

106TH CONGRESS
1ST SESSION

S. 881

To ensure confidentiality with respect to medical records and health care-related information, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 27, 1999

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

A BILL

To ensure confidentiality with respect to 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 “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.

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 use and disclosure of protected health information for treatment, payment, and health care operations.
- Sec. 203. Authorizations for use or disclosure of protected health information other than for treatment, payment, and 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. Individual representatives.
- Sec. 213. No liability for permissible disclosures.
- Sec. 214. Sale of business, mergers, etc.

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

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

Subtitle B—Civil Sanctions

- Sec. 311. Civil penalty violation.
- Sec. 312. Procedures for imposition of penalties.
- Sec. 313. Enforcement by State insurance commissioners.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. Conforming amendment.
- Sec. 403. Study by Institute of Medicine.
- Sec. 405. Effective date.

1 SEC. 2. FINDINGS.

2 The Congress finds that—

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

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

7 (3) an erosion of the right of confidentiality
8 may reduce the willingness of patients to confide in
9 physicians and other practitioners, thus jeopardizing
10 quality health care;

11 (4) an individual's confidentiality right means
12 that an individual's consent is needed to disclose his
13 or her protected health information, except in lim-
14 ited circumstances required by the public interest;

15 (5) any disclosure of protected health informa-
16 tion should be limited to that information or portion
17 of the medical record necessary to fulfill the purpose
18 of the disclosure;

19 (6) the availability of timely and accurate per-
20 sonal health data for the delivery of health care serv-
21 ices throughout the Nation is needed;

22 (7) personal health care data is essential for
23 medical research;

1 (8) public health uses of personal health data
2 are critical to both personal health as well as public
3 health; and

4 (9) confidentiality of an individual's health in-
5 formation must be assured without jeopardizing the
6 pursuit of clinical and epidemiological research un-
7 dertaken to improve health care and health outcomes
8 and to assure the quality and efficiency of health
9 care.

10 **SEC. 3. PURPOSES.**

11 The purpose of this Act is to—

12 (1) establish strong and effective mechanisms
13 to protect against the unauthorized and inappro-
14 priate disclosure of protected health information that
15 is created or maintained as part of health care treat-
16 ment, diagnosis, enrollment, payment, plan adminis-
17 tration, testing, or research processes;

18 (2) promote the efficiency and security of the
19 health information infrastructure so that members
20 of the health care community may more effectively
21 exchange and transfer health information in a man-
22 ner that will ensure the confidentiality of protected
23 health information without impeding the delivery of
24 high quality health care; and

1 (3) establish strong and effective remedies for
2 violations of this Act.

3 **SEC. 4. DEFINITIONS.**

4 As used in this Act:

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

15 (2) AGENT.—The term “agent” means a per-
16 son, including a contractor, who represents and acts
17 for another under the contract or relation of agency,
18 or whose function is to bring about, modify, effect,
19 accept performance of, or terminate contractual obli-
20 gations between the principal and a third person.

21 (3) COMMON RULE.—The term “common rule”
22 means the Federal policy for protection of human
23 subjects from research risks originally published as
24 56 Federal Register 28.025 (1991) as adopted and
25 implemented by a Federal department or agency.

1 (4) DISCLOSE AND DISCLOSURE.—

2 (A) DISCLOSE.—The term “disclose”
3 means to release, transfer, provide access to, or
4 otherwise divulge protected health information
5 to any person other than the individual who is
6 the subject of such information.

7 (B) DISCLOSURE.—

8 (i) IN GENERAL.—The term “disclo-
9 sure” refers to a release, transfer, provi-
10 sion for access to, or communication of in-
11 formation as described in subparagraph
12 (A).

13 (ii) USE.—The use of protected health
14 information by an authorized person and
15 its agents shall not be considered a disclo-
16 sure for purposes of this Act if the use is
17 consistent with the purposes for which the
18 information was lawfully obtained. Using
19 or providing access to health information
20 in the form of nonidentifiable health infor-
21 mation shall not be construed as a disclo-
22 sure of protected health information.

23 (5) EMPLOYER.—The term “employer” has the
24 meaning given such term under section 3(5) of the
25 Employee Retirement Income Security Act of 1974

1 (29 U.S.C. 1002(5)), except that such term shall in-
2 clude only employers of two or more employees.

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

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

10 (i) with respect to the physical or
11 mental condition of an individual; or

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

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

21 (7) HEALTH CARE OPERATIONS.—The term
22 “health care operations” means services provided by
23 or on behalf of a health plan or health care provider
24 for the purpose of carrying out the management
25 functions of a health care provider or health plan, or

1 implementing the terms of a contract for health plan
2 benefits, including—

3 (A) coordinating health care, including
4 health care management of the individual
5 through risk assessment and case management;

6 (B) conducting quality assessment and im-
7 provement activities, including outcomes evalua-
8 tion, clinical guideline development, and im-
9 provement;

10 (C) reviewing the competence or qualifica-
11 tions of health care professionals, evaluating
12 provider performance, and conducting health
13 care education, accreditation, certification, li-
14 censing, or credentialing activities;

15 (D) carrying out utilization review activi-
16 ties, including precertification and
17 preauthorization of services, and health plan
18 rating and insurance activities, including under-
19 writing, experience rating and reinsurance; and

20 (E) conducting or arranging for auditing
21 services, including fraud detection and compli-
22 ance programs.

23 (8) HEALTH CARE PROVIDER.—The term
24 “health care provider” means a person, who with re-
25 spect to a specific item of protected health informa-

1 tion, receives, creates, uses, maintains, or discloses
2 the information while acting in whole or in part in
3 the capacity of—

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

9 (B) a Federal, State, employer sponsored
10 or other privately sponsored program that di-
11 rectly provides items or services that constitute
12 health care to beneficiaries; or

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

15 (9) HEALTH OVERSIGHT AGENCY.—The term
16 “health oversight agency” means a person who, with
17 respect to a specific item of protected health infor-
18 mation, receives, creates, uses, maintains, or dis-
19 closes the information while acting in whole or in
20 part in the capacity of—

21 (A) a person who performs or oversees the
22 performance of an assessment, evaluation, de-
23 termination, or investigation, relating to the li-
24 censing, accreditation, certification, or
25 credentialing of health care providers; or

1 (B) a person who—

2 (i) performs or oversees the perform-
3 ance of an audit, assessment, evaluation,
4 determination, or investigation relating to
5 the effectiveness of, compliance with, or
6 applicability of, legal, fiscal, medical, or
7 scientific standards or aspects of perform-
8 ance related to the delivery of health care;
9 and

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

17 (10) HEALTH PLAN.—The term “health plan”
18 means any health insurance issuer, health insurance
19 plan, including any hospital or medical service plan,
20 dental or other health service plan or health mainte-
21 nance organization plan, provider sponsored organi-
22 zation, or other program providing or arranging for
23 the provision of health benefits. Such term does not
24 include any policy, plan or program to the extent
25 that it provides, arranges or administers health ben-

1 efits pursuant to a program of workers compensa-
2 tion or automobile insurance.

3 (11) HEALTH RESEARCH AND HEALTH RE-
4 SEARCHER.—

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

14 (B) HEALTH RESEARCHER.—The term
15 “health researcher” means a person involved in
16 health research, or an officer, employee, or
17 agent of such person.

18 (12) KEY.—The term “key” means a method
19 or procedure used to transform nonidentifiable
20 health information that is in a coded or encrypted
21 form into protected health information.

22 (13) LAW ENFORCEMENT INQUIRY.—The term
23 “law enforcement inquiry” means a lawful investiga-
24 tion or official proceeding inquiring into a violation
25 of, or failure to comply with, any criminal or civil

1 statute or any regulation, rule, or order issued pur-
2 suant to such a statute.

3 (14) LIFE INSURER.—The term “life insurer”
4 means life insurance company as defined in section
5 816 of the Internal Revenue Code of 1986.

6 (15) NONIDENTIFIABLE HEALTH INFORMA-
7 TION.—The term “nonidentifiable health informa-
8 tion” means protected health information from
9 which personal identifiers, that directly reveal the
10 identity of the individual who is the subject of such
11 information or provide a direct means of identifying
12 the individual (such as name, address, and social se-
13 curity number), have been removed, encrypted, or
14 replaced with a code, such that the identity of the
15 individual is not evident without (in the case of
16 encrypted or coded information) use of key.

17 (16) ORIGINATING PROVIDER.—The term “orig-
18 inating provider” means a health care provider who
19 initiates a treatment episode, such as prescribing a
20 drug, ordering a diagnostic test, or admitting an in-
21 dividual to a health care facility. A hospital or nurs-
22 ing facility is the originating provider with respect to
23 protected health information created or received as
24 part of inpatient or outpatient treatment provided in
25 such settings.

1 (17) PAYMENT.—The term “payment”
2 means—

3 (A) the activities undertaken by—

4 (i) or on behalf of a health plan to de-
5 termine its responsibility for coverage
6 under the plan; or

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

13 (B) activities undertaken as described in
14 subparagraph (A) including—

15 (i) billing, claims management, med-
16 ical data processing, other administrative
17 services, and actual payment;

18 (ii) determinations of coverage or ad-
19 judication of health benefit or subrogation
20 claims; and

21 (iii) review of health care services with
22 respect to coverage under a health plan or
23 justification of charges.

24 (18) PERSON.—The term “person” means a
25 government, governmental subdivision, agency or au-

1 thority; corporation; company; association; firm;
2 partnership; society; estate; trust; joint venture; indi-
3 vidual; individual representative; tribal government;
4 and any other legal entity.

5 (19) PROTECTED HEALTH INFORMATION.—The
6 term “protected health information” with respect to
7 the individual who is the subject of such information
8 means any information which identifies such indi-
9 vidual, whether oral or recorded in any form or me-
10 dium, that—

11 (A) is created or received by a health care
12 provider, health plan, health oversight agency,
13 public health authority, employer, life insurer,
14 school or university;

15 (B) relates to the past, present, or future
16 physical or mental health or condition of an in-
17 dividual (including individual cells and their
18 components);

19 (C) is derived from—

20 (i) the provision of health care to the
21 individual; or

22 (ii) payment for the provision of
23 health care to the individual; and

24 (D) is not nonidentifiable health informa-
25 tion.

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

6 (A) primarily responsible for health or wel-
7 fare matters; and

8 (B) primarily engaged in activities such as
9 incidence reporting, public health surveillance,
10 and investigation or intervention.

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

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

21 (23) SIGNED.—The term “signed” refers to
22 documentation of assent in any medium, whether
23 ink, digital or biometric signatures, or recorded oral
24 authorizations.

1 (24) 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 (25) TREATMENT.—The term “treatment”
6 means the provision of health care by a health care
7 provider.

8 (26) WRITING AND WRITTEN.—

9 (A) WRITING.—The term “writing” means
10 any form of documentation, whether paper,
11 electronic, digital, biometric or tape recorded.

12 (B) WRITTEN.—The term “written” in-
13 cludes paper, electronic, digital, biometric and
14 tape-recorded formats.

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) GENERAL RULES.—

22 (1) COMPLIANCE WITH SECTION.—At the re-
23 quest of an individual who is the subject of protected
24 health information and except as provided in sub-
25 section (c), a health care provider, a health plan,

1 employer, life insurer, school, or university shall ar-
2 range for inspection or copying of protected health
3 information concerning the individual, including
4 records created under section 102, as provided for in
5 this section.

6 (2) AVAILABILITY OF INFORMATION THROUGH
7 ORIGINATING PROVIDER.—Protected health informa-
8 tion that is created or received by a health plan or
9 health care provider as part of treatment or pay-
10 ment shall be made available for inspection or copy-
11 ing as provided for in this title through the origi-
12 nating provider.

13 (3) OTHER ENTITIES.—An employer, life in-
14 surer, school, or university that creates or receives
15 protected health information in performing any func-
16 tion other than providing treatment, payment, or
17 health care operations with respect to the individual
18 who is the subject of such information, shall make
19 such information available for inspection or copying
20 as provided for in this title, or through any provider
21 designated by the individual.

22 (4) PROCEDURES.—The person providing ac-
23 cess to information under this title may set forth ap-
24 propriate procedures to be followed for such inspec-
25 tion or copying and may require an individual to pay

1 reasonable costs associated with such inspection or
2 copying.

3 (b) SPECIAL CIRCUMSTANCES.—If an originating
4 provider, its agent, or contractor no longer maintains the
5 protected health information sought by an individual pur-
6 suant to subsection (a), a health plan or another health
7 care provider that maintains such information shall ar-
8 range for inspection or copying.

9 (c) EXCEPTIONS.—Unless ordered by a court of com-
10 petent jurisdiction, a person acting pursuant to subsection
11 (a) or (b) is not required to permit the inspection or copy-
12 ing of protected health information if any of the following
13 conditions are met:

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

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

24 (3) INFORMATION COMPILED IN ANTICIPATION
25 OF OR IN CONNECTION WITH A FRAUD INVESTIGA-

1 TION OR LITIGATION.—The information is compiled
2 principally—

3 (A) in anticipation of or in connection with
4 a fraud investigation, an investigation of mate-
5 rial misrepresentation in connection with an in-
6 surance policy, a civil, criminal, or administra-
7 tive action or proceeding; or

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

9 (4) INVESTIGATIONAL INFORMATION.—The pro-
10 tected health information was created, received or
11 maintained by a health researcher as provided in
12 section 208.

13 (d) DENIAL OF A REQUEST FOR INSPECTION OR
14 COPYING.—If a person described in subsection (a) or (b)
15 denies a request for inspection or copying pursuant to sub-
16 section (c), the person shall inform the individual in writ-
17 ing of—

18 (1) the reasons for the denial of the request for
19 inspection or copying;

20 (2) the availability of procedures for further re-
21 view of the denial; and

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

1 (e) STATEMENT REGARDING REQUEST.—If an indi-
2 vidual has filed a statement under subsection (d)(3), the
3 person in any subsequent disclosure of the portion of the
4 information requested under subsection (a) or (b)—

5 (1) shall include a notation concerning the indi-
6 vidual's statement; and

7 (2) may include a concise statement of the rea-
8 sons for denying the request for inspection or copy-
9 ing.

10 (f) INSPECTION AND COPYING OF SEGREGABLE POR-
11 TION.—A person described in subsection (a) or (b) shall
12 permit the inspection and copying of any reasonably seg-
13 regable portion of a record after deletion of any portion
14 that is exempt under subsection (c).

15 (g) DEADLINE.—A person described in subsection (a)
16 or (b) shall comply with or deny, in accordance with sub-
17 section (d), a request for inspection or copying of pro-
18 tected health information under this section not later than
19 60 days after the date on which the person receives the
20 request.

21 (h) RULES OF CONSTRUCTION.—

22 (1) AGENTS.—An agent of a person described
23 in subsection (a) or (b) shall not be required to pro-
24 vide for the inspection and copying of protected
25 health information, except where—

1 (A) the protected health information is re-
2 tained by the agent; and

3 (B) the agent has been asked in writing by
4 the person involved to fulfill the requirements of
5 this section.

6 (2) NO REQUIREMENT FOR HEARING.—This
7 section shall not be construed to require a person
8 described in subsection (a) or (b) to conduct a for-
9 mal, informal, or other hearing or proceeding con-
10 cerning a request for inspection or copying of pro-
11 tected health information.

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

14 (a) RIGHT TO AMEND.—

15 (1) IN GENERAL.—Protected health information
16 shall be subject to amendment as provided for in
17 this section.

18 (2) COMPLIANCE WITH REQUEST.—Except as
19 provided in subsection (c), not later than 45 days
20 after the date on which an originating provider, em-
21 ployer, life insurer, school, or university receives
22 from an individual a request in writing to amend
23 protected health information, such person shall—

24 (A) make the amendment requested;

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

3 (C) inform any person identified by the in-
4 dividual in the request for amendment and—

5 (i) who is not an officer, employee, or
6 agent of the person; and

7 (ii) to whom the unamended portion
8 of the information was disclosed within the
9 previous year by sending a notice to the in-
10 dividual's last known address that there
11 has been a substantive amendment to the
12 protected health information of such indi-
13 vidual.

14 (b) REQUEST OF ORIGINATING PROVIDERS.—

15 (1) IN GENERAL.—Protected health information
16 that is created or received by a health plan or health
17 care provider as part of treatment or payment shall
18 be subject to amendment as provided for in this sec-
19 tion upon a written request made to the originating
20 provider.

21 (2) SPECIAL CIRCUMSTANCES.—If an origi-
22 nating provider, its agent, or contractor no longer
23 maintains the protected health information sought to
24 be amended by an individual pursuant to paragraph
25 (1), a health plan or another health care provider

1 that maintains such information may arrange for
2 amendment consistent with this section.

3 (c) REFUSAL TO AMEND.—If a person described in
4 subsection (a)(2) refuses to make the amendment re-
5 quested under such subsection, the person shall inform the
6 individual in writing of—

7 (1) the reasons for the refusal to make the
8 amendment;

9 (2) the availability of procedures for further re-
10 view of the refusal; and

11 (3) the procedures by which the individual may
12 file with the person a concise statement setting forth
13 the requested amendment and the individual's rea-
14 sons for disagreeing with the refusal.

15 (d) STATEMENT OF DISAGREEMENT.—If an indi-
16 vidual has filed a statement of disagreement under sub-
17 section (c)(3), the person involved, in any subsequent dis-
18 closure of the disputed portion of the information—

19 (1) shall include a notation concerning the indi-
20 vidual's statement; and

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

23 (e) RULES GOVERNING AGENTS.—The agent of a
24 person described in subsection (a)(2) shall not be required

1 to make amendments to protected health information, ex-
2 cept where—

3 (1) the protected health information is retained
4 by the agent; and

5 (2) the agent has been asked in writing by such
6 person to fulfill the requirements of this section.

7 (f) REPEATED REQUESTS FOR AMENDMENTS.—If a
8 person described in subsection (a)(2) receives a request
9 for an amendment of information as provided for in such
10 subsection and a statement of disagreement has been filed
11 pursuant to subsection (d), the person shall inform the
12 individual of such filing and shall not be required to carry
13 out the procedures required under this section.

14 (g) RULES OF CONSTRUCTION.—This section shall
15 not be construed to—

16 (1) require that a person described in sub-
17 section (a)(2) conduct a formal, informal, or other
18 hearing or proceeding concerning a request for an
19 amendment to protected health information;

20 (2) require a provider to amend an individual's
21 protected health information as to the type, dura-
22 tion, or quality of treatment the individual believes
23 he or she should have been provided; or

24 (3) permit any deletions or alterations of the
25 original information.

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

2 (a) PREPARATION OF WRITTEN NOTICE.—A health
3 care provider, health plan, health oversight agency, public
4 health authority, employer, life insurer, health researcher,
5 school, or university shall post or provide, in writing and
6 in a clear and conspicuous manner, notice of the person’s
7 confidentiality practices, that shall include—

8 (1) a description of an individual’s rights with
9 respect to protected health information;

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

12 (3) the procedures for authorizing disclosures of
13 protected health information and for revoking such
14 authorizations;

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

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

19 (b) MODEL NOTICE.—The Secretary, after notice
20 and opportunity for public comment, shall develop and dis-
21 seminate model notices of confidentiality practices, using
22 the advice of the National Committee on Vital Health Sta-
23 tistics, for use under this section. Use of the model notice
24 shall serve as an absolute defense against claims of receiv-
25 ing inappropriate notice.

1 **Subtitle B—Establishment of**
2 **Safeguards**

3 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

4 (a) **IN GENERAL.**—A health care provider, health
5 plan, health oversight agency, public health authority, em-
6 ployer, life insurer, health researcher, law enforcement of-
7 ficial, school, or university shall establish and maintain ap-
8 propriate administrative, technical, and physical safe-
9 guards to protect the confidentiality, security, accuracy,
10 and integrity of protected health information created, re-
11 ceived, obtained, maintained, used, transmitted, or dis-
12 posed of by such person.

13 (b) **FUNDAMENTAL SAFEGUARDS.**—The safeguards
14 established pursuant to subsection (a) shall address the
15 following factors:

16 (1) The purpose for which protected health in-
17 formation is needed and whether that purpose can
18 be accomplished with nonidentifiable health informa-
19 tion.

20 (2) Appropriate procedures for maintaining the
21 security of protected health information and assur-
22 ing the appropriate use of any key used in creating
23 nonidentifiable health information.

24 (3) The categories of personnel who will have
25 access to protected health information and appro-

1 appropriate training, supervision and sanctioning of such
2 personnel with respect to their use of protected
3 health information and adherence to established
4 safeguards.

5 (4) Appropriate limitations on access to indi-
6 vidual identifiers.

7 (5) Appropriate mechanisms for limiting disclo-
8 sures of protected information to the information
9 necessary to respond to the request for disclosure.

10 (6) Procedures for handling requests for pro-
11 tected health information by persons other than the
12 individual who is the subject of such information, in-
13 cluding relatives and affiliates of such individual,
14 law enforcement officials, parties in civil litigation,
15 health care providers, and health plans.

16 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

17 (a) IN GENERAL.—A health care provider, health
18 plan, health oversight agency, public health authority, em-
19 ployer, life insurer, health researcher, law enforcement of-
20 ficial, school, or university shall establish and maintain a
21 process for documenting the disclosure of protected health
22 information by any such person through the recording of
23 the name and address of the recipient of the information,
24 or through the recording of another mean of contacting
25 the recipient, and the purpose of the disclosure.

1 (b) RECORD OF DISCLOSURE.—A record (or other
2 means of documentation) established under subsection (a)
3 shall be maintained for not less than 7 years.

4 (c) IDENTIFICATION OF DISCLOSED INFORMATION AS
5 PROTECTED HEALTH INFORMATION.—Except as other-
6 wise provided in this title, protected health information
7 shall be clearly identified as protected health information
8 that is subject to this Act.

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

11 **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-**
12 **SURE.**

13 (a) DISCLOSURE PROHIBITED.—A health care pro-
14 vider, health plan, health oversight agency, public health
15 authority, employer, life insurer, health researcher, law en-
16 forcement official, school, or university, or any agents of
17 such a person, may not disclose protected health informa-
18 tion except as authorized under this Act or as authorized
19 by the individual who is the subject of such information.

20 (b) APPLICABILITY TO AGENTS.—

21 (1) IN GENERAL.—A person described in sub-
22 section (a) may use an agent, including a contractor,
23 to carry out an otherwise lawful activity using pro-
24 tected health information maintained by such person
25 if the person specifies the activities for which the

1 agent is authorized to use such protected health in-
2 formation and prohibits the agent from using or dis-
3 closing protected health information for purposes
4 other than carrying out the specified activities.

5 (2) LIMITATION ON LIABILITY.—Notwith-
6 standing any other provision of this Act, a person
7 who has limited the activities of an agent as pro-
8 vided for in paragraph (1), shall not be liable for the
9 actions or disclosures of the agent that are not in
10 fulfillment of those activities.

11 (3) LIMITATIONS ON AGENTS.—An agent who
12 receives protected health information from a person
13 described in subsection (a) shall, in its own right, be
14 subject to the applicable provisions of this Act.

15 (c) APPLICABILITY TO EMPLOYERS.—

16 (1) IN GENERAL.—An employer may use an
17 employee or agent to create, receive, or maintain
18 protected health information in order to carry out an
19 otherwise lawful activity so long as—

20 (A) the disclosure of the protected em-
21 ployee health information within the entity is
22 compatible with the purpose for which the in-
23 formation was obtained and limited to informa-
24 tion necessary to accomplish the purpose of the
25 disclosure; and

1 (B) the employer prohibits the release,
2 transfer or communication of the protected
3 health information to officers, employees, or
4 agents responsible for hiring, promotion, and
5 making work assignment decisions with respect
6 to the subject of the information.

7 (2) DETERMINATION.—For purposes of para-
8 graph (1)(A), the determination of what constitutes
9 information necessary to accomplish the purpose for
10 which the information is obtained shall be made by
11 a health care provider, except in situations involving
12 payment for health plan operations undertaken by
13 the employer.

14 (d) CREATION OF NONIDENTIFIABLE HEALTH IN-
15 FORMATION.—A person described in subsection (a) may
16 use protected health information for the purpose of cre-
17 ating nonidentifiable health information.

18 (e) INDIVIDUAL AUTHORIZATION.—To be valid, an
19 authorization to disclose protected health information
20 under this title shall—

21 (1) identify the individual who is the subject of
22 the protected health information;

23 (2) describe the nature of the information to be
24 disclosed;

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

3 (4) describe the purpose of the disclosure;

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) be in writing, dated, and signed by the indi-
8 vidual, a family member or other authorized rep-
9 resentative.

10 (f) **MANIPULATION OF NONIDENTIFIABLE HEALTH**
11 **INFORMATION.**—Any person who manipulates nonidentifi-
12 able health information in order to identify an individual,
13 or uses a key to identify an individual without authoriza-
14 tion, is deemed to have disclosed protected health informa-
15 tion.

16 **SEC. 202. PROCUREMENT OF AUTHORIZATIONS FOR USE**
17 **AND DISCLOSURE OF PROTECTED HEALTH**
18 **INFORMATION FOR TREATMENT, PAYMENT,**
19 **AND HEALTH CARE OPERATIONS.**

20 (a) **AUTHORIZATIONS.**—

21 (1) **IN GENERAL.**—With respect to each indi-
22 vidual, a single authorization that substantially com-
23 plies with section 201(e) must be secured to permit
24 the use and disclosure of protected health informa-
25 tion concerning such individual for treatment, pay-

1 ment, and health care operations, as provided for in
2 this subsection.

3 (2) EMPLOYERS.—Every employer offering a
4 health plan to its employees shall, at the time of,
5 and as a condition of enrollment in the health plan,
6 obtain a signed, written authorization that is a legal,
7 informed authorization concerning the use and dis-
8 closure of protected health information for treat-
9 ment, payment, and health care operations with re-
10 spect to each individual who is eligible to receive
11 care under the health plan.

12 (3) HEALTH PLANS.—Every health plan offer-
13 ing enrollment to individuals or non-employer groups
14 shall, at the time of, and as a condition of enroll-
15 ment in the health plan, obtain a signed, written au-
16 thorization that is a legal, informed authorization
17 concerning the use and disclosure of protected health
18 information for treatment, payment, and health care
19 operations, with respect to each individual who is eli-
20 gible to receive care under the plan.

21 (4) UNINSURED.—An originating provider pro-
22 viding health care to an uninsured individual, shall
23 obtain a signed, written authorization to use and
24 disclose protected health information with respect to
25 such individual for treatment, payment, and health

1 care operations of such provider, and in arranging
2 for treatment and payment from other providers.

3 (5) PROVIDERS.—Any health care provider pro-
4 viding health care to an individual may, in connec-
5 tion with providing such care, obtain a signed, writ-
6 ten authorization that is a legal, informed authoriza-
7 tion concerning the use and disclosure of protected
8 health information with respect to such individual
9 for treatment, payment, and health care operations
10 of such provider.

11 (b) REVOCATION OF AUTHORIZATION.—

12 (1) IN GENERAL.—An individual may revoke an
13 authorization under this section at any time, by
14 sending written notice to the person who obtained
15 such authorization, unless the disclosure that is the
16 subject of the authorization is required to complete
17 a course of treatment, effectuate payment, or con-
18 duct health care operations for health care that has
19 been provided to the individual.

20 (2) HEALTH PLANS.—With respect to a health
21 plan, the authorization of an individual is deemed to
22 be revoked at the time of the cancellation or non-re-
23 newal of enrollment in the health plan, except as
24 may be necessary to conduct health care operations

1 and complete payment requirements related to the
2 individual's period of enrollment.

3 (3) TERMINATION OF PLAN.—With respect to
4 the revocation of an authorization under this section
5 by an enrollee in a health plan, the health plan may
6 terminate the coverage of such enrollee under such
7 plan if the health plan determines that the revoca-
8 tion has resulted in the inability of the plan to pro-
9 vide care for the enrollee or conduct health care op-
10 erations.

11 (c) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND
12 REVOCATIONS.—Each person who obtains or is required
13 to obtain an authorization under this section shall main-
14 tain a record for a period of 7 years of each such author-
15 ization of an individual and revocation thereof.

16 (d) MODEL AUTHORIZATIONS.—The Secretary, after
17 notice and opportunity for public comment, shall develop
18 and disseminate model written authorizations of the type
19 described in subsection (a). The Secretary shall consult
20 with the National Committee on Vital and Health Statis-
21 tics in developing such authorizations. An authorization
22 obtained on a model authorization form developed by the
23 Secretary pursuant to the preceding sentence shall be
24 deemed to meet the authorization requirements of this sec-
25 tion.

1 (e) RULES OF CONSTRUCTION.—

2 (1) SINGLE AUTHORIZATIONS.—An employer or
3 health plan shall be deemed to meet the require-
4 ments of subsection (a) with respect to a spouse,
5 child, or other eligible dependent if, at the time of
6 enrollment, a single authorization under subsection
7 (a) is obtained from the employee or other individual
8 who accepts responsibility for health plan enroll-
9 ment.

10 (2) REQUIREMENT FOR SEPARATE AUTHORIZA-
11 TION.—An authorization for the disclosure of pro-
12 tected health information for treatment, payment,
13 and health care operations shall not directly or indi-
14 rectly authorize the disclosure of such information
15 for any other purpose. Any other such disclosures
16 shall require a separate authorization under section
17 203.

18 **SEC. 203. AUTHORIZATIONS FOR USE OR DISCLOSURE OF**
19 **PROTECTED HEALTH INFORMATION OTHER**
20 **THAN FOR TREATMENT, PAYMENT, AND**
21 **HEALTH CARE OPERATIONS.**

22 (a) IN GENERAL.—An individual who is the subject
23 of protected health information may authorize any person
24 to disclose or use such information for any purpose. An
25 authorization under this section shall not be valid if the

1 signing of such authorization by the individual is a pre-
2 requisite for the signing of an authorization under section
3 202.

4 (b) WRITTEN AUTHORIZATIONS.—A person may dis-
5 close and use protected health information, for purposes
6 other than those authorized under section 202, pursuant
7 to a written authorization signed by the individual who
8 is the subject of the information that meets the require-
9 ments of section 201(e). An authorization under this sec-
10 tion shall be separate from any authorization provided
11 under section 202.

12 (c) LIMITATION ON AUTHORIZATIONS.—

13 (1) IN GENERAL.—Notwithstanding any other
14 provision of Federal law, life insurers, and any other
15 entity that offers disability income or long term care
16 insurance under the laws of any State, shall meet
17 the requirements of section 201(a) with respect to
18 an individual for purposes of life, disability income
19 or long term care insurance, by obtaining the au-
20 thorization of the individual under this section.

21 (2) DURING PERIOD OF COVERAGE.—Notwith-
22 standing paragraph (1), an authorization obtained in
23 the ordinary course of business in connection with
24 life, disability income or long-term care insurance
25 under this section shall remain in effect during the

1 term of the individual's insurance coverage and as
2 may be necessary to enable the issuer to meet its
3 obligations with respect to such individual under the
4 terms of the policy, plan or program.

5 (3) OTHER AUTHORIZATIONS.—An authoriza-
6 tion obtained from an individual in connection with
7 an application that does not result in coverage with
8 respect to such individual shall expire the earlier of
9 the date specified in the individual's authorization or
10 the effective date of any revocation under subsection
11 (d).

12 (d) REVOCATION OR AMENDMENT OF AUTHORIZA-
13 TION.—

14 (1) IN GENERAL.—Except as otherwise pro-
15 vided for in this section, an individual may revoke or
16 amend an authorization described in this section by
17 providing written notice to the person who obtained
18 such authorization unless the disclosure that is the
19 subject of the authorization is related to the evalua-
20 tion of an application for life, disability income or
21 long-term care insurance coverage or a claim for life,
22 disability income or long-term care insurance bene-
23 fits.

24 (2) NOTICE OF REVOCATION.—A person that
25 discloses protected health information pursuant to

1 an authorization that has been revoked under para-
2 graph (1) shall not be subject to any liability or pen-
3 alty under this title if that person had no actual no-
4 tice of the revocation.

5 (e) DISCLOSURE FOR PURPOSE ONLY.—A recipient
6 of protected health information pursuant to an authoriza-
7 tion under subsection (b) may disclose such information
8 only to carry out the purposes for which the information
9 was authorized to be disclosed.

10 (f) MODEL AUTHORIZATIONS.—

11 (1) IN GENERAL.—The Secretary, after notice
12 and opportunity for public comment, shall develop
13 and disseminate model written authorizations of the
14 type described in subsection (b). The Secretary shall
15 consult with the National Committee on Vital and
16 Health Statistics in developing such authorizations.

17 (2) AUTHORITY OF INSURANCE COMMIS-
18 SIONER.—Notwithstanding paragraph (1), the insur-
19 ance commissioner of the State of domicile of a life
20 insurer may exercise exclusive authority in devel-
21 oping and disseminating model written authoriza-
22 tions for purposes of subsection (c).

23 (3) COMPLIANCE WITH REQUIREMENTS.—An
24 authorization obtained using a model authorization
25 promulgated under this subsection shall be deemed

1 to meet the authorization requirements of this sec-
2 tion.

3 (g) AUTHORIZATIONS FOR RESEARCH.—This section
4 applies to health research only where such research is not
5 governed by section 208.

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

7 (a) NEXT OF KIN.—A health care provider, or a per-
8 son who receives protected health information under sec-
9 tion 205, may disclose protected health information re-
10 garding an individual to the individual’s spouse, parent,
11 child, sister, brother, next of kin, or to another person
12 whom the individual has identified, if—

13 (1) the individual who is the subject of the
14 information—

15 (A) has been notified of the individual’s
16 right to object to such disclosure and the indi-
17 vidual has not objected to the disclosure; or

18 (B) is in a physical or mental condition
19 such that the individual is not capable of object-
20 ing, and there are no prior indications that the
21 individual would object;

22 (2) the information disclosed relates to health
23 care currently being provided to that individual; and

1 (3) the disclosure of the protected health infor-
2 mation is consistent with good medical or profes-
3 sional practice.

4 (b) DIRECTORY INFORMATION.—

5 (1) DISCLOSURE.—

6 (A) IN GENERAL.—Except as provided in
7 paragraph (2), a person described in subsection
8 (a) may disclose the information described in
9 subparagraph (B) to any person if the indi-
10 vidual who is the subject of the information—

11 (i) has been notified of the individ-
12 ual's right to object and the individual has
13 not objected to the disclosure; or

14 (ii) is in a physical or mental condi-
15 tion such that the individual is not capable
16 of objecting, the individual's next of kin
17 has not objected, and there are no prior in-
18 dications that the individual would object.

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

22 (i) The name of the individual who is
23 the subject of the information.

24 (ii) The general health status of the
25 individual, described as critical, poor, fair,

1 stable, or satisfactory or in terms denoting
2 similar conditions.

3 (iii) The location of the individual on
4 premises controlled by a provider.

5 (2) EXCEPTION.—

6 (A) LOCATION.—Paragraph (1)(B)(iii)
7 shall not apply if disclosure of the location of
8 the individual would reveal specific information
9 about the physical or mental condition of the
10 individual, unless the individual expressly au-
11 thorizes such disclosure.

12 (B) DIRECTORY OR NEXT OF KIN INFOR-
13 MATION.—A disclosure may not be made under
14 this section if the health care provider involved
15 has reason to believe that the disclosure of di-
16 rectory or next of kin information could lead to
17 the physical or mental harm of the individual,
18 unless the individual expressly authorizes such
19 disclosure.

20 **SEC. 205. EMERGENCY CIRCUMSTANCES.**

21 Any person who creates or receives protected health
22 information under this title may disclose protected health
23 information in emergency circumstances when necessary
24 to protect the health or safety of the individual who is
25 the subject of such information from serious, imminent

1 harm. No disclosure made in the good faith belief that
2 the disclosure was necessary to protect the health or safety
3 of an individual from serious, imminent harm shall be in
4 violation of, or punishable under, this Act.

5 **SEC. 206. OVERSIGHT.**

6 (a) IN GENERAL.—Any person may disclose pro-
7 tected health information to an accrediting body or public
8 health authority, a health oversight agency, or a State in-
9 surance department, for purposes of an oversight function
10 authorized by law.

11 (b) PROTECTION FROM FURTHER DISCLOSURE.—
12 Protected health information this is disclosed under this
13 section shall not be further disclosed by an accrediting
14 body or public health authority, a health oversight agency,
15 a State insurance department, or their agents for any pur-
16 pose unrelated to the authorized oversight function. Not-
17 withstanding any other provision of law, protected health
18 information disclosed under this section shall be protected
19 from further disclosure by an accrediting body or public
20 health authority, a health oversight agency, a State insur-
21 ance department, or their agents pursuant to a subpoena,
22 discovery request, introduction as evidence, testimony, or
23 otherwise.

24 (c) AUTHORIZATION BY A SUPERVISOR.—For pur-
25 poses of this section, the individual with authority to au-

1 thorize the oversight function involved shall provide to the
 2 person described in subsection (a) a statement that the
 3 protected health information is being sought for a legally
 4 authorized oversight function.

5 (d) USE IN ACTION AGAINST INDIVIDUALS.—Pro-
 6 tected health information about an individual that is dis-
 7 closed under this section may not be used by the recipient
 8 in, or disclosed by the recipient to any person for use in,
 9 an administrative, civil, or criminal action or investigation
 10 directed against the individual who is the subject of the
 11 protected health information unless the action or inves-
 12 tigation arises out of and is directly related to—

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

15 (2) a fraudulent claim related to health care, or
 16 a fraudulent or material misrepresentation of the
 17 health of the individual.

18 **SEC. 207. PUBLIC HEALTH.**

19 (a) IN GENERAL.—A health care provider, health
 20 plan, public health authority, health researcher, employer,
 21 life insurer, law enforcement official, school, or university
 22 may disclose protected health information to a public
 23 health authority or other person authorized by law for use
 24 in a legally authorized—

25 (1) disease or injury report;

- 1 (2) public health surveillance;
- 2 (3) public health investigation or intervention;
- 3 (4) vital statistics report, such as birth or death
- 4 information;
- 5 (5) report of abuse or neglect information about
- 6 any individual; or
- 7 (6) report of information concerning a commu-
- 8 nicable disease status.

9 (b) IDENTIFICATION OF DECEASED INDIVIDUAL.—

10 Any person may disclose protected health information if
11 such disclosure is necessary to assist in the identification
12 or safe handling of a deceased individual.

13 (c) REQUIREMENT TO RELEASE PROTECTED
14 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-
15 AMINERS.—

16 (1) IN GENERAL.—When a Coroner or a Med-
17 ical Examiner, or the duly appointed deputy of a
18 Coroner or Medical Examiner, seeks protected health
19 information for the purpose of inquiry into and de-
20 termination of, the cause, manner, and cir-
21 cumstances of a death, the health care provider,
22 health plan, health oversight agency, public health
23 authority, employer, life insurer, health researcher,
24 law enforcement official, school, or university in-
25 volved shall provide the protected health information

1 to the Coroner or Medical Examiner or to the duly
2 appointed deputy without undue delay.

3 (2) PRODUCTION OF ADDITIONAL INFORMA-
4 TION.—If a Coroner or Medical Examiner, or the
5 duly appointed deputy of a Coroner or Medical Ex-
6 aminer, receives health information from a person
7 referred to in paragraph (1), such health informa-
8 tion shall remain as protected health information
9 unless the health information is attached to or oth-
10 erwise made a part of a Coroner’s or Medical Exam-
11 iner’s official report, in which case it shall no longer
12 be protected.

13 (3) EXEMPTION.—Health information attached
14 to or otherwise made a part of a Coroner’s or Med-
15 ical Examiner’s official report, shall be exempt from
16 the provisions of this Act.

17 **SEC. 208. HEALTH RESEARCH.**

18 (a) IN GENERAL.—A person lawfully in possession of
19 protected health information may disclose such informa-
20 tion to a health researcher under any of the following ar-
21 rangements:

22 (1) RESEARCH GOVERNED BY THE COMMON
23 RULE.—A person identified in subsection (a) may
24 disclose protected health information to a health re-
25 searcher if the research project has been approved

1 by an institutional review board pursuant to the re-
2 quirements of the common rule as implemented by
3 a Federal agency.

4 (2) ANALYSES OF HEALTH CARE RECORDS AND
5 MEDICAL ARCHIVES.—A person identified in sub-
6 section (a) may disclose protected health information
7 to a health researcher if—

8 (A) consistent with the safeguards estab-
9 lished pursuant to section 111 and the person's
10 policies and procedures established under this
11 section, the health research has been reviewed
12 by a board, committee, or other group formally
13 designated by such person to review research
14 programs;

15 (B) the health research involves analysis of
16 protected health information previously created
17 or collected by the person;

18 (C) the person that maintains the pro-
19 tected health information to be used in the
20 analyses has in place a written policy and pro-
21 cedure to assure the security and confidentiality
22 of protected health information and to specify
23 permissible and impermissible uses of such in-
24 formation for health research;

1 (D) the person that maintains the pro-
2 tected health information to be used in the
3 analyses enters into a written agreement with
4 the recipient health researcher that specifies the
5 permissible and impermissible uses of the pro-
6 tected health information and provides notice to
7 the researcher that any misuse or further dis-
8 closure of the information to other persons is
9 prohibited and may provide a basis for action
10 against the health researcher under this Act;
11 and

12 (E) the person keeps a record of health re-
13 searchers to whom protected health information
14 has been disclosed.

15 (3) SAFETY AND EFFICACY REPORTS.—A per-
16 son may disclose protected health information to a
17 manufacturer of a drug, biologic or medical device,
18 in connection with any monitoring activity or reports
19 made to such manufacturer for use in verifying the
20 safety or efficacy of such manufacturer's approved
21 product in special populations or for long term use.

22 (b) OVERSIGHT.—On the advice of the National Com-
23 mittee on Vital and Health Statistics, the Secretary shall
24 report to the Congress not later than 18 months after the
25 effective date of this section concerning the adequacy of

1 the policies and procedures implemented pursuant to sub-
2 section (a)(2) for protecting the confidentiality of pro-
3 tected health information while promoting its use in re-
4 search concerning health care outcomes, the epidemiology
5 and etiology of diseases and conditions and the safety, effi-
6 cacy and cost effectiveness of health care interventions.
7 Based on the conclusions of such report, the Secretary
8 may promulgate model language for written agreements
9 deemed to comply with subsection (a)(2)(C).

10 (c) STATUTORY ASSURANCE OF CONFIDEN-
11 TIALITY.—

12 (1) IN GENERAL.—Protected health information
13 obtained by a health researcher pursuant to this sec-
14 tion shall be used and maintained in confidence, con-
15 sistent with the confidentiality practices established
16 by the health researcher pursuant to section 111.

17 (2) LIMITATION ON COMPELLED DISCLO-
18 SURE.—A health researcher may not be compelled in
19 any Federal, State, or local civil, criminal, adminis-
20 trative, legislative, or other proceeding to disclose
21 protected health information created, maintained or
22 received under this section. Nothing in this para-
23 graph shall be construed to prevent an audit or law-
24 ful investigation pursuant to the authority of a Fed-
25 eral department or agency, of a research project con-

1 ducted, supported or subject to regulation by such
2 department or agency.

3 (3) LIMITATION ON FURTHER USE OR DISCLO-
4 SURE.—Notwithstanding any other provision of law,
5 information disclosed by a health researcher to a
6 Federal department or agency under this subsection
7 may not be further used or disclosed by the depart-
8 ment or agency for a purpose unrelated to the de-
9 partment’s or agency’s oversight or investigation.

10 **SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINIS-**
11 **TRATIVE PROCEDURES.**

12 (a) IN GENERAL.—A health care provider, health
13 plan, public health authority, employer, life insurer, law
14 enforcement official, school, or university may disclose
15 protected health information pursuant to a discovery re-
16 quest or subpoena in a civil action brought in a Federal
17 or State court or a request or subpoena related to a Fed-
18 eral or State administrative proceeding if such discovery
19 request or subpoena is made through or pursuant to a
20 court order as provided for in subsection (b).

21 (b) COURT ORDERS.—

22 (1) STANDARD FOR ISSUANCE.—In considering
23 a request for a court order regarding the disclosure
24 of protected health information under subsection (a),
25 the court shall issue such order if the court deter-

1 mines that without the disclosure of such informa-
2 tion, the person requesting the order would be im-
3 paired from establishing a claim or defense.

4 (2) REQUIREMENTS.—An order issued under
5 paragraph (1) shall—

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

8 (B) specify to whom the information may
9 be disclosed;

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

12 (D) meet any other requirements that the
13 court determines are needed to protect the con-
14 fidentiality of the information.

15 (c) APPLICABILITY.—This section shall not apply in
16 a case in which the protected health information sought
17 under such discovery request or subpoena relates to a
18 party to the litigation or an individual whose medical con-
19 dition is at issue.

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

1 **SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PUR-**
2 **POSES.**

3 A person who receives protected health information
4 pursuant to sections 202 through 207, may disclose such
5 information to a State or Federal law enforcement agency
6 if such disclosure is pursuant to—

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

9 (2) an administrative or judicial subpoena or
10 summons;

11 (3) a warrant issued upon a showing of prob-
12 able cause;

13 (4) a Federal or State law requiring the report-
14 ing of specific medical information to law enforce-
15 ment authorities;

16 (5) a written consent or waiver of privilege by
17 an individual allowing access to the individual's pro-
18 tected health information; or

19 (6) by other court order.

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

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

1 scribed in subsection (b) only such protected health infor-
2 mation about the individual as is necessary in connection
3 with activities described in subsection (b), including the
4 processing of the payment transaction or the billing or col-
5 lection of amounts charged to, debited from, or otherwise
6 paid by, the individual using the card, number, or other
7 means.

8 (b) TRANSACTION PROCESSING.—A person who is a
9 debit, credit, or other payment card issuer, a payment sys-
10 tem operator, a financial institution participant in a pay-
11 ment system or is an entity assisting such an issuer, oper-
12 ator, or participant in connection with activities described
13 in this subsection, may use or disclose protected health
14 information about an individual in connection with—

15 (1) the authorization, settlement, billing, proc-
16 essing, clearing, transferring, reconciling, or collec-
17 tion of amounts charged, debited or otherwise paid
18 using a debit, credit, or other payment card or ac-
19 count number, or by other payment means;

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

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

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

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

5 (6) fraud protection, risk control, resolving cus-
6 tomer disputes or inquiries, communicating with the
7 person to whom the information relates, or reporting
8 to consumer reporting agencies.

9 (c) SPECIFIC PROHIBITIONS.—A person described in
10 subsection (b) may not disclose protected health informa-
11 tion for any purpose that is not described in subsection
12 (b). Notwithstanding any other provision of law, any
13 health care provider, health plan, health oversight agency,
14 health researcher, employer, life insurer, school or univer-
15 sity who makes a good faith disclosure of protected health
16 information to an entity and for the purposes described
17 in subsection (b) shall not be liable for subsequent disclo-
18 sures by such entity.

19 (d) SCOPE.—

20 (1) IN GENERAL.—The use of protected health
21 information by a person described in subsection (b)
22 and its agents shall not be considered a disclosure
23 for purposes of this Act, so long as the use involved
24 is consistent with the activities authorized in sub-

1 section (b) or other purposes for which the informa-
2 tion was lawfully obtained.

3 (2) REGULATED INSTITUTIONS.—A person who
4 is subject to enforcement pursuant to section 8 of
5 the Federal Deposit Insurance Act or who is a Fed-
6 eral credit union or State credit union as defined in
7 the Federal Credit Union Act or who is registered
8 pursuant to the Securities and Exchange Act, or
9 who is an entity assisting such a person—

10 (A) shall not be subject to this Act to the
11 extent that such person or entity is described in
12 subsection (b) and to the extent that such per-
13 son or entity is engaged in activities authorized
14 in that subsection; and

15 (B) shall be subject to enforcement exclu-
16 sively under section 8 of the Federal Deposit
17 Insurance Act, the Federal Credit Union Act,
18 or the Securities and Exchange Act, as applica-
19 ble, to the extent that such person or entity is
20 engaged in activities other than those permitted
21 under subsection (b).

22 (3) RULE OF CONSTRUCTION.—Nothing in this
23 subsection shall be construed to exempt entities de-
24 scribed in paragraph (2) from the prohibition set
25 forth in subsection (c).

1 **SEC. 212. INDIVIDUAL REPRESENTATIVES.**

2 (a) IN GENERAL.—Except as provided in subsections
3 (b) and (c), a person who is authorized by law (based on
4 grounds other than the individual being a minor), or by
5 an instrument recognized under law, to act as an agent,
6 attorney, proxy, or other legal representative of a pro-
7 tected individual, may, to the extent so authorized, exer-
8 cise and discharge the rights of the individual under this
9 Act.

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

18 (c) NO COURT DECLARATION.—If a health care pro-
19 vider determines that an individual, who has not been de-
20 clared to be legally incompetent, suffers from a medical
21 condition that prevents the individual from acting know-
22 ingly or effectively on the individual's own behalf, the right
23 of the individual to authorize disclosure under this Act
24 may be exercised and discharged in the best interest of
25 the individual by—

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

3 (2) a person described in subsection (a) with re-
4 spect to the individual, but only if a person de-
5 scribed in paragraph (1) cannot be contacted after
6 a reasonable effort;

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

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

13 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
14 provisions of this Act shall continue to prevent disclosure
15 of protected health information concerning a deceased in-
16 dividual.

17 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
18 CEASED INDIVIDUAL.—

19 (1) IN GENERAL.—A person who is authorized
20 by law or by an instrument recognized under law, to
21 act as an executor of the estate of a deceased indi-
22 vidual, or otherwise to exercise the rights of the de-
23 ceased individual, may, to the extent so authorized,
24 exercise and discharge the rights of such deceased
25 individual under this Act for a period of 2 years fol-

1 lowing the death of such individual. If no such des-
2 ignee has been authorized, the rights of the deceased
3 individual may be exercised as provided for in sub-
4 section (c).

5 (2) **INSURED INDIVIDUALS.**—In the case of an
6 individual who is deceased and who was the insured
7 under an insurance policy or policies, the right to
8 authorize disclosure of protected health information
9 may be exercised by the beneficiary or beneficiaries
10 of such insurance policy or policies.

11 (f) **RIGHTS OF MINORS.**—The rights of minors under
12 this Act shall be exercised by a parent, the minor or other
13 person as provided under applicable state law.

14 **SEC. 213. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

15 A health care provider, health plan, health oversight
16 agency, health researcher, employer, life insurer, school,
17 or university, or an agent of any such person, that makes
18 a disclosure of protected health information about an indi-
19 vidual that is permitted by this Act shall not be liable to
20 the individual for such disclosure under common law.

21 **SEC. 214. SALE OF BUSINESS, MERGERS, ETC.**

22 (a) **IN GENERAL.**—A health care provider, health
23 plan, health oversight agency, employer, life insurer,
24 school, or university may disclose protected health infor-
25 mation to a person or persons for purposes of enabling

1 business decisions to be made about or in connection with
 2 the purchase, transfer, merger, or sale of a business or
 3 businesses.

4 (b) NO FURTHER USE OR DISCLOSURE.—A person
 5 or persons who receive protected health information under
 6 this section shall make no further use or disclosure of such
 7 information unless otherwise authorized under this Act.

8 **TITLE III—SANCTIONS**

9 **Subtitle A—Criminal Provisions**

10 **SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED** 11 **HEALTH INFORMATION.**

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

14 **“CHAPTER 124—WRONGFUL DISCLOSURE** 15 **OF PROTECTED HEALTH INFORMATION**

16 **“SEC. 2801. Wrongful disclosure of protected health informa-** 17 **tion.**

18 “(a) OFFENSE.—The penalties described in sub-
 19 section (b) shall apply to a person that knowingly and
 20 intentionally—

21 “(1) obtains protected health information relat-
 22 ing to an individual from a health care provider,
 23 health plan, health oversight agency, public health
 24 authority, employer, life insurer, health researcher,
 25 law enforcement official, school, or university except

1 as provided in title II of the Medical Information
2 Protection Act of 1999; or

3 “(2) discloses protected health information to
4 another person in a manner other than that which
5 is permitted under title II of the Medical Informa-
6 tion Protection Act of 1999.

7 “(b) PENALTIES.—A person described in subsection
8 (a) shall—

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

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

14 “(3) if the offense is committed with the intent
15 to sell, transfer, or use protected health information
16 for monetary gain or malicious harm, be fined not
17 more than \$250,000, imprisoned not more than 10
18 years, or both.

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 information 2801”.

5 **Subtitle B—Civil Sanctions**

6 **SEC. 311. CIVIL PENALTY VIOLATION.**

7 A person who the Secretary, in consultation with the
 8 Attorney General, determines has substantially and mate-
 9 rially failed to comply with this Act shall be subject, in
 10 addition to any other penalties that may be prescribed by
 11 law—

12 (1) in a case in which the violation relates to
 13 title I, to a civil penalty of not more than \$500 for
 14 each such violation, but not to exceed \$5,000 in the
 15 aggregate for multiple violations arising from the
 16 same failure to comply with the Act;

17 (2) in a case in which the violation relates to
 18 title II, to a civil penalty of not more than \$10,000
 19 for each such violation, but not to exceed \$50,000
 20 in the aggregate for multiple violations arising from
 21 the same failure to comply with the Act; or

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

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

2 (a) INITIATION OF PROCEEDINGS.—

3 (1) IN GENERAL.—The Secretary, in consulta-
4 tion with the Attorney General, may initiate a pro-
5 ceeding to determine whether to impose a civil
6 money penalty under section 311. The Secretary
7 may not initiate an action under this section with re-
8 spect to any violation described in section 311 after
9 the expiration of the 6-year period beginning on the
10 date on which such violation was alleged to have oc-
11 curred. The Secretary may initiate an action under
12 this section by serving notice of the action in any
13 manner authorized by Rule 4 of the Federal Rules
14 of Civil Procedure.

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

23 (3) SANCTIONS FOR FAILURE TO COMPLY.—
24 The official conducting a hearing under this section
25 may sanction a person, including any party or attor-
26 ney, for failing to comply with an order or proce-

1 dure, failing to defend an action, or other mis-
2 conduct as would interfere with the speedy, orderly,
3 or fair conduct of the hearing. Such sanction shall
4 reasonably relate to the severity and nature of the
5 failure or misconduct. Such sanction may include—

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

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

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

15 (D) staying the proceedings;

16 (E) dismissal of the action;

17 (F) entering a default judgment;

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

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

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

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

6 (2) the degree of culpability, history of prior of-
7 fenses, and financial condition of the person pre-
8 senting the claims;

9 (3) evidence of good faith endeavor to protect
10 the confidentiality of protected health information;
11 and

12 (4) such other matters as justice may require.

13 (c) REVIEW OF DETERMINATION.—

14 (1) IN GENERAL.—Any person adversely af-
15 fected by a determination of the Secretary under
16 this section may obtain a review of such determina-
17 tion in the United States Court of Appeals for the
18 circuit in which the person resides, or in which the
19 claim was presented, by filing in such court (within
20 60 days following the date the person is notified of
21 the determination of the Secretary) a written peti-
22 tion requesting that the determination be modified
23 or set aside.

24 (2) FILING OF RECORD.—A copy of the petition
25 filed under paragraph (1) shall be forthwith trans-

1 mitted by the clerk of the court to the Secretary,
2 and thereupon the Secretary shall file in the Court
3 the record in the proceeding as provided in section
4 2112 of title 28, United States Code. Upon such fil-
5 ing, the court shall have jurisdiction of the pro-
6 ceeding and of the question determined therein, and
7 shall have the power to make and enter upon the
8 pleadings, testimony, and proceedings set forth in
9 such record a decree affirming, modifying, remand-
10 ing for further consideration, or setting aside, in
11 whole or in part, the determination of the Secretary
12 and enforcing the same to the extent that such order
13 is affirmed or modified.

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

20 (4) FINDINGS.—The findings of the Secretary
21 with respect to questions of fact in an action under
22 this subsection, if supported by substantial evidence
23 on the record considered as a whole, shall be conclu-
24 sive. If any party shall apply to the court for leave
25 to adduce additional evidence and shall show to the

1 satisfaction of the court that such additional evi-
2 dence is material and that there were reasonable
3 grounds for the failure to adduce such evidence in
4 the hearing before the Secretary, the court may
5 order such additional evidence to be taken before the
6 Secretary and to be made a part of the record. The
7 Secretary may modify findings as to the facts, or
8 make new findings, by reason of additional evidence
9 so taken and filed, and shall file with the court such
10 modified or new findings, and such findings with re-
11 spect to questions of fact, if supported by substan-
12 tial evidence on the record considered as a whole,
13 and the recommendations of the Secretary, if any,
14 for the modification or setting aside of the original
15 order, shall be conclusive.

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

23 (d) RECOVERY OF PENALTIES.—

24 (1) IN GENERAL.—Civil money penalties im-
25 posed under this subtitle may be compromised by

1 the Secretary and may be recovered in a civil action
2 in the name of the United States brought in United
3 States district court for the district where the claim
4 was presented, or where the claimant resides, as de-
5 termined by the Secretary. Amounts recovered under
6 this section shall be paid to the Secretary and depos-
7 ited as miscellaneous receipts of the Treasury of the
8 United States.

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

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

24 (f) SUBPOENA AUTHORITY.—

1 (1) IN GENERAL.—For the purpose of any
2 hearing, investigation, or other proceeding author-
3 ized or directed under this section, or relative to any
4 other matter within the jurisdiction of the Attorney
5 General hereunder, the Attorney General, acting
6 through the Secretary shall have the power to issue
7 subpoenas requiring the attendance and testimony of
8 witnesses and the production of any evidence that
9 relates to any matter under investigation or in ques-
10 tion before the Secretary. Such attendance of wit-
11 nesses and production of evidence at the designated
12 place of such hearing, investigation, or other pro-
13 ceeding may be required from any place in the
14 United States or in any Territory or possession
15 thereof.

16 (2) SERVICE.—Subpoenas of the Secretary
17 under paragraph (1) shall be served by anyone au-
18 thorized by the Secretary by delivering a copy there-
19 of to the individual named therein.

20 (3) PROOF OF SERVICE.—A verified return by
21 the individual serving the subpoena under this sub-
22 section setting forth the manner of service shall be
23 proof of service.

24 (4) FEES.—Witnesses subpoenaed under this
25 subsection shall be paid the same fees and mileage

1 as are paid witnesses in the district court of the
2 United States.

3 (5) REFUSAL TO OBEY.—In case of contumacy
4 by, or refusal to obey a subpoenaed duly served
5 upon, any person, any district court of the United
6 States for the judicial district in which such person
7 charged with contumacy or refusal to obey is found
8 or resides or transacts business, upon application by
9 the Secretary, shall have jurisdiction to issue an
10 order requiring such person to appear and give testi-
11 mony, or to appear and produce evidence, or both.
12 Any failure to obey such order of the court may be
13 punished by the court as contempt thereof.

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

1 (h) AGENCY.—A principal is liable for penalties
 2 under section 311 for the actions of the principal’s agent
 3 acting within the scope of the agency.

4 **SEC. 313. ENFORCEMENT BY STATE INSURANCE COMMIS-**
 5 **SIONERS.**

6 (a) STATE PENALTIES.—Subject to section 401, and
 7 notwithstanding any other provision of this title, the insur-
 8 ance commissioner of the State of residence of an insured
 9 under a life, disability income or long-term care insurance
 10 policy may exercise exclusive authority to impose any pen-
 11 alties on a life insurer for violations of this Act in connec-
 12 tion with life, disability income or long-term care insur-
 13 ance pursuant to the administrative procedures provided
 14 under that State’s insurance laws.

15 (b) FAIL-SAFE FEDERAL AUTHORITY.—In the case
 16 of a State that fails to substantially enforce the require-
 17 ments of title I or title II of this Act with respect to life
 18 insurers regulated by such State, the provisions of this
 19 title shall apply with respect to a life insurer in the same
 20 way that they apply to other persons subject to the Act.

21 **TITLE IV—MISCELLANEOUS**

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

23 (a) STATE AND FEDERAL LAW.—Except as provided
 24 in this section, the provisions of this Act shall preempt
 25 any State law that relates to matters covered by this Act.

1 Nothing in this Act shall be construed to preempt, modify,
2 repeal or affect the interpretation of a provision of Federal
3 or State law that relates to the disclosure of protected
4 health information or any other information about a minor
5 to a parent or guardian of such minor. This Act shall not
6 be construed as repealing, explicitly or implicitly, other
7 Federal laws or regulations relating to protected health
8 information or relating to an individual's access to pro-
9 tected health information or health care services.

10 (b) PRIVILEGES.—Nothing in this title shall be con-
11 strued to preempt or modify any provisions of State statu-
12 tory or common law to the extent that such law concerns
13 a privilege of a witness or person in a court of that State.
14 This title shall not be construed to supersede or modify
15 any provision of Federal statutory or common law to the
16 extent such law concerns a privilege of a witness or person
17 in a court of the United States. Authorizations pursuant
18 to sections 202 and 203 shall not be construed as a waiver
19 of any such privilege.

20 (c) REPORTS CONCERNING FEDERAL PRIVACY
21 ACT.—Not later than 1 year after the date of enactment
22 of this Act, the head of each Federal agency shall prepare
23 and submit to Congress a report concerning the effect of
24 this Act on each such agency. Such reports shall include

1 recommendations for legislation to address concerns relat-
2 ing to the Federal Privacy Act.

3 (d) APPLICATION TO CERTAIN FEDERAL AGEN-
4 CIES.—

5 (1) DEPARTMENT OF DEFENSE.—

6 (A) EXCEPTIONS.—The Secretary of De-
7 fense may, by regulation, establish exceptions to
8 the disclosure requirements of this Act to the
9 extent such Secretary determines that disclo-
10 sure of protected health information relating to
11 members of the armed forces from systems of
12 records operated by the Department of Defense
13 is necessary under circumstances different from
14 those permitted under this Act for the proper
15 conduct of national defense functions by mem-
16 bers of the armed forces.

17 (B) APPLICATION TO CIVILIAN EMPLOY-
18 EES.—The Secretary of Defense may, by regu-
19 lation, establish for civilian employees of the
20 Department of Defense and employees of De-
21 partment of Defense contractors, limitations on
22 the right of such persons to revoke or amend
23 authorizations for disclosures under section 203
24 when such authorizations were provided by such
25 employees as a condition of employment and

1 the disclosure is determined necessary by the
2 Secretary of Defense to the proper conduct of
3 national defense functions by such employees.

4 (2) DEPARTMENT OF TRANSPORTATION.—

5 (A) EXCEPTIONS.—The Secretary of
6 Transportation may, with respect to members
7 of the Coast Guard, exercise the same powers
8 as the Secretary of Defense may exercise under
9 paragraph (1)(A).

10 (B) APPLICATION TO CIVILIAN EMPLOY-
11 EES.—The Secretary of Transportation may,
12 with respect to civilian employees of the Coast
13 Guard and Coast Guard contractors, exercise
14 the same powers as the Secretary of Defense
15 may exercise under paragraph (1)(B).

16 (3) DEPARTMENT OF VETERANS AFFAIRS.—
17 The limitations on use and disclosure of protected
18 health information under this Act shall not be con-
19 strued to prevent any exchange of such information
20 within and among components of the Department of
21 Veterans Affairs that determine eligibility for or en-
22 titlement to, or that provide, benefits under laws ad-
23 ministered by the Secretary of Veteran Affairs.

1 **SEC. 402. CONFORMING AMENDMENT.**

2 Section 1171(6) of the Social Security Act (42 U.S.C.
3 1320d(6)) is amended to read as follows:

4 “(6) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
5 FORMATION.—The term ‘individually identifiable
6 health information’ has the same meaning given the
7 term ‘protected health information’ by section 4 of
8 the Medical Information Protection Act of 1999.”.

9 **SEC. 403. STUDY BY INSTITUTE OF MEDICINE.**

10 Not later than 2 years after the date of enactment
11 of this Act, the National Research Council in conjunction
12 with the Institute of Medicine of the National Academy
13 of Sciences shall conduct a study to examine research
14 issues relating to protected health information, such as the
15 quality and uniformity of institutional review boards and
16 their practices with respect to data management for both
17 researchers and institutional review boards, as well as cur-
18 rent and proposed protection of health information in rela-
19 tion to the legitimate needs of law enforcement. The Coun-
20 cil shall prepare and submit to Congress a report con-
21 cerning the results of such study.

22 **SEC. 405. EFFECTIVE DATE.**

23 (a) EFFECTIVE DATE.—Except as provided in sub-
24 section (b), this Act shall take effect on the date that is
25 12 months after the date on which regulations are promul-
26 gated as required under subsection (c).

1 (b) APPLICABILITY.—The provisions of this Act shall
2 only apply to protected health information collected and
3 disclosed 12 months after the date on which regulations
4 are promulgated as required under subsection (c).

5 (c) REGULATIONS.—Not later than 12 months after
6 the date of enactment of this Act, the Secretary shall, in
7 consultation with the National Committee on Vital and
8 Health Statistics, promulgate regulations implementing
9 this Act.

10 (d) EXCEPTION.—If, not later than 18 months after
11 the date of enactment of this Act, the Secretary has not
12 promulgated the regulations required under subsection (c),
13 the effective date for purposes of subsections (a) and (b)
14 shall be the date that is 30 months after the date of enact-
15 ment of this Act or 12 months after the promulgation of
16 such regulations, whichever is earlier.

○