about any individual;

13 (3) regulates the disclosure or reporting of in-  
14 formation concerning an individual’s mental health;  
15 or

16 (4) governs a minor’s rights to access protected  
17 health information or health care services.

18 (d) FEDERAL PRIVACY ACT.—

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

22 “(w) CERTAIN PROTECTED HEALTH INFORMA-  
23 TION.—The head of an agency that is a health care pro-  
24 vider, health plan, health oversight agency, employer, in-  
25 surer, health or life insurer, school or university, or person

1 who receives protected health information under section  
2 204 of the Personal Medical Information Protection Act  
3 shall promulgate rules, in accordance with the require-  
4 ments (including general notice) of subsections (b)(1),  
5 (b)(2), (b)(3), (c), (e) of section 553 of this title, to ex-  
6 empt a system of records within the agency, to the extent  
7 that the system of records contains protected health infor-  
8 mation (as defined in section 4 of such Act), from all pro-  
9 visions of this section except subsections (b)(6), (d),  
10 (e)(1), (e)(2), subparagraphs (A) through (C) and (E)  
11 through (I) of subsection (e)(4), and subsections (e)(5),  
12 (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (q), (r), and (u).”.

13           (2)       TECHNICAL       AMENDMENT.—Section  
14       552a(f)(3) of title 5, United States Code, is amend-  
15       ed by striking “pertaining to him,” and all that fol-  
16       lows through the semicolon and inserting “per-  
17       taining to the individual.”

18       (e) CONSTITUTION.—Nothing in this Act shall be  
19       construed to alter, diminish, or otherwise weaken existing  
20       legal standards under the Constitution regarding the con-  
21       fidentiality of protected health information.

22       **SEC. 402. NOTIFICATION OF SENIORS.**

23       The Secretary shall publish a pamphlet which ex-  
24       plains the provisions of this Act and the resulting final  
25       regulations in plain language as directed in the President’s

1 memorandum of June 1, 1998, to the heads of executive  
2 departments and agencies (63 Federal Register 31885, 3  
3 CFR 1998 Comp., p. 289) within 1 year from the effective  
4 date. The secretary shall also ensure that the contents of  
5 such pamphlet may be viewed and downloaded online free  
6 of charge through the website of the Department of  
7 Health and Human Services.

8 **SEC. 403. EFFECTIVE DATE.**

9 (a) EFFECTIVE DATE.—Unless specifically provided  
10 for otherwise, this Act shall take effect on the date that  
11 is 12 months after the date of the promulgation of the  
12 regulations required under subsection (b), or 30 months  
13 after the date of enactment of this Act, whichever is ear-  
14 lier.

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

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