

106TH CONGRESS
1ST SESSION

H. R. 2470

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

IN THE HOUSE OF REPRESENTATIVES

JULY 12, 1999

Mr. GREENWOOD (for himself, Mr. SHAYS, Mr. NORWOOD, Mr. LATOURETTE, Mr. BURR of North Carolina, and Mr. UPTON) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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 and Research Enhance-
6 ment Act of 1999”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Definitions.

TITLE I—INDIVIDUAL’S RIGHTS

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

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

Subtitle B—Establishment of Safeguards

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

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. General rules regarding use and disclosure of health care information.
- Sec. 203. Authorizations for use or disclosure of protected health information other than for treatment, payment, health care operations, or health research.
- 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. 404. Effective date.

1 **SEC. 2. DEFINITIONS.**

2 As used in this Act:

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

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

17 (3) COMMON RULE.—The term “common rule”
18 means the Federal policy for protection of human
19 subjects from research risks originally published as
20 56 Federal Register 28.025 (1991) as adopted and
21 implemented by a Federal department or agency.

22 (4) DISCLOSE/DISCLOSURE.—The term “dis-
23 close” means to release, transfer, provide access to,
24 or otherwise divulge protected health information to
25 any person other than the individual who is the sub-

1 ject of such information. The term “disclosure” re-
2 fers to such a release, transfer, provisions for access
3 to, or communication of such information. The use
4 of protected health information by an authorized
5 person and its agents shall not be considered a dis-
6 closure for purposes of this Act, provided that the
7 use is consistent with the purposes for which the in-
8 formation was lawfully obtained. Using or providing
9 access to health information in the form of non-
10 identifiable health information shall not be construed
11 as a disclosure of protected health information.

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

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

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

24 (i) with respect to the physical or
25 mental condition of an individual; or

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

6 (B) pursuant to a prescription or medical
7 order any sale or dispensing of a drug, device,
8 equipment, or other health care related item to
9 an individual, or for the use of an individual.

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

17 (A) coordinating health care, including
18 health care management of the individual
19 through risk assessment and case management;

20 (B) conducting quality assessment and im-
21 provement activities, including outcomes evalua-
22 tion, clinical guideline development, and im-
23 provement;

24 (C) reviewing the competence or qualifica-
25 tions of health care professionals, evaluating

1 provider performance, and conducting health
2 care education, accreditation, certification, li-
3 censing, or credentialing activities;

4 (D) carrying out utilization review activi-
5 ties, including precertification and
6 preauthorization of services, and health plan
7 rating and insurance activities, including under-
8 writing, experience rating and reinsurance; and

9 (E) conducting or arranging for auditing
10 services, including fraud detection and compli-
11 ance programs.

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

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

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

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

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

5 Such term does not include a person that provides
6 no health care and that provides only a religious
7 method for healing.

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

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

19 (B) a person who—

20 (i) performs or oversees the perform-
21 ance of an audit, assessment, evaluation,
22 determination, or investigation relating to
23 the effectiveness of, compliance with, or
24 applicability of, legal, fiscal, medical, or
25 scientific standards or aspects of perform-

1 ance related to the delivery of health care;
2 and

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

10 (10) HEALTH PLAN.—The term “health
11 plan” has the meaning given such term in sec-
12 tion 1171(5) of the Social Security Act (42
13 U.S.C. 1320d(5)) and includes any health in-
14 surance issuer, health insurance plan (including
15 any hospital or medical service plan, dental or
16 other health service plan, or health maintenance
17 organization plan), provider sponsored organi-
18 zation, or other program providing or arranging
19 for the provision of health benefits. Such term
20 does not include any policy, plan, or program to
21 the extent that it provides, arranges, supports,
22 or administers any excepted benefits (as defined
23 in section 2791(c)(1) of the Public Health Serv-
24 ice Act (42 U.S.C. 300gg–91(c)(1))).

1 (11) HEALTH RESEARCH/HEALTH RE-
2 SEARCHER.—The term “health research” means a
3 systematic investigation of health (including but not
4 limited to basic biological processes and structures),
5 health care, or its delivery and financing, including
6 research development, testing and evaluation, de-
7 signed to develop or contribute to generalizable
8 knowledge concerning human health, health care, or
9 health care delivery. The term “health researcher”
10 means a person involved in health research, or an of-
11 ficer, employee, or agent of such person.

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

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

22 (14) LIFE INSURER.—The term “life insurer”
23 means life insurance company as defined in section
24 816 of the Internal Revenue Code of 1986.

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

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

21 (17) PAYMENT.—The term “payment”
22 means—

23 (A) the activities undertaken by—

1 (i) or on behalf of a health plan to de-
2 termine its responsibility for coverage
3 under the plan; or

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

10 (B) activities undertaken as described in
11 subparagraph (A) including—

12 (i) billing, claims management, med-
13 ical data processing, other administrative
14 services, and actual payment;

15 (ii) determinations of coverage or ad-
16 judication of health benefit or subrogation
17 claims; and

18 (iii) review of health care services with
19 respect to coverage under a health plan or
20 justification of charges.

21 (18) PERSON.—The term “person” means a
22 government, governmental subdivision, agency or au-
23 thority; corporation; company; association; firm;
24 partnership; society; estate; trust; joint venture; indi-

vidual; individual representative; tribal government;
and any other legal entity.

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

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

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

(C) is derived from—

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

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

(D) is not nonidentifiable health informa-
tion.

(20) PUBLIC HEALTH AUTHORITY.—The term
“public health authority” means an authority or in-

1 strumentality of the United States, a tribal govern-
2 ment, a State, or a political subdivision of a State
3 that is—

4 (A) primarily responsible for health and/or
5 welfare matters; and

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

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

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

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

23 (24) STATE.—The term “State” includes the
24 District of Columbia, Puerto Rico, the Virgin Is-

1 lands, Guam, American Samoa, and the Northern
2 Mariana Islands.

3 (25) TREATMENT.—The term “treatment”
4 means the provision of health care by a health care
5 provider.

6 (26) WRITING/WRITTEN.—The term “writing”
7 means any form of documentation, whether paper,
8 electronic, digital, biometric or tape recorded. The
9 term “written” includes paper, electronic, digital, bi-
10 ometric and tape-recorded formats.

11 **TITLE I—INDIVIDUAL’S RIGHTS**
12 **Subtitle A—Review of Protected**
13 **Health Information by Subjects**
14 **of the Information**

15 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
16 **HEALTH INFORMATION.**

17 (a) GENERAL RULES.—

18 (1) COMPLIANCE WITH SECTION.—At the re-
19 quest of an individual who is the subject of protected
20 health information and except as provided in sub-
21 section (c), a health care provider, a health plan,
22 employer, life insurer, school, or university shall ar-
23 range for inspection or copying of protected health
24 information concerning the individual, including

1 records created under section 102, as provided for in
2 this section.

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

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

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

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

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

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

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

22 (3) INFORMATION COMPILED IN ANTICIPATION
23 OF OR IN CONNECTION WITH A FRAUD INVESTIGA-
24 TION OR LITIGATION.—The information is compiled
25 principally—

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

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

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

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

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

18 (2) the availability of procedures for further re-
19 view of the denial; and

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

23 (e) STATEMENT REGARDING REQUEST.—If an indi-
24 vidual has filed a statement under subsection (d)(3), the

1 person in any subsequent disclosure of the portion of the
2 information requested under subsection (a) or (b)—

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

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

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

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

19 (h) RULES OF CONSTRUCTION.—

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

24 (A) the protected health information is re-
25 tained by the agent; and

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

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

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

12 (a) IN GENERAL.—Protected health information shall
13 be subject to amendment as provided for in this section.
14 Protected health information that is created or received
15 by a health plan or health care provider as part of treat-
16 ment or payment shall be subject to amendment as pro-
17 vided in this section upon request to the originating pro-
18 vider. Except as provided in subsection (b), not later than
19 45 days after the date on which an originating provider,
20 employer, life insurer, school, or university receives from
21 an individual a request in writing to amend protected
22 health information, such person shall—

23 (1) make the amendment requested;

24 (2) inform the individual of the amendment
25 that has been made; and

1 (3) inform any person identified by the indi-
2 vidual in the request for amendment and—

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

5 (B) to whom the unamended portion of the
6 information was disclosed within the previous
7 year by sending a notice to the individual's last
8 known address that there has been a sub-
9 stantive amendment to the protected health in-
10 formation of such individual.

11 (b) SPECIAL CIRCUMSTANCES.—If an originating
12 provider, its agent, or contractor no longer maintains the
13 protected health information sought to be amended by an
14 individual pursuant to subsection (a), a health plan or an-
15 other health care provider that maintains such informa-
16 tion may arrange for amendment consistent with this sec-
17 tion.

18 (c) REFUSAL TO AMEND.—If a person described in
19 subsection (a) refuses to make the amendment requested
20 under such subsection, the person shall inform the indi-
21 vidual in writing of—

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

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

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

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

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

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

13 (e) RULES GOVERNING AGENTS.—The agent of a
14 person described in subsection (a) shall not be required
15 to make amendments to protected health information, ex-
16 cept where—

17 (1) the protected health information is retained
18 by the agent; and

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

21 (f) REPEATED REQUESTS FOR AMENDMENTS.—If a
22 person described in subsection (a) receives a request for
23 an amendment of information as provided for in such sub-
24 section and a statement of disagreement has been filed
25 pursuant to subsection (d), the person shall inform the

1 individual of such filing and shall not be required to carry
2 out the procedures required under this section.

3 (g) RULES OF CONSTRUCTION.—This section shall
4 not be construed to—

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

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

13 (3) permit any deletions or alterations of the
14 original information.

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

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

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

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

1 (3) the procedures for authorizing disclosures of
 2 protected health information and for revoking such
 3 authorizations;

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

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

8 (b) MODEL NOTICE.—The Secretary, after notice
 9 and opportunity for public comment, shall develop and dis-
 10 seminate model notices of confidentiality practices, using
 11 the advice of the National Committee on Vital Health Sta-
 12 tistics, for use under this section. Use of the model notice
 13 shall serve as an absolute defense against claims of receiv-
 14 ing inappropriate notice.

15 **Subtitle B—Establishment of** 16 **Safeguards**

17 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

18 (a) IN GENERAL.—A health care provider, health
 19 plan, health oversight agency, public health authority, em-
 20 ployer, life insurer, health researcher, law enforcement of-
 21 ficial, school, or university shall establish and maintain ap-
 22 propriate administrative, technical, and physical safe-
 23 guards to protect the confidentiality, security, accuracy,
 24 and integrity of protected health information created, re-

1 ceived, obtained, maintained, used, transmitted, or dis-
2 posed of by such person.

3 (b) FUNDAMENTAL SAFEGUARDS.—The safeguards
4 established pursuant to subsection (a) shall address the
5 following factors:

6 (1) The need for protected health information
7 and whether the purpose can be accomplished with
8 nonidentifiable health information.

9 (2) Appropriate procedures for maintaining the
10 security and assuring appropriate use of any key
11 used in creating nonidentifiable health information.

12 (3) The categories of personnel who will have
13 access to protected health information and appro-
14 priate training, supervision and sanctioning of such
15 persons with respect to their use of protected health
16 information and adherence to established safe-
17 guards.

18 (4) Appropriate limitations on access to indi-
19 vidual identifiers.

20 (5) Appropriate mechanism for limiting disclo-
21 sures to the protected health information necessary
22 to respond to the request for disclosure.

23 (6) Procedures for handling requests for pro-
24 tected health information by persons other than the
25 individual who is the subject of such information, in-

1 including but not limited to relatives and affiliates of
2 such individual, law enforcement officials, parties in
3 civil litigation, health care providers, and health
4 plans.

5 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

6 (a) IN GENERAL.—A health care provider, health
7 plan, health oversight agency, public health authority, em-
8 ployer, life insurer, health researcher, law enforcement of-
9 ficial, school, or university shall establish and maintain a
10 process for documenting its disclosures of protected health
11 information by recording the name and address or other
12 means of contacting the recipient, and the purpose of the
13 disclosure.

14 (b) RECORD OF DISCLOSURE.—A record established
15 under subsection (a) shall be maintained for not less than
16 7 years.

17 (c) IDENTIFICATION OF DISCLOSED INFORMATION AS
18 PROTECTED HEALTH INFORMATION.—Except as other-
19 wise provided in this title, protected health information
20 shall be clearly identified as protected health information
21 that is subject to this Act.

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

3 **SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-**
4 **SURE.**

5 (a) **DISCLOSURE PROHIBITED.**—A health care pro-
6 vider, health plan, health oversight agency, public health
7 authority, employer, life insurer, health researcher, law en-
8 forcement official, school, or university, or any of their
9 agents may not disclose protected health information ex-
10 cept as authorized under this Act or as authorized by the
11 individual who is the subject of such information.

12 (b) **APPLICABILITY TO AGENTS.**—A person described
13 in subsection (a) may use an agent, including a contractor,
14 to carry out an otherwise lawful activity using protected
15 health information maintained by such person, provided
16 that the person specifies the activities for which the agent
17 is authorized and prohibits the agent from using or dis-
18 closing protected health information for purposes other
19 than carrying out the specified activities.

20 (1) Notwithstanding any other provision of this
21 Act, a person who has limited the activities of an
22 agent as provided in this subsection, shall not be lia-
23 ble for the actions or disclosures of the agent that
24 are not in fulfillment of the agent’s specified activi-
25 ties.

1 (2) An agent who receives protected health in-
2 formation from a person described in subsection (a)
3 shall in its own right be subject to the applicable
4 provisions of this Act.

5 (c) CREATION OF NONIDENTIFIABLE HEALTH IN-
6 FORMATION.—A person described in subsection (a) may
7 use protected health information for the purpose of cre-
8 ating nonidentifiable health information.

9 (d) INDIVIDUAL AUTHORIZATION.—To be valid, an
10 authorization to disclose protected health information
11 under this title shall—

12 (1) identify the individual who is the subject of
13 the protected health information;

14 (2) describe the nature of the information to be
15 disclosed;

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

18 (4) describe the purpose of the disclosure;

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

22 (6) be in writing, dated, and signed by the indi-
23 vidual, a family member or other authorized rep-
24 resentative.

1 (e) MANIPULATION OF NONIDENTIFIABLE HEALTH
 2 INFORMATION.—Any person who manipulates nonidentifi-
 3 able health information in order to identify an individual,
 4 or uses a key to identify an individual without authoriza-
 5 tion, is deemed to have disclosed protected health informa-
 6 tion.

7 **SEC. 202. GENERAL RULES REGARDING USE AND DISCLO-**
 8 **SURE OF HEALTH CARE INFORMATION.**

9 (a) IN GENERAL.—An individual who furnishes pro-
 10 tected health information in the context of obtaining
 11 health care or health care benefits has a justifiable expect-
 12 tation that such information will not be misused and that
 13 its confidentiality will be maintained. Protected health in-
 14 formation in possession or control of a health care pro-
 15 vider or health plan shall be available—

16 (1) for use by a health plan or a health care
 17 provider in furnishing health care to an individual
 18 who is the subject of such information, including ar-
 19 rangements for treatment, payment, and health care
 20 operations; and

21 (2) for use in health research that is not incon-
 22 sistent with the requirements of other applicable
 23 Federal laws.

24 (3) LIMITATION.—For purposes of subsection
 25 (b), use of protected health information in activities

1 described in this subsection is not a disclosure of
2 such information by persons lawfully engaged in
3 such activities.

4 (b) PROHIBITION.—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 may not disclose
8 protected health information except as authorized under
9 this title.

10 (1) RULES OF CONSTRUCTION.—

11 (A) Disclosure of health information in the
12 form of nonidentifiable health information shall
13 not be construed as a disclosure of protected
14 health information.

15 (B) Arrangements by a person and its
16 agents for carrying out an authorized use of
17 protected health information, including uses au-
18 thorized under subsection (a), shall not be con-
19 sidered disclosures for purposes of this Act,
20 provided that the use is consistent with the pur-
21 poses for which the information was lawfully
22 obtained by such person.

23 (C) Nothing in this title shall be construed
24 to require disclosure by a health care provider
25 or a health plan.

1 (2) DISCLOSURE BY AGENTS.—An agent who
2 receives protected health information from a person
3 described in subsection (b) shall be subject to all
4 rules of disclosure and safeguard requirements
5 under this title.

6 (c) SCOPE OF DISCLOSURE.—Every disclosure of pro-
7 tected health information by a person under this title shall
8 be limited to the information necessary to accomplish the
9 purpose for which the information is disclosed.

10 (d) IDENTIFICATION OF DISCLOSED INFORMATION
11 AS PROTECTED HEALTH INFORMATION.—Except as oth-
12 erwise provided in this title, protected health information
13 may not be disclosed unless such information is clearly
14 identified as protected health information that is subject
15 to this Act.

16 (e) CREATION OF NONIDENTIFIABLE HEALTH IN-
17 FORMATION.—A person described in subsection (b) may
18 use protected health information for the purpose of cre-
19 ating nonidentifiable health information, if the person pro-
20 hibits the employee or agent creating the nonidentifiable
21 health information from using or disclosing the protected
22 health information for purposes other than the sole pur-
23 pose of creating nonidentifiable health information as
24 specified by the person.

1 (f) DISCLOSURE USING THE KEY.—Any person who
 2 manipulates nonidentifiable health information in order to
 3 identity an individual, without lawfully using the key, is
 4 deemed to have disclosed protected health information.

5 **SEC. 203. AUTHORIZATIONS FOR USE OR DISCLOSURE OF**
 6 **PROTECTED HEALTH INFORMATION OTHER**
 7 **THAN FOR TREATMENT, PAYMENT, HEALTH**
 8 **CARE OPERATIONS, OR HEALTH RESEARCH.**

9 (a) IN GENERAL.—An individual who is the subject
 10 of protected health information may authorize any person
 11 to disclose or use such information for any purpose. An
 12 authorization under this section is not valid if its signing
 13 by the individual is a prerequisite for signing an authoriza-
 14 tion under section 202.

15 (b) WRITTEN AUTHORIZATIONS.—A person may dis-
 16 close and use protected health information, for purposes
 17 other than those authorized under section 202, pursuant
 18 to a written authorization signed by the individual who
 19 is the subject of the information that meets the require-
 20 ments of section 201(d). An authorization under this sec-
 21 tion shall be separate from any authorization provided
 22 under section 202.

23 (c) LIMITATION ON AUTHORIZATIONS.—Notwith-
 24 standing any other provision of Federal law, life insurers,
 25 and other entities issuing disability income or long-term

1 care insurance under the laws of any State, shall meet
2 the requirements of section 201(a) with respect to an indi-
3 vidual for purposes of life, disability income or long-term
4 care insurance, by obtaining authorization of such indi-
5 vidual under this section 203.

6 (1) Notwithstanding subsection (d), an author-
7 ization obtained in the ordinary course of business
8 by a life insurer under this section shall remain in
9 effect during the term of the individual's insurance
10 coverage and as may be necessary for the issuer to
11 meet its obligations with respect to such individual
12 under the terms of the policy, plan or program.

13 (2) An authorization obtained from an indi-
14 vidual in connection with an application that does
15 not result in coverage with respect to such individual
16 shall expire the earlier of the date specified in the
17 individual's authorization or the effective date of any
18 revocation under subsection (d).

19 (d) REVOCATION OR AMENDMENT OF AUTHORIZA-
20 TION.—

21 (1) IN GENERAL.—Except as otherwise pro-
22 vided in this section, an individual may revoke or
23 amend an authorization described in this section by
24 providing written notice to the person who obtained
25 such authorization unless the disclosure that is the

1 subject of the authorization is related to the evalua-
2 tion of an application for life insurance coverage or
3 a claim for life insurance benefits.

4 (2) NOTICE OF REVOCATION.—A person that
5 discloses protected health information pursuant to
6 an authorization that has been revoked under para-
7 graph (1) shall not be subject to any liability or pen-
8 alty under this title if that person had no actual no-
9 tice of the revocation.

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

15 (f) MODEL AUTHORIZATIONS.—

16 (1) The Secretary, after notice and opportunity
17 for public comment, shall develop and disseminate
18 model written authorizations of the type described in
19 subsection (b). The Secretary shall consult with the
20 National Committee on Vital and Health Statistics
21 in developing such authorizations.

22 (2) Notwithstanding paragraph (1), the insur-
23 ance commissioner of the State of domicile of a life
24 insurer may exercise exclusive authority in devel-

1 oping and disseminating model written authoriza-
 2 tions for purposes of subsection (c).

3 (3) Any authorization obtained using a model
 4 authorization promulgated under this subsection
 5 shall be deemed to meet the authorization require-
 6 ments of this section.

7 (g) AUTHORIZATIONS FOR RESEARCH.—This section
 8 applies to health research only where such research is not
 9 governed by section 208.

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

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

17 (1) the individual who is the subject of the
 18 information—

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

22 (B) is in a physical or mental condition
 23 such that the individual is not capable of object-
 24 ing, and there are no prior indications that the
 25 individual would object;

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

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

6 (b) DIRECTORY INFORMATION.—

7 (1) DISCLOSURE.—

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

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

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

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

24 (i) The name of the individual who is
25 the subject of the information.

1 (ii) The general health status of the
 2 individual, described as critical, poor, fair,
 3 stable, or satisfactory or in terms denoting
 4 similar conditions.

5 (iii) The location of the individual on
 6 premises controlled by a provider.

7 (2) EXCEPTION.—

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

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

22 **SEC. 205. EMERGENCY CIRCUMSTANCES.**

23 Any person who creates or receives protected health
 24 information under this title may disclose protected health
 25 information in emergency circumstances when necessary

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

7 **SEC. 206. OVERSIGHT.**

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

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

1 (c) AUTHORIZATION BY A SUPERVISOR.—For pur-
 2 poses of this section, the individual with authority to au-
 3 thorize the oversight function involved shall provide to the
 4 person described in subsection (a) a statement that the
 5 protected health information is being sought for a legally
 6 authorized oversight function.

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

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

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

20 **SEC. 207. PUBLIC HEALTH.**

21 (a) IN GENERAL.—A health care provider, health
 22 plan, public health authority, health researcher, employer,
 23 life insurer, law enforcement official, school, or university
 24 may disclose protected health information to a public

1 health authority or other person authorized by law for use
2 in a legally authorized—

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

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

16 (c) REQUIREMENT TO RELEASE PROTECTED
17 HEALTH INFORMATION TO CORONERS AND MEDICAL
18 EXAMINERS.—

19 (1) IN GENERAL.—When a Coroner or Medical
20 Examiner or their duly appointed deputies seek pro-
21 tected health information for the purpose of inquiry
22 into and determination of, the cause, manner, and
23 circumstances of a death, the health care provider,
24 health plan, health oversight agency, public health
25 authority, employer, life insurer, health researcher,

1 law enforcement official, school, or university in-
2 volved shall provide the protected health information
3 to the Coroner or Medical Examiner or to the duly
4 appointed deputies without undue delay.

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

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

18 **SEC. 208. HEALTH RESEARCH.**

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

23 (1) RESEARCH GOVERNED BY THE COMMON
24 RULE.—A person identified in subsection (a) may
25 disclose protected health information to a health re-

1 searcher if the research project has been approved
2 by an institutional review board pursuant to the re-
3 quirements of the common rule as implemented by
4 a Federal agency.

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

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

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

19 (C) the person that maintains the pro-
20 tected 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 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) Protected health information obtained by a
13 health researcher pursuant to this section shall be
14 used and maintained in confidence, consistent with
15 the confidentiality practices established by the health
16 researcher pursuant to section 111.

17 (2) A recipient health researcher may not be
18 compelled in any Federal, State, or local civil, crimi-
19 nal, administrative, legislative, or other proceeding
20 to disclose protected health information created,
21 maintained or received under this section, provided
22 that nothing in this paragraph shall be construed to
23 prevent an audit or lawful investigation pursuant to
24 the authority of a Federal department or agency, of

1 a research project conducted, supported or subject to
2 regulation by such department or agency.

3 (3) Notwithstanding any other provision of law,
4 information disclosed by a health researcher to a
5 Federal agency under this subsection may not be
6 further used or disclosed by the agency for a pur-
7 pose unrelated to the agency's oversight or investiga-
8 tion.

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

11 (a) IN GENERAL.—A health care provider, health
12 plan, public health authority, employer, life insurer, law
13 enforcement official, school, or university may disclose
14 protected health information—

15 (1) pursuant to a discovery request or subpoena
16 in a civil action brought in a Federal or State court
17 or a request or subpoena related to a Federal or
18 State administrative proceeding, provided that

19 (2) such discovery request or subpoena is made
20 through or pursuant to a court order as provided for
21 in subsection (b).

22 (b) COURT ORDERS.—

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

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

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

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

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

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

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

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

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

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

3 (a) DISCLOSURE.—

4 (1) IN GENERAL.—A person who receives pro-
5 tected health information pursuant to sections 202
6 through 207, may disclose such information to a
7 State or Federal law enforcement agency if such dis-
8 closure is pursuant to—

9 (A) a subpoena issued under the authority
10 of a grand jury;

11 (B) an administrative subpoena or sum-
12 mons or a judicial subpoena or warrant if the
13 determination described in paragraph (2) has
14 been made;

15 (C) a warrant issued upon a showing of
16 probable cause if the determination described in
17 paragraph (2) has been made;

18 (D) a Federal or state law requiring the
19 reporting of specific medical information to law
20 enforcement authorities;

21 (E) a written consent or waiver of privilege
22 by an individual allowing access to the individ-
23 ual's protected health information; or

24 (F) by other court order if the determina-
25 tion described in paragraph (2) has been made.

1 (2) HIGHER STANDARD FOR DISCLOSURE OF
2 CERTAIN INFORMATION.—The determination under
3 this paragraph is a determination, by the court or
4 administrative body issuing the subpoena, summons,
5 warrant, or order involved, that the need of the per-
6 son requesting the disclosure for the information
7 substantially outweighs the privacy interest of each
8 individual whose health or health care is the subject
9 of the information.

10 (b) REDACTIONS.—To the extent practicable and
11 consistent with the requirements of due process, in the
12 case of information disclosed under subsection (a) the
13 State or Federal law enforcement agency to which the in-
14 formation is disclosed shall redact personal identifiers
15 from protected health information prior to the public dis-
16 closure of such information in a judicial or administrative
17 proceeding.

18 (c) USE OF INFORMATION.—Protected health infor-
19 mation obtained by a State or Federal law enforcement
20 agency under subsection (a) may only be used for purposes
21 of a legitimate law enforcement activity.

22 (d) EXCEPTION IN EXIGENT CIRCUMSTANCES.—Sub-
23 section (a) shall not be construed to limit or restrict the
24 ability of State or Federal law enforcement agencies to

1 gain protected health information if exigent circumstances
 2 exist.

3 **SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT**
 4 **TRANSACTION.**

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

17 (b) TRANSACTION PROCESSING.—A person who is a
 18 debit, credit, or other payment card issuer, a payment sys-
 19 tem operator, a financial institution participant in a pay-
 20 ment system or is an entity assisting such an issuer, oper-
 21 ator, or participant in connection with activities described
 22 in this subsection, may use or disclose protected health
 23 information about an individual in connection with—

24 (1) the authorization, settlement, billing, proc-
 25 essing, clearing, transferring, reconciling, or collec-

1 tion of amounts charged, debited or otherwise paid
2 using a debit, credit, or other payment card or ac-
3 count number, or by other payment means;

4 (2) the transfer of receivables, accounts, or in-
5 terest therein;

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

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

9 (5) compliance with a properly authorized civil,
10 criminal, or regulatory investigation by Federal,
11 State, or local authorities as governed by the re-
12 quirements of this section; or

13 (6) fraud protection, risk control, resolving cus-
14 tomer disputes or inquiries, communicating with the
15 person to whom the information relates, or reporting
16 to consumer reporting agencies.

17 (c) SPECIFIC PROHIBITIONS.—A person described in
18 subsection (b) may not disclose protected health informa-
19 tion for any purpose that is not described in subsection
20 (b). Notwithstanding any other provision of law, any
21 health care provider, health plan, health oversight agency,
22 health researcher, employer, life insurer, school or univer-
23 sity who makes a good faith disclosure of protected health
24 information to an entity and for the purposes described

1 in subsection (b) shall not be liable for subsequent disclo-
2 sures by such entity.

3 (d) SCOPE.—

4 (1) IN GENERAL.—The use of protected health
5 information by a person described in subsection (b)
6 and its agents shall not be considered a disclosure
7 for purposes of this Act, so long as the use involved
8 is consistent with the activities authorized in sub-
9 section (b) or other purposes for which the informa-
10 tion was lawfully obtained.

11 (2) REGULATED INSTITUTIONS.—A person who
12 is subject to enforcement pursuant to section 8 of
13 the Federal Deposit Insurance Act or who is a Fed-
14 eral credit union or State credit union as defined in
15 the Federal Credit Union Act or who is registered
16 pursuant to the Securities and Exchange Act, or
17 who is an entity assisting such a person—

18 (A) shall not be subject to this Act to the
19 extent that such person or entity is described in
20 subsection (b) and to the extent that such per-
21 son or entity is engaged in activities authorized
22 in that subsection; and

23 (B) shall be subject to enforcement exclu-
24 sively under section 8 of the Federal Deposit
25 Insurance Act, the Federal Credit Union Act,

1 or the Securities and Exchange Act, as applica-
2 ble, to the extent that such person or entity is
3 engaged in activities other than those permitted
4 under subsection (b).

5 (3) RULE OF CONSTRUCTION.—Nothing in this
6 subsection shall be deemed to exempt entities de-
7 scribed in paragraph (2) from the prohibition set
8 forth in subsection (c).

9 **SEC. 212. INDIVIDUAL REPRESENTATIVES.**

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

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

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

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

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

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

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

21 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
22 provisions of this Act shall continue to prevent disclosure
23 of protected health information concerning a deceased in-
24 dividual.

1 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
2 CEASED INDIVIDUAL.—

3 (1) IN GENERAL.—A person who is authorized
4 by law or by an instrument recognized under law, to
5 act as an executor of the estate of a deceased indi-
6 vidual, or otherwise to exercise the rights of the de-
7 ceased individual, may, to the extent so authorized,
8 exercise and discharge the rights of such deceased
9 individual under this Act for a period of 2 years fol-
10 lowing the death of such individual. If no such des-
11 ignee has been authorized, the rights of the deceased
12 individual may be exercised as provided for in sub-
13 section (c).

14 (2) INSURED INDIVIDUALS.—In the case of an
15 individual who is deceased and who was the insured
16 under an insurance policy or policies, the right to
17 authorize disclosure of protected health information
18 may be exercised by the beneficiary or beneficiaries
19 of such insurance policy or policies.

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

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

24 A health care provider, health plan, health oversight
25 agency, health researcher, employer, life insurer, school,

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

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

6 (a) IN GENERAL.—A health care provider, health
 7 plan, health oversight agency, employer, life insurer,
 8 school, or university may disclose protected health infor-
 9 mation to a person or persons for purposes of enabling
 10 business decisions to be made about or in connection with
 11 the purchase, transfer, merger, or sale of a business or
 12 businesses.

13 (b) NO FURTHER DISCLOSURE.—A person or per-
 14 sons who receive protected health information under this
 15 section shall make no further use or disclosure of such
 16 information unless otherwise authorized under this Act.

17 **TITLE III—SANCTIONS**

18 **Subtitle A—Criminal Provisions**

19 **SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED**
 20 **HEALTH INFORMATION.**

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

1 **“CHAPTER 124—WRONGFUL DISCLOSURE**
2 **OF PROTECTED HEALTH INFORMATION**
3 **“§ 2801. Wrongful disclosure of protected health in-**
4 **formation**

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

8 “(1) obtains protected health information relat-
9 ing to an individual from a health care provider,
10 health plan, health oversight agency, public health
11 authority, employer, life insurer, health researcher,
12 law enforcement official, school, or university except
13 as provided in title II of the Medical Information
14 Protection Act of 1999; or

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

19 “(b) PENALTIES.—A person described in subsection
20 (a) shall—

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

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

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

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

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

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

17 **Subtitle B—Civil Sanctions**

18 **SEC. 311. CIVIL PENALTY VIOLATION.**

19 A person who the Secretary, in consultation with the
 20 Attorney General, determines has substantially and mate-
 21 rially failed to comply with this Act shall be subject, in
 22 addition to any other penalties that may be prescribed by
 23 law—

24 (1) in a case in which the violation relates to
 25 title I, to a civil penalty of not more than \$500 for

1 each such violation, but not to exceed \$5,000 in the
2 aggregate for multiple violations arising from the
3 same failure to comply with the Act;

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

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

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

14 (a) INITIATION OF PROCEEDINGS.—

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

1 manner authorized by Rule 4 of the Federal Rules
2 of Civil Procedure.

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

11 (3) SANCTIONS FOR FAILURE TO COMPLY.—
12 The official conducting a hearing under this section
13 may sanction a person, including any party or attor-
14 ney, for failing to comply with an order or proce-
15 dure, failing to defend an action, or other mis-
16 conduct as would interfere with the speedy, orderly,
17 or fair conduct of the hearing. Such sanction shall
18 reasonably relate to the severity and nature of the
19 failure or misconduct. Such sanction may include—

20 (A) in the case of refusal to provide or per-
21 mit discovery, drawing negative factual infer-
22 ences or treating such refusal as an admission
23 by deeming the matter, or certain facts, to be
24 established;

1 (B) prohibiting a party from introducing
2 certain evidence or otherwise supporting a par-
3 ticular claim or defense;

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

5 (D) staying the proceedings;

6 (E) dismissal of the action;

7 (F) entering a default judgment;

8 (G) ordering the party or attorney to pay
9 attorneys' fees and other costs caused by the
10 failure or misconduct; and

11 (H) refusing to consider any motion or
12 other action which is not filed in a timely man-
13 ner.

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

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

19 (2) the degree of culpability, history of prior of-
20 fenses, and financial condition of the person pre-
21 senting the claims;

22 (3) evidence of good faith endeavor to protect
23 the confidentiality of protected health information;
24 and

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

1 (c) REVIEW OF DETERMINATION.—

2 (1) IN GENERAL.—Any person adversely af-
3 fected by a determination of the Secretary under
4 this section may obtain a review of such determina-
5 tion in the United States Court of Appeals for the
6 circuit in which the person resides, or in which the
7 claim was presented, by filing in such court (within
8 60 days following the date the person is notified of
9 the determination of the Secretary) a written peti-
10 tion requesting that the determination be modified
11 or set aside.

12 (2) FILING OF RECORD.—A copy of the petition
13 filed under paragraph (1) shall be forthwith trans-
14 mitted by the clerk of the court to the Secretary,
15 and thereupon the Secretary shall file in the Court
16 the record in the proceeding as provided in section
17 2112 of title 28, United States Code. Upon such fil-
18 ing, the court shall have jurisdiction of the pro-
19 ceeding and of the question determined therein, and
20 shall have the power to make and enter upon the
21 pleadings, testimony, and proceedings set forth in
22 such record a decree affirming, modifying, remand-
23 ing for further consideration, or setting aside, in
24 whole or in part, the determination of the Secretary

1 and enforcing the same to the extent that such order
2 is affirmed or modified.

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

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

1 tial evidence on the record considered as a whole,
2 and the recommendations of the Secretary, if any,
3 for the modification or setting aside of the original
4 order, shall be conclusive.

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

12 (d) RECOVERY OF PENALTIES.—

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

23 (2) DEDUCTION FROM AMOUNTS OWING.—The
24 amount of any penalty, when finally determined
25 under this section, or the amount agreed upon in

1 compromise under paragraph (1), may be deducted
2 from any sum then or later owing by the United
3 States or a State to the person against whom the
4 penalty has been assessed.

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

13 (f) SUBPOENA AUTHORITY.—

14 (1) IN GENERAL.—For the purpose of any
15 hearing, investigation, or other proceeding author-
16 ized or directed under this section, or relative to any
17 other matter within the jurisdiction of the Attorney
18 General hereunder, the Attorney General, acting
19 through the Secretary shall have the power to issue
20 subpoenas requiring the attendance and testimony of
21 witnesses and the production of any evidence that
22 relates to any matter under investigation or in ques-
23 tion before the Secretary. Such attendance of wit-
24 nesses and production of evidence at the designated
25 place of such hearing, investigation, or other pro-

1 ceeding may be required from any place in the
2 United States or in any Territory or possession
3 thereof.

4 (2) SERVICE.—Subpoenas of the Secretary
5 under paragraph (1) shall be served by anyone au-
6 thorized by the Secretary by delivering a copy there-
7 of to the individual named therein.

8 (3) PROOF OF SERVICE.—A verified return by
9 the individual serving the subpoena under this sub-
10 section setting forth the manner of service shall be
11 proof of service.

12 (4) FEES.—Witnesses subpoenaed under this
13 subsection shall be paid the same fees and mileage
14 as are paid witnesses in the district court of the
15 United States.

16 (5) REFUSAL TO OBEY.—In case of contumacy
17 by, or refusal to obey a duly served upon, any per-
18 son, any district court of the United States for the
19 judicial district in which such person charged with
20 contumacy or refusal to obey is found or resides or
21 transacts business, upon application by the Sec-
22 retary, shall have jurisdiction to issue an order re-
23 quiring such person to appear and give testimony, or
24 to appear and produce evidence, or both. Any failure

1 to obey such order of the court may be punished by
2 the court as contempt thereof.

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

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

17 **SEC. 313. ENFORCEMENT BY STATE INSURANCE COMMIS-**
18 **SIONERS.**

19 (a) STATE PENALTIES.—Subject to section 401, and
20 notwithstanding any other provision of this title, a state
21 insurance commissioner of the State of domicile of a life
22 insurer may exercise exclusive authority to impose any
23 penalties on a life insurer for violations of this Act pursu-
24 ant to the administrative procedures provided under that
25 State's insurance laws.

1 (b) FAIL-SAFE FEDERAL AUTHORITY.—In the case
 2 of a State that fails to substantially enforce the require-
 3 ments of title I and title II of this Act with respect to
 4 life insurers regulated by such State, the provisions of this
 5 title shall apply with respect to a life insurer in the same
 6 way that they apply to other persons subject to the Act.

7 **TITLE IV—MISCELLANEOUS**

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

9 (a) STATE AND FEDERAL LAW.—Except as provided
 10 in this section, the provisions of this Act shall preempt
 11 any State law that relates to matters covered by this Act.
 12 Nothing in this Act shall be construed to preempt, modify,
 13 repeal or affect the interpretation of a provision of State
 14 or Federal law that relates to the disclosure of protected
 15 health information or any other information about a minor
 16 to a parent or guardian of such minor. This Act shall not
 17 be construed as repealing, explicitly or implicitly, other
 18 Federal laws or regulations relating to protected health
 19 information or relating to an individual's access to pro-
 20 tected health information or health care services.

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

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

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

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

15 (1) DEPARTMENT OF DEFENSE.—

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

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

3 (B) APPLICATION TO CIVILIAN EMPLOY-
4 EES.—The Secretary of Defense may, by regu-
5 lation, establish for civilian employees of the
6 Department of Defense and employees of De-
7 partment of Defense contractors, limitations on
8 the right of such persons to revoke or amend
9 authorizations for disclosures under section 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. CONFORMING AMENDMENT.**

12 Section 1171(6) of the Social Security Act (42 U.S.C.
13 1320d(6)) is amended to read as follows:

14 “(6) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
15 FORMATION.—The term ‘individually identifiable
16 health information’ has the same meaning given the
17 term ‘protected health information’ by section 2 of
18 the Medical Information Protection Act of 1999.”.

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

20 Not later than 2 years after the date of enactment
21 of this Act, the National Research Council in conjunction
22 with the Institute of Medicine of the National Academy
23 of Sciences shall conduct a study to examine research
24 issues relating to protected health information, such as the
25 quality and uniformity of institutional review boards and

1 their practices with respect to data management for both
2 researchers and institutional review boards, as well as cur-
3 rent and proposed protection of health information in rela-
4 tion to the legitimate needs of law enforcement. The Coun-
5 cil shall prepare and submit to Congress a report con-
6 cerning the results of such study.

7 **SEC. 404. EFFECTIVE DATE.**

8 (a) EFFECTIVE DATE.—Except as provided in sub-
9 section (b), this Act shall take effect on the date that is
10 12 months after the date on which regulations are promul-
11 gated as required under subsection (c).

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

16 (c) REGULATIONS.—Not later than 12 months after
17 the date of enactment of this Act, the Secretary shall, in
18 consultation with the National Committee on Vital and
19 Health Statistics, promulgate regulations implementing
20 this Act.

21 (d) EXCEPTION.—If, not later than 18 months after
22 the date of enactment of this Act, the Secretary has not
23 promulgated the regulations required under subsection (c),
24 the effective date for purposes of subsections (a) and (b)
25 shall be the date that is 30 months after the date of enact-

- 1 ment of this Act or 12 months after the promulgation of
- 2 such regulations, whichever is earlier.

