

105TH CONGRESS
2D SESSION

S. 2609

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 9 (legislative day, OCTOBER 2), 1998

Mr. BENNETT (for himself and Mr. MACK) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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 1998”.

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 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, 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. Standards for electronic disclosures.
- Sec. 213. Individual representatives.
- Sec. 214. No liability for permissible disclosures.
- Sec. 215. Sale of business, merger, etc.

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. Enforcement by State insurance commissioners.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. Enforcement of provisions through conditions on participation.
- Sec. 403. Conforming amendment.
- Sec. 404. 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 inappropri-
14 ate disclosure of protected health information that is
15 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 “accredit-
6 ing body” means a national body, committee, organi-
7 zation, or institution (such as the Joint Commission
8 on Accreditation of Health Care Organizations or
9 the National Committee for Quality Assurance) that
10 has been authorized by law or is recognized by a
11 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, affect,
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.—The term “disclose” means to
2 release, transfer, provide access to, or otherwise di-
3 vulge protected health information to any person
4 other than the individual who is the subject of such
5 information.

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

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

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

18 (i) with respect to the physical or
19 mental condition of an individual; or

20 (ii) affecting the structure or function
21 of the human body or any part of the
22 human body, including the banking of
23 blood, sperm, organs, or any other tissue;
24 or

1 (B) pursuant to a prescription or medical
2 order any sale or dispensing of a drug, device,
3 equipment, or other health care related item to
4 an individual, or for the use of an individual.

5 (7) HEALTH CARE OPERATIONS.—The term
6 “health care operations” means services provided by
7 or on behalf of a health plan or health care provider
8 for the purpose of carrying out the management
9 functions of a health care provider or health plan, or
10 implementing the terms of a contract for health plan
11 benefits, including—

12 (A) coordinating health care, including
13 health care management of the individual
14 through risk assessment and case management;

15 (B) conducting quality assessment and im-
16 provement activities, including outcomes evalua-
17 tion, clinical guideline development, and im-
18 provement;

19 (C) reviewing the competence or qualifica-
20 tions of health care professionals, evaluating
21 provider performance, and conducting health
22 care education, accreditation, certification, li-
23 censing, or credentialing activities;

24 (D) carrying out utilization review activi-
25 ties, including precertification and

1 preauthorization of services, and health plan
2 rating and insurance activities, including under-
3 writing, experience rating and reinsurance; and

4 (E) conducting or arranging for auditing
5 services, including fraud detection and compli-
6 ance programs.

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

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

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

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

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

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

4 (10) HEALTH OVERSIGHT AGENCY.—The term
5 “health oversight agency” means a person who, with
6 respect to a specific item of protected health infor-
7 mation, receives, creates, uses, maintains, or dis-
8 closes the information while acting in whole or in
9 part in the capacity of—

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

15 (B) a person who—

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

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

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

6 (11) HEALTH PLAN.—The term “health plan”
7 means any health insurance plan, including any hos-
8 pital or medical service plan, dental or other health
9 service plan or health maintenance organization
10 plan, provider sponsored organization, or other pro-
11 gram providing or arranging for the provision of
12 health benefits. Such term does not include any pol-
13 icy, plan or program to the extent that it provides,
14 arranges or administers health benefits pursuant to
15 a program of workers compensation or automobile
16 insurance.

17 (12) HEALTH RESEARCHER.—The term “health
18 researcher” means a person, or an officer, employee,
19 or agent of a person, who—

20 (A) receives protected health information
21 as part of a research project that meets existing
22 Federal standards for ensuring informed con-
23 sent and protecting the confidentiality of
24 human subjects as provided for in the imple-
25 mentation of the common rule; or

1 (B) receives protected health information
2 as part of a research project that is subject to
3 the confidentiality protections provided for
4 under this Act.

5 (13) KEY.—The term “key” means a method
6 or procedure used to transform nonidentifiable
7 health information that is in a coded or encrypted
8 form into protected health information.

9 (14) LAW ENFORCEMENT INQUIRY.—The term
10 “law enforcement inquiry” means a lawful investiga-
11 tion or official proceeding inquiring into a violation
12 of, or failure to comply with, any criminal or civil
13 statute or any regulation, rule, or order issued pur-
14 suant to such a statute.

15 (15) NONIDENTIFIABLE HEALTH INFORMA-
16 TION.—The term “nonidentifiable health informa-
17 tion” means protected health information from
18 which personal identifiers, that directly reveal the
19 identity of the individual who is the subject of such
20 information or provide a direct means of identifying
21 the individual (such as name, address, and social se-
22 curity number), have been removed, encrypted, or
23 replaced with a code, such that the identity of the
24 individual is not evident without (in the case of
25 encrypted or coded information) use of key.

1 (16) ORIGINATING PROVIDER.—The term “orig-
2 inating provider” means a health care provider who
3 initiates a treatment episode, such as prescribing a
4 drug, ordering a diagnostic test, or admitting an in-
5 dividual to a health care facility.

6 (17) PAYMENT.—The term “payment”
7 means—

8 (A) the activities undertaken by—

9 (i) or on behalf of a health plan to de-
10 termine its responsibility for coverage
11 under the plan; or

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

18 (B) activities undertaken as described in
19 subparagraph (A) including—

20 (i) billing, claims management, medi-
21 cal data processing, other administrative
22 services, and actual payment;

23 (ii) determinations of coverage or ad-
24 judication of health benefit or subrogation
25 claims; and

1 (iii) review of health care services with
2 respect to coverage under a health plan or
3 justification of charges.

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

10 (19) PROTECTED HEALTH INFORMATION.—The
11 term “protected health information” with respect to
12 the individual who is the subject of such information
13 means any information which identified such individ-
14 ual, whether oral or recorded in any form or me-
15 dium, that—

16 (A) is created or received by a health care
17 provider, health plan, health oversight agency,
18 public health authority, employer, health or life
19 insurer, school or university;

20 (B) relates to the past, present, or future
21 physical or mental health or condition of an in-
22 dividual (including individual cells and their
23 components);

24 (C) is derived from—

1 (i) the provision of health care to an
2 individual; or

3 (ii) payment for the provision of
4 health care to an individual; and

5 (D) is not nonidentifiable health informa-
6 tion.

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

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

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

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

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

3 (23) SIGNED.—The term “signed” refers to
4 both signatures in ink and electronic signatures, and
5 “written” refers to both paper and computerized for-
6 mats.

7 (24) STATE.—The term “State” includes the
8 District of Columbia, Puerto Rico, the Virgin Is-
9 lands, Guam, American Samoa, and the Northern
10 Mariana Islands.

11 (25) TREATMENT.—The term “treatment”
12 means the provision of health care by a health care
13 provider.

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

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

21 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
22 **HEALTH INFORMATION.**

23 (a) GENERAL RULES.—

24 (1) COMPLIANCE WITH SECTION.—At the re-
25 quest of an individual who is the subject of protected

1 health information and except as provided in sub-
2 section (c), a health care provider, a health plan,
3 employer, health or life insurer, school, or university
4 shall arrange for inspection or copying of protected
5 health information concerning the individual, includ-
6 ing records created under section 102, as provided
7 for in this section.

8 (2) ORIGINATING PROVIDER.—For purposes of
9 this title, the term “originating provider” means a
10 health care provider who initiates a treatment epi-
11 sode, such as prescribing a drug or ordering a diag-
12 nostic test. A hospital or nursing facility is the origi-
13 nating provider with respect to protected health in-
14 formation created or received as part of inpatient or
15 outpatient treatment provided in such settings.

16 (3) AVAILABILITY OF INFORMATION THROUGH
17 ORIGINATING PROVIDER.—Protected health informa-
18 tion that is created or received by a health plan or
19 health care provider as part of treatment or pay-
20 ment shall be made available for inspection or copy-
21 ing as provided for in this title through the originat-
22 ing provider.

23 (4) OTHER ENTITIES.—An employer, life in-
24 surer, school, or university that creates or receives
25 protected health information in performing any func-

1 tion other than providing treatment, payment, or
2 health care operations with respect to the individual
3 who is the subject of such information, shall make
4 such information available for inspection or copying
5 as provided for in this title, or through any provider
6 designated by the individual.

7 (5) PROCEDURES.—The person providing ac-
8 cess to information under this title may set forth ap-
9 propriate procedures to be followed for such inspec-
10 tion or copying and may require an individual to pay
11 reasonable costs associated with such inspection or
12 copying.

13 (b) SPECIAL CIRCUMSTANCES.—If an originating
14 provider, its agent, or contractor no longer maintains the
15 protected health information sought by an individual pur-
16 suant to subsection (a), a health plan or another health
17 care provider that maintains such information shall ar-
18 range for inspection or copying.

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

24 (1) ENDANGERMENT TO LIFE OR SAFETY.—
25 The person determines that the disclosure of the in-

1 formation could reasonably be expected to endanger
2 the life or physical safety of any individual.

3 (2) CONFIDENTIAL SOURCE.—The information
4 identifies, or could reasonably lead to the identifica-
5 tion of, a person who provided information under a
6 promise of confidentiality to a health care provider
7 concerning the individual who is the subject of the
8 information.

9 (3) INFORMATION COMPILED IN CONNECTION
10 WITH A FRAUD INVESTIGATION AND LITIGATION.—
11 The information is compiled principally—

12 (A) in connection with a fraud investiga-
13 tion, civil, criminal, or administrative action or
14 proceeding; or

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

16 (4) INVESTIGATIONAL INFORMATION.—With re-
17 spect to protected health information that was cre-
18 ated as part of the individual's participation in a
19 clinical trial monitored by an institutional review
20 board, access to information shall be provided con-
21 sistent with the common rule.

22 (d) DENIAL OF A REQUEST FOR INSPECTION OR
23 COPYING.—If a person described in subsection (a) or (b)
24 denies a request for inspection or copying pursuant to sub-

1 section (c), the person shall inform the individual in writ-
2 ing of—

3 (1) the reasons for the denial of the request for
4 inspection or copying;

5 (2) the availability of procedures for further re-
6 view of the denial; and

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

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

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

16 (2) may include a concise statement of the rea-
17 sons for denying the request for inspection or copy-
18 ing.

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

24 (g) DEADLINE.—A person described in subsection (a)
25 or (b) shall comply with or deny, in accordance with sub-

1 section (d), a request for inspection or copying of pro-
2 tected health information under this section not later than
3 60 days after the date on which the person receives the
4 request.

5 (h) RULES OF CONSTRUCTION.—

6 (1) AGENTS OR CONTRACTORS.—An agent or
7 contractor of a person described in subsection (a) or
8 (b) shall not be required to provide for the inspec-
9 tion and copying of protected health information, ex-
10 cept where—

11 (A) the protected health information is re-
12 tained by the agent or contractor; and

13 (B) the agent or contractor has been asked
14 in writing by the person involved to fulfill the
15 requirements of this section.

16 (2) NO REQUIREMENT FOR HEARING.—This
17 section shall not be construed to require a person
18 described in subsection (a) or (b) to conduct a for-
19 mal, informal, or other hearing or proceeding con-
20 cerning a request for inspection or copying of pro-
21 tected health information.

22 **SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-**
23 **TION.**

24 (a) IN GENERAL.—Except as provided in subsection
25 (b), not later than 45 days after the date on which a

1 health care provider, health plan, employer, health or life
2 insurer, school, or university receives from an individual
3 a request in writing to amend information, such person
4 shall—

5 (1) make the amendment requested;

6 (2) inform the individual of the amendment
7 that has been made; and

8 (3) inform any person identified by the individ-
9 ual in the request for amendment and—

10 (A) who is not an officer, employee, or
11 agent of the person; and

12 (B) to whom the unamended portion of the
13 information was disclosed within the previous
14 year

15 by sending a notice to the person's last known ad-
16 dress that there has been a substantive amendment
17 to the protected health information of such individ-
18 ual.

19 (b) REFUSAL TO AMEND.—If a person described in
20 subsection (a) refuses to make the amendment requested
21 under such subsection, the person shall inform the individ-
22 ual in writing of—

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

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

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

7 (c) STATEMENT OF DISAGREEMENT.—If an individ-
8 ual has filed a statement of disagreement under subsection
9 (b)(3), the person involved, in any subsequent disclosure
10 of the disputed portion of the information—

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

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

15 (d) RULES GOVERNING AGENTS AND CONTRAC-
16 TORS.—The agent or contractor of a person described in
17 subsection (a) shall not be required to make amendments
18 to protected health information, except where—

19 (1) the protected health information is retained
20 by the agent or contractor; and

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

24 (e) REPEATED REQUESTS FOR AMENDMENTS.—If a
25 person described in subsection (a) receives a request for

1 an amendment of information as provided for in such sub-
2 section and a statement of disagreement has been filed
3 pursuant to subsection (c), the person shall inform the in-
4 dividual of such filing and shall not be required to carry
5 out the procedures required under this section.

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

8 (1) require that a person described in sub-
9 section (a) conduct a formal, informal, or other
10 hearing or proceeding concerning a request for an
11 amendment to protected health information;

12 (2) permit an individual to modify statements
13 in his or her record that document the factual obser-
14 vation of another individual or state the results of
15 diagnostic tests; or

16 (3) permit an individual to amend his or her
17 record as to the type, duration, or quality of treat-
18 ment the individual believes he or she should have
19 been provided.

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

21 (a) PREPARATION OF WRITTEN NOTICE.—A health
22 care provider, health plan, health oversight agency, public
23 health authority, employer, health or life insurer, health
24 researcher, school, or university shall post or provide, in

1 writing and in a clear and conspicuous manner, notice of
2 the person's confidentiality practices, that shall include—

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

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

7 (3) the procedures for authorizing disclosures of
8 protected health information and for revoking such
9 authorizations;

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

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

14 (b) MODEL NOTICE.—The Secretary, after notice
15 and opportunity for public comment, shall develop and dis-
16 seminate model notices of confidentiality practices, using
17 the advice of the National Committee on Vital Health Sta-
18 tistics as derived based upon testimony from groups such
19 as the National Association of Insurance Commissioners
20 and others, for use under this section. Use of the model
21 notice shall serve as an absolute defense against claims
22 of receiving 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, health or life insurer, health researcher, law en-
7 forcement official, school, or university shall establish and
8 maintain appropriate administrative, technical, and phys-
9 ical safeguards to protect the confidentiality, security, ac-
10 curacy, and integrity of protected health information cre-
11 ated, received, obtained, maintained, used, transmitted, or
12 disposed of by such person.

13 (b) FACTORS TO BE CONSIDERED.—The following
14 factors shall be considered in establishing safeguards pur-
15 suant to subsection (a):

16 (1) The need for protected health information.

17 (2) The categories of personnel who will have
18 access to protected health information.

19 (3) The feasibility of limiting access to individ-
20 ual identifiers.

21 (c) REGULATIONS.—In promulgating regulations
22 under this Act, the Secretary shall consult with the Na-
23 tional Committee on Vital and Health Statistics.

24 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

25 (a) IN GENERAL.—

1 (1) HEALTH RELATED ENTITIES.—A health
 2 care provider, health plan, health oversight agency,
 3 public health authority, employer, health or life in-
 4 surer, health researcher, law enforcement official,
 5 school, or university shall establish and maintain,
 6 with respect to any protected health information dis-
 7 closure not made within the entity, a record of such
 8 disclosure in accordance with regulations issued by
 9 the Secretary.

10 (2) AGENT.—An agent shall maintain a record
 11 of its disclosures made pursuant to sections 205
 12 through 212.

13 (b) RECORD OF DISCLOSURE.—A record established
 14 under subsection (a) shall be maintained for not less than
 15 7 years.

16 **TITLE II—RESTRICTIONS ON** 17 **USE AND DISCLOSURE**

18 **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-** 19 **SURE.**

20 (a) PROHIBITION.—

21 (1) GENERAL RULE.—A health care provider,
 22 health plan, health oversight agency, public health
 23 authority, employer, health or life insurer, health re-
 24 searcher, law enforcement official, school, or univer-

1 sity may not disclose protected health information
2 except as authorized under this title.

3 (2) RULES OF CONSTRUCTION.—

4 (A) DISCLOSURE.—Disclosure of health in-
5 formation in the form of nonidentifiable health
6 information shall not be construed as a disclo-
7 sure of protected health information.

8 (B) USE.—The use of protected health in-
9 formation by a person described in paragraph
10 (1) and its agents shall not be considered a dis-
11 closure for purposes of this Act, provided that
12 the use is consistent with the purposes for
13 which the information was lawfully obtained.

14 (b) NO GENERAL REQUIREMENTS TO DISCLOSE.—
15 Nothing in this title shall be construed to require disclo-
16 sure by a health care provider within an entity described
17 in subsection (a).

18 (c) DISCLOSURE BY AGENTS.—An agent who receives
19 protected health information from a person described in
20 subsection (a) shall be subject to all rules of disclosure
21 and safeguard requirements under this title.

22 (d) SCOPE OF DISCLOSURE.—Every disclosure of
23 protected health information by a person under this title
24 shall be limited to the information necessary to accomplish
25 the purpose for which the information is disclosed.

1 (e) IDENTIFICATION OF DISCLOSED INFORMATION AS
2 PROTECTED HEALTH INFORMATION.—Except as other-
3 wise provided in this title, protected health information
4 may not be disclosed unless such information is clearly
5 identified as protected health information that is subject
6 to this Act.

7 (f) CREATION OF NONIDENTIFIABLE HEALTH IN-
8 FORMATION.—A person described in subsection (a) may
9 use protected health information for the purpose of creat-
10 ing nonidentifiable health information, if the person pro-
11 hibits the employee or agent creating the nonidentifiable
12 health information from using or disclosing the protected
13 health information for purposes other than the sole pur-
14 pose of creating nonidentifiable health information as
15 specified by the person.

16 (g) DISCLOSURE USING THE KEY.—Any person who
17 manipulates nonidentifiable health information in order to
18 identify an individual, without lawfully using the key, is
19 deemed to have disclosed protected health information.
20 Disclosure of the key is deemed to be a disclosure of pro-
21 tected health information.

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 PROVID-
7 ERS.—

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

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

23 (3) HEALTH PLANS.—Every health plan offer-
24 ing enrollment to individuals or non-employer groups
25 shall, at the time of, and as a condition of enroll-
26 ment in the health plan, obtain a signed, written au-

1 thorization that is a legal, informed authorization
2 concerning the use and disclosure of protected health
3 information for treatment, payment, and health care
4 operations, with respect to each individual who is eli-
5 gible to receive care under the plan.

6 (4) UNINSURED.—An originating provider pro-
7 viding health care to an uninsured individual, shall
8 obtain a signed, written authorization to use and
9 disclose protected health information with respect to
10 such individual for treatment, payment, and health
11 care operations of such provider, and in arranging
12 for treatment and payment from other providers.

13 (5) PROVIDERS.—Any health care provider pro-
14 viding health care to an individual may, at the time
15 of providing such care, obtain a signed, written au-
16 thorization that is a legal, informed authorization
17 concerning the use and disclosure of protected health
18 information with respect to such individual for treat-
19 ment, payment, and health care operations of such
20 provider.

21 (b) REQUIREMENTS FOR INDIVIDUAL AUTHORIZA-
22 TION.—To be valid, an authorization to disclose protected
23 health information shall—

24 (1) identify the individual involved;

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

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

5 (4) describe the purpose of the disclosure;

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

9 (6)(A) be either—

10 (i) in writing, dated, and signed by the in-
11 dividual; or

12 (ii) in electronic form, dated and authenti-
13 cated by the individual using a unique identi-
14 fier; and

15 (B) not have been revoked under subsection (e).

16 (c) REVOCATION OF AUTHORIZATION.—

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

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

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

13 (4) TERMINATION OF PLAN.—With respect to
14 the revocation of an authorization under this section
15 by an enrollee in a health plan, the health plan may
16 terminate the coverage of such enrollee under such
17 plan if the health plan determines that the revoca-
18 tion has resulted in the inability of the plan to pro-
19 vide appropriate care for the enrollee or conduct es-
20 sential health care operations.

21 (d) RECORD OF INDIVIDUAL’S AUTHORIZATIONS AND
22 REVOCATIONS.—Each person who obtains or is required
23 to obtain an authorization under this section shall main-
24 tain a record for a period of 7 years of each such author-
25 ization of an individual and revocation thereof.

1 (e) MODEL AUTHORIZATIONS.—The Secretary, after
2 notice and opportunity for public comment, shall develop
3 and disseminate model written authorizations of the type
4 described in subsection (a). The Secretary shall consult
5 with the National Committee on Vital and Health Statis-
6 ties in developing such authorizations. Any authorization
7 obtained on a model authorization form developed by the
8 Secretary pursuant to the preceding sentence shall be
9 deemed to meet the authorization requirements of this sec-
10 tion.

11 (f) RULE OF CONSTRUCTION.—Authorizations for
12 the disclosure of protected health information for treat-
13 ment, payment, and health care operations shall not au-
14 thorize the disclosure of such information by an individual
15 with the intent to sell, transfer, or use protected health
16 information for commercial advantage unrelated to the
17 purposes of the authorization. For such disclosures a sepa-
18 rate authorization is required under section 203.

19 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
20 **TECTED HEALTH INFORMATION OTHER THAN**
21 **FOR TREATMENT, PAYMENT, AND HEALTH**
22 **CARE OPERATIONS.**

23 (a) IN GENERAL.—An individual who is the subject
24 of protected health information may authorize any person
25 to disclose or use such information for any purpose.

1 (b) WRITTEN AUTHORIZATIONS.—A health care pro-
2 vider, health plan, health oversight agency, public health
3 authority, employer, health or life insurer, health re-
4 searcher, law enforcement official, school, or university
5 may disclose protected health information, for purposes
6 other than those authorized under section 202, pursuant
7 to an authorization executed by the individual who is the
8 subject of the information that meets the requirements of
9 section 202(b). An authorization under this section shall
10 be separate from any authorization provided under section
11 202.

12 (c) LIMITATION ON AUTHORIZATIONS.—A person
13 may not condition the delivery of treatment or payment
14 for services by a health insurer or plan on the receipt of
15 an authorization described in this section.

16 (d) REVOCATION OR AMENDMENT OF AUTHORIZA-
17 TION.—

18 (1) IN GENERAL.—An individual may revoke or
19 amend an authorization described in this section by
20 providing written notice to the person who obtained
21 such authorization unless the disclosure that is the
22 subject of the authorization is related to the evalua-
23 tion of an application for life insurance coverage or
24 a claim for life insurance benefits.

1 (2) NOTICE OF REVOCATION.—A person de-
2 scribed in subsection (b) that discloses protected
3 health information pursuant to an authorization that
4 has been revoked under paragraph (1) shall not be
5 subject to any liability or penalty under this title if
6 that person had no actual notice of the revocation.

7 (3) ACTIONS.—An individual may not maintain
8 an action against a person for disclosure of pro-
9 tected health information made in good faith reli-
10 ance on the individual's authorization at the time
11 disclosure was made.

12 (e) DISCLOSURE FOR PURPOSE ONLY.—A recipient
13 of protected health information pursuant to an authoriza-
14 tion under section 203(b) may disclose such information
15 to carry out the purposes for which the information was
16 authorized for release.

17 (f) AUTHORIZATIONS FOR RESEARCH.—Notwith-
18 standing the provisions of this section, any authorization
19 required for health research shall comply with the require-
20 ments of section 208 and, where applicable, section
21 202(b).

22 (g) MODEL AUTHORIZATIONS.—The Secretary, after
23 notice and opportunity for public comment, shall develop
24 and disseminate model written authorizations of the type
25 described in subsection (b). The Secretary shall consult

1 with the National Committee on Vital and Health Statis-
2 ties in developing such authorizations. Any authorization
3 obtained on a model authorization form developed by the
4 Secretary pursuant to the preceding sentence shall be
5 deemed to meet the authorization requirements of this sec-
6 tion.

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

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

13 (1) the individual who is the subject of the in-
14 formation—

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; or

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 individ-
10 ual 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. Protected health information disclosed
11 under this section shall not be used or further disclosed
12 for any purpose unrelated to the authorized oversight
13 function.

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

20 (c) USE IN ACTION AGAINST INDIVIDUALS.—Pro-
21 tected health information about an individual that is dis-
22 closed under this section may not be used in, or disclosed
23 to any person for use in, an administrative, civil, or crimi-
24 nal action or investigation directed against the individual
25 who is the subject of the protected health information un-

1 less the action or investigation arises out of and is directly
2 related to—

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

5 (2) an action involving a fraudulent claim relat-
6 ed to health care, or an action involving a fraudulent
7 misrepresentation of the health of the individual.

8 **SEC. 207. PUBLIC HEALTH.**

9 (a) IN GENERAL.—A health care provider, health
10 plan, public health authority, health researcher, employer,
11 health or life insurer, law enforcement official, school, or
12 university may disclose protected health information to a
13 public health authority or other person authorized by law
14 for use in a legally authorized—

15 (1) disease or injury report;

16 (2) public health surveillance;

17 (3) public health investigation or intervention;

18 (4) vital statistics report, such as birth or death
19 information;

20 (5) report of abuse or neglect information about
21 any individual; or

22 (6) report of information concerning a commu-
23 nicable disease status otherwise permissible under
24 this Act.

1 (b) IDENTIFICATION OF DECEASED INDIVIDUAL.—
2 Any person may disclose protected health information if
3 such disclosure is necessary to assist in the identification
4 or safe handling of a deceased individual.

5 (c) REQUIREMENT TO RELEASE PROTECTED
6 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-
7 AMINERS.—

8 (1) IN GENERAL.—When a Coroner or Medical
9 Examiner or their duly appointed deputies seek pro-
10 tected health information for the purpose of inquiry
11 into and determination of, the cause, manner, and
12 circumstances of a death, the health care provider,
13 health plan, health oversight agency, public health
14 authority, employer, health or life insurer, health re-
15 searcher, law enforcement official, school, or univer-
16 sity involved shall provide the protected health infor-
17 mation to the Coroner or Medical Examiner or to
18 the duly appointed deputies without undue delay.

19 (2) PRODUCTION OF ADDITIONAL INFORMA-
20 TION.—If a Coroner or Medical Examiner or their
21 duly appointed deputies receives health information
22 from a person referred to in paragraph (1), such
23 health information shall remain as protected health
24 information unless the health information is at-
25 tached to or otherwise made a part of a Coroner's

1 or Medical Examiner's official report, in which case
2 it shall no longer be protected.

3 (3) EXEMPTION.—Health information attached
4 to or otherwise made a part of a Coroner's or Medi-
5 cal Examiner's official report, shall be exempt from
6 the provisions of this Act except as provided for in
7 this subsection.

8 (4) REIMBURSEMENT.—A Coroner or Medical
9 Examiner may require a person to reimburse their
10 Office for the reasonable costs associated with such
11 inspection or copying.

12 **SEC. 208. HEALTH RESEARCH.**

13 (a) IN GENERAL.—Notwithstanding the require-
14 ments of section 203, a health care provider, health plan,
15 public health authority, health researcher, employer,
16 health or life insurer, school or university may disclose
17 protected health information to a health researcher under
18 any of the following arrangements:

19 (1) RESEARCH GOVERNED BY THE COMMON
20 RULE.—A person identified in subsection (a) may
21 disclose protected health information to a health re-
22 searcher if the research project has been approved
23 by an institutional review board pursuant to the re-
24 quirements of the common rule as implemented by
25 a Federal agency.

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

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

12 (B) the health research involves analysis of
13 protected health information previously created
14 or collected by the health care provider, health
15 plan, public health authority, employer, health
16 or life insurer, school or university;

17 (C) the health care provider, health plan,
18 public health authority, employer health or life
19 insurer, school or university that maintains the
20 protected health information to be used in the
21 analyses has in place a written policy and pro-
22 cedure to assure the security and confidentiality
23 of protected health information and to specify
24 permissible and impermissible uses of such in-
25 formation for health research;

1 (D) the health care provider, health plan,
2 public health authority, employer, health or life
3 insurer, school, or university enters into a writ-
4 ten agreement with the recipient health re-
5 searcher that specifies the permissible and im-
6 permissible uses of the protected health infor-
7 mation and provides notice to the researcher
8 that any misuse or further disclosure of the in-
9 formation to other persons is prohibited and
10 may provide a basis for action against the
11 health researcher under this Act; and

12 (E) the health care provider, health plan,
13 public health authority, employer, health or life
14 insurer, school or university keeps a record of
15 all health researchers to whom protected health
16 information has been made available.

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

1 (b) OVERSIGHT.—On the advice of the National Com-
2 mittee on Vital and Health Statistics, the Secretary shall
3 report to the Congress not later than 18 months after the
4 effective date of this section concerning the adequacy of
5 the policies and procedures implemented pursuant to sub-
6 section (a)(2) for protecting the confidentiality of pro-
7 tected health information while promoting its use in re-
8 search concerning health care outcomes, the epidemiology
9 and etiology of diseases and conditions and the safety, effi-
10 cacy and cost effectiveness of health care interventions.
11 Based on the conclusions of such report, the Secretary
12 may promulgate model language for written agreements
13 deemed to comply with subsection (a)(2)(C).

14 (c) STATUTORY ASSURANCE OF CONFIDENTIAL-
15 ITY.—Protected health information obtained by a health
16 researcher pursuant to this section shall be used and
17 maintained in confidence, consistent with the confiden-
18 tiality practices established by the health researcher pursuant
19 to section 111 and, except as permitted by section 205
20 or 207, or to fulfill the safety and efficacy objectives of
21 the Federal Food, Drug and Cosmetic Act or correspond-
22 ing laws of other countries, may not be disclosed by the
23 recipient health researcher in a form that directly reveals
24 the identity of any individual who is the subject of such
25 information without a court order.

1 **SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINIS-**
2 **TRATIVE PROCEDURES.**

3 (a) IN GENERAL.—A health care provider, health
4 plan, public health authority, employer, health or life in-
5 surer, law enforcement official, school, or university may
6 disclose protected health information—

7 (1) pursuant to a discovery request or subpoena
8 in a civil action brought in a Federal or State court
9 or a request or subpoena related to a Federal or
10 State administrative proceeding; and

11 (2) such discovery request or subpoena is made
12 through or pursuant to a court order as provided for
13 in subsection (b).

14 (b) COURT ORDERS.—

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

22 (2) REQUIREMENTS.—An order issued under
23 paragraph (1) shall—

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

1 (B) specify to whom the information may
2 be disclosed;

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

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

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

11 (1) unidentifiable health information; or

12 (2) related to a party to the litigation or an in-
13 dividual whose medical condition is at issue.

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

18 **SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PUR-**
19 **POSES.**

20 A person who receives protected health information
21 pursuant to sections 202 through 207, may disclose pro-
22 tected health information under this section if the dislo-
23 sure is—

24 (1) pursuant to—

1 (A) a subpoena issued under the authority
2 of a grand jury;

3 (B) an administrative or judicial subpoena
4 or summons; or

5 (C) a request from a law enforcement
6 agency otherwise authorized by Federal or
7 State law;

8 (2) to prevent or prosecute the perpetration of
9 fraud; or

10 (3) to report a reasonable belief that illegal ac-
11 tivities have been conducted.

12 **SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT**
13 **TRANSACTION.**

14 (a) **PAYMENT FOR HEALTH CARE THROUGH CARD**
15 **OR ELECTRONIC MEANS.**—If an individual pays for health
16 care by presenting a debit, credit, or other payment card
17 or account number, or by any other payment means, the
18 person receiving the payment may disclose to a person de-
19 scribed in subsection (b) only such protected health infor-
20 mation about the individual as is necessary in connection
21 with activities described in subsection (b), including the
22 processing of the payment transaction or the billing or col-
23 lection of amounts charged to, debited from, or otherwise
24 paid by, the individual using the card, number, or other
25 means.

1 (b) TRANSACTION PROCESSING.—A person who is a
2 debit, credit, or other payment card issuer, a payment sys-
3 tem operator, a financial institution participant in a pay-
4 ment system or is an entity assisting such an issuer, oper-
5 ator, or participant in connection with activities described
6 in this subsection, may use or disclose protected health
7 information about an individual in connection with—

8 (1) the authorization, settlement, billing, proc-
9 essing, clearing, transferring, reconciling, or collec-
10 tion of amounts charged, debited or otherwise paid
11 using a debit, credit, or other payment card or ac-
12 count number, or by other payment means;

13 (2) the transfer of receivables, accounts, or in-
14 terest therein;

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

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

18 (5) compliance with a properly authorized civil,
19 criminal, or regulatory investigation by Federal,
20 State, or local authorities as governed by the re-
21 quirements of this section; or

22 (6) fraud protection, risk control, resolving cus-
23 tomer disputes or inquiries, communicating with the
24 person to whom the information relates, or reporting
25 to consumer reporting agencies.

1 (c) SPECIFIC PROHIBITIONS.—A person described in
2 subsection (b) may not disclose protected health informa-
3 tion for any purpose that is not described in subsection
4 (b). Notwithstanding any other provision of law, any
5 health care provider, health plan, health oversight agency,
6 health researcher, employer, health or life insurer, school
7 or university who makes a good faith disclosure of pro-
8 tected health information to an entity and for the purposes
9 described in subsection (b) shall not be liable for subse-
10 quent disclosures by such entity.

11 (d) SCOPE.—

12 (1) IN GENERAL.—The use of protected health
13 information by a person described in subsection (b)
14 and its agents shall not be considered a disclosure
15 for purposes of this Act, so long as the use involved
16 is consistent with the activities authorized in sub-
17 section (b) or other purposes for which the informa-
18 tion was lawfully obtained.

19 (2) REGULATED INSTITUTIONS.—A person who
20 is subject to enforcement pursuant to section 8 of
21 the Federal Deposit Insurance Act or who is a Fed-
22 eral credit union or State credit union as defined in
23 the Federal Credit Union Act or who is registered
24 pursuant to the Securities and Exchange Act, or
25 who is an entity assisting such a person—

1 (A) shall not be subject to this Act to the
2 extent that such person or entity is described in
3 subsection (b) and to the extent that such per-
4 son or entity is engaged in activities authorized
5 in that subsection; and

6 (B) shall be subject to enforcement exclu-
7 sively under section 8 of the Federal Deposit
8 Insurance Act, the Federal Credit Union Act,
9 or the Securities and Exchange Act, as applica-
10 ble, to the extent that such person or entity is
11 engaged in activities other than those permitted
12 under subsection (b).

13 (3) **RULE OF CONSTRUCTION.**—Nothing in this
14 subsection shall be deemed to exempt entities de-
15 scribed in paragraph (2) from the prohibition set
16 forth in subsection (c).

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

18 The Secretary shall promulgate standards for disclos-
19 ing, authorizing, and authenticating, protected health in-
20 formation in electronic form consistent with this title.

21 **SEC. 213. INDIVIDUAL REPRESENTATIVES.**

22 (a) **IN GENERAL.**—Except as provided in subsections
23 (b) and (c), a person who is authorized by law (based on
24 grounds other than the individual being a minor), or by
25 an instrument recognized under law, to act as an agent,

1 attorney, proxy, or other legal representative of a pro-
2 tected individual, may, to the extent so authorized, exer-
3 cise and discharge the rights of the individual under this
4 Act.

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

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

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

23 (2) a person described in subsection (a) with re-
24 spect to the individual, but only if a person de-

1 scribed in paragraph (1) cannot be contacted after
2 a reasonable effort;

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

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

9 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
10 provisions of this Act shall continue to apply to protected
11 health information concerning a deceased individual for a
12 period of 2 years following the death of that individual.

13 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
14 CEASED INDIVIDUAL.—

15 (1) IN GENERAL.—A person who is authorized
16 by law or by an instrument recognized under law, to
17 act as an executor of the estate of a deceased indi-
18 vidual, or otherwise to exercise the rights of the de-
19 ceased individual, may, to the extent so authorized,
20 exercise and discharge the rights of such deceased
21 individual under this Act for a period of 2 years fol-
22 lowing the death of that individual. If no such des-
23 ignee has been authorized, the rights of the deceased
24 individual may be exercised as provided for in sub-
25 section (c).

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

7 (f) RIGHTS OF MINORS.—

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

10 (A) who is 18 years of age or older, all
11 rights of the individual under this title shall be
12 exercised by the individual; or

13 (B) who, acting alone, can obtain a type of
14 health care without violating any applicable
15 Federal or State law, and who has sought such
16 care, the individual shall exercise all rights of
17 the individual under this title with respect to
18 protected health information relating to such
19 health care.

20 (2) INDIVIDUALS UNDER 18.—Except as pro-
21 vided in paragraph (1)(B), in the case of an individ-
22 ual who is—

23 (A) under 14 years of age, all of the indi-
24 viduals rights under this title shall be exercised
25 through the parent or legal guardian; or

1 (B) at least 14 but under 18 years of age,
2 the rights of inspection and supplementation,
3 and the right to authorize use and disclosure of
4 protected health information of the individual
5 shall be exercised by the individual, or by the
6 parent or legal guardian of the individual.

7 **SEC. 214. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

8 A health care provider, health plan, health oversight
9 agency, health researcher, employer, health or life insurer,
10 school, or university who makes a disclosure of protected
11 health information about an individual that is permitted
12 by this Act shall not be liable to the individual for such
13 disclosure under common law.

14 **SEC. 215. SALE OF BUSINESS, MERGERS, ETC.**

15 (a) IN GENERAL.—A health care provider, health
16 plan, health oversight agency, employer, health or life in-
17 surer, school, or university may disclose protected health
18 information to a person or persons for purposes of ena-
19 bling business decisions to be made about or in connection
20 with the purchase, transfer, merger, or sale of a business
21 or businesses.

22 (b) NO FURTHER DISCLOSURE.—A person or per-
23 sons who receive protected health information under this
24 section shall make no further disclosure of such informa-
25 tion unless otherwise authorized under this Act.

1 **TITLE III—SANCTIONS**
 2 **Subtitle A—Criminal Provisions**

3 **SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED**
 4 **HEALTH INFORMATION.**

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

7 **“CHAPTER 124—WRONGFUL DISCLOSURE**
 8 **OF PROTECTED HEALTH INFORMATION**

9 **“§ 2801. Wrongful disclosure of protected health in-**
 10 **formation**

11 “(a) OFFENSE.—The penalties described in sub-
 12 section (b) shall apply to a person that knowingly and in-
 13 tentiously—

14 “(1) obtains protected health information relat-
 15 ing to an individual from a health care provider,
 16 health plan, health oversight agency, public health
 17 authority, employer, health or life insurer, health re-
 18 searcher, law enforcement official, school, or univer-
 19 sity except as provided in title II of the Medical In-
 20 formation Protection Act of 1998; or

21 “(2) discloses protected health information to
 22 another person in a manner other than that which
 23 is permitted under title II of the Medical Informa-
 24 tion Protection Act of 1998.

1 “(b) PENALTIES.—A person described in subsection
2 (a) shall—

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

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

8 “(3) if the offense is committed with the intent
9 to sell, transfer, or use protected health information
10 for commercial advantage, personal gain, or mali-
11 cious harm, be fined not more than \$250,000, im-
12 prisoned not more than 10 years, or both.

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

20 (b) CLERICAL AMENDMENT.—The table of chapters
21 for part I of title 18, United States Code, is amended by
22 inserting after the item relating to chapter 123 the follow-
23 ing new item:

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

1 **Subtitle B—Civil Sanctions**

2 **SEC. 311. CIVIL PENALTY.**

3 (a) VIOLATION.—A person who the Secretary, in con-
4 sultation with the Attorney General, determines has sub-
5 stantially and materially failed to comply with this Act
6 shall be subject, in addition to any other penalties that
7 may be prescribed by law—

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

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

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

22 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
23 Section 1128A of the Social Security Act, other than sub-
24 sections (a) and (b) and the second sentence of subsection
25 (f) of that section, shall apply to the imposition of a civil

1 or monetary penalty under this section in the same man-
2 ner as such provisions apply with respect to the imposition
3 of a penalty under section 1128A of such Act.

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

5 (a) INITIATION OF PROCEEDINGS.—

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

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

1 (3) SANCTIONS FOR FAILURE TO COMPLY.—

2 The official conducting a hearing under this section
3 may sanction a person, including any party or attor-
4 ney, for failing to comply with an order or proce-
5 dure, failing to defend an action, or other mis-
6 conduct as would interfere with the speedy, orderly,
7 or fair conduct of the hearing. Such sanction shall
8 reasonably relate to the severity and nature of the
9 failure or misconduct. Such sanction may include—

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

15 (B) prohibiting a party from introducing
16 certain evidence or otherwise supporting a par-
17 ticular claim or defense;

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

19 (D) staying the proceedings;

20 (E) dismissal of the action;

21 (F) entering a default judgment;

22 (G) ordering the party or attorney to pay
23 attorneys' fees and other costs caused by the
24 failure or misconduct; and

1 (H) refusing to consider any motion or
2 other action which is not filed in a timely man-
3 ner.

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

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

9 (2) the degree of culpability, history of prior of-
10 fenses, and financial condition of the person present-
11 ing the claims; and

12 (3) 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 proceed-
6 ing 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 321 shall
18 be final upon the expiration of the 60-day period referred
19 to in subsection (e)(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 (e) may not be
22 raised as a defense to a civil action by the United States
23 to collect a penalty under section 321.

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 duly served upon, any per-
5 son, any district court of the United States for the
6 judicial district in which such person charged with
7 contumacy or refusal to obey is found or resides or
8 transacts business, upon application by the Sec-
9 retary, shall have jurisdiction to issue an order re-
10 quiring such person to appear and give testimony, or
11 to appear and produce evidence, or both. Any failure
12 to obey such order of the court may be punished by
13 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 Notwithstanding any other provision of the Act, in-
 7 cluding sections 301, 311 and 312, the insurance commis-
 8 sioner of the State of domicile of a life insurer may exer-
 9 cise exclusive authority in enforcing this Act as it relates
 10 to a life insurer pursuant to the administrative procedures
 11 provided under that State’s insurance laws.

12 **TITLE IV—MISCELLANEOUS**

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

14 (a) STATE LAW.—Except as provided in subsections
 15 (b) and (c), the provision of this Act shall preempt any
 16 State law that relates to matters covered by this Act. This
 17 Act shall not be construed as repealing, explicitly or im-
 18 plicitly, other Federal laws or regulations relating to pro-
 19 tected health information or relating to an individual’s ac-
 20 cess to protected health information or health care serv-
 21 ices.

22 (b) PRIVILEGES.—Nothing in this title shall be con-
 23 strued to preempt or modify any provisions of State statu-
 24 tory or common law to the extent that such law concerns
 25 a privilege of a witness or person in a court of that State.

1 This title shall not be construed to supersede or modify
2 any provision of Federal statutory or common law to the
3 extent such law concerns a privilege of a witness or person
4 in a court of the United States. Authorizations pursuant
5 to sections 202 and 203 shall not be construed as a waiver
6 of any such privilege.

7 (c) REPORTS CONCERNING FEDERAL PRIVACY
8 ACT.—Not later than 1 year after the date of enactment
9 of this Act, the head of each Federal agency shall prepare
10 and submit to Congress a report concerning the effect of
11 this Act on each such agency. Such reports shall include
12 recommendations for legislation to address concerns relat-
13 ing to the Federal Privacy Act.

14 (d) APPLICATION TO CERTAIN FEDERAL AGEN-
15 CIES.—

16 (1) DEPARTMENT OF DEFENSE.—

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

1 conduct of national defense functions by mem-
2 bers of the armed forces.

3 (B) APPLICATION TO CIVILIAN EMPLOY-
4 EES.—The Secretary of Defense may, by regu-
5 lation, establish for civilian employees of the
6 Department of Defense and employees of De-
7 partment of Defense contractors, limitations on
8 the right of such persons to revoke or amend
9 authorizations for disclosures under section 203
10 when such authorizations were provided by such
11 employees as a condition of employment and
12 the disclosure is determined necessary by the
13 Secretary of Defense to the proper conduct of
14 national defense functions by such employees.

15 (2) DEPARTMENT OF TRANSPORTATION.—

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

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

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

3 (3) DEPARTMENT OF VETERANS AFFAIRS.—

4 The limitations on use and disclosure of protected
5 health information under this Act shall not be con-
6 strued to prevent any exchange of such information
7 within and among components of the Department of
8 Veterans Affairs that determine eligibility for or en-
9 titlement to, or that provide, benefits under laws ad-
10 ministered by the Secretary of Veteran Affairs.

11 **SEC. 402. ENFORCEMENT OF PROVISIONS THROUGH CON-**
12 **DITIONS ON PARTICIPATION.**

13 (a) PARTICIPATING PHYSICIANS AND SUPPLIERS.—

14 Section 1842(h) of the Social Security Act (42 U.S.C.
15 1395u(h)) is amended by adding at the end the following:

16 “(9) The Secretary may refuse to enter into an
17 agreement with a physician or supplier under this
18 subsection, or may terminate or refuse to renew
19 such agreement, in the event that such physician or
20 supplier has been found to have violated a provision
21 of the Medical Information Protection Act of
22 1998.”.

23 (b) MEDICARE+CHOICE ORGANIZATIONS.—Section
24 1852(h) of the Social Security Act (42 U.S.C. 1395w-
25 22(h)) is amended—

1 (1) in the matter preceding paragraph (1), by
2 striking “procedures—” and inserting “procedures,
3 consistent with the Medical Information Protection
4 Act of 1998—”; and

5 (2) in paragraph (1), by striking “privacy of
6 any individually identifiable enrollee information;”
7 and inserting “confidentiality of protected health in-
8 formation concerning enrollees;”.

9 (c) **MEDICARE PROVIDERS.**—Section 1866(b)(2) of
10 the Social Security Act (42 U.S.C. 1395cc(a)(1)) is
11 amended—

12 (1) by inserting a semicolon at the end of sub-
13 paragraph (R);

14 (2) by striking the period at the end of sub-
15 paragraph (S) and inserting “; and”; and

16 (3) by inserting immediately after subpara-
17 graph (S) the following new subparagraph:

18 “(T) to comply with the Medical Informa-
19 tion Protection Act of 1998.”.

20 (d) **HEALTH MAINTENANCE ORGANIZATIONS WITH**
21 **RISK-SHARING CONTRACTS.**—Section 1876(k)(4) of the
22 Social Security Act (42 U.S.C. 1395mm(k)(4)) is amend-
23 ed by adding at the end the following:

1 “(E) The procedural requirements regard-
2 ing the confidentiality and accuracy of enrollee
3 records under section 1852(h).”.

4 **SEC. 403. CONFORMING AMENDMENT.**

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

7 “(6) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
8 FORMATION.—The term ‘individually identifiable
9 health information’ has the same meaning given the
10 term ‘protected health information’ by section 4 of
11 the Medical Information Protection Act of 1998.”.

12 **SEC. 404. STUDY BY INSTITUTE OF MEDICINE.**

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

1 **SEC. 405. EFFECTIVE DATE.**

2 (a) EFFECTIVE DATE.—Except as provided in sub-
3 section (b), this Act shall take effect on the date that is
4 12 months after the date on which regulations are promul-
5 gated as required under subsection (c).

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

10 (c) REGULATIONS.—Not later than 12 months after
11 the date of enactment of this Act, the Secretary shall pro-
12 mulgate regulations implementing this Act.

13 (d) EXCEPTION.—If, not later than 18 months after
14 the date of enactment of this Act, the Secretary has not
15 promulgated the regulations required under subsection (c),
16 the effective date for purposes of subsections (a) and (b)
17 shall be the date that is 30 months after the date of enact-
18 ment of this Act or 6 months after the promulgation of
19 such regulations, whichever is earlier.

○