

105TH CONGRESS
2D SESSION

S. 1921

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

IN THE SENATE OF THE UNITED STATES

APRIL 2, 1998

Mr. JEFFORDS (for himself and Mr. DODD) 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 “Health Care Personal Information Nondisclosure Act of
6 1998” or the “Health Care PIN Act”.

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. Findings.
- Sec. 3. Purposes.
- Sec. 4. Definitions.

TITLE I—INDIVIDUAL'S RIGHTS

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

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

Subtitle B—Establishment of Safeguards

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

TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Procurement of authorizations for disclosure of protected health information for treatment, payment, or health care operations.
- Sec. 203. Authorizations for disclosure of protected health information other than for treatment, payment, or health care operations.
- Sec. 204. Next of kin and directory information.
- Sec. 205. Emergency circumstances.
- Sec. 206. Oversight.
- Sec. 207. Public health.
- Sec. 208. Health research.
- Sec. 209. Disclosure in civil, judicial, and administrative procedures.
- Sec. 210. Disclosure for law enforcement purposes.
- Sec. 211. Disclosures for postmarketing adverse experience reporting for human drug and licensed biological products.
- Sec. 212. Payment card and electronic payment transaction.
- Sec. 213. Standards for electronic disclosures.
- Sec. 214. Individual representatives.
- Sec. 215. Limited liability for law enforcement officers.
- Sec. 216. No liability for permissible disclosures.

TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

- Sec. 301. Wrongful disclosure of protected health information.
- Sec. 302. Debarment for crimes.

Subtitle B—Civil Sanctions

- Sec. 311. Civil penalty.
- Sec. 312. Procedures for imposition of penalties.
- Sec. 313. Report on use of existing enforcement mechanisms.
- Sec. 314. Civil action by individuals.

TITLE IV—MISCELLANEOUS

- Sec. 401. Relationship to other laws.
- Sec. 402. Study by GAO.
- Sec. 403. Effective date.

1 **SEC. 2. FINDINGS.**

2 The Congress finds that—

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

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

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

13 (4) an individual's confidentiality right means
14 that an individual's consent is needed to disclose his
15 or her protected health information, except in rare
16 and limited circumstances required by the public in-
17 terest;

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

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

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

1 (8) personal health care data may be essential
2 for selected types of medical research;

3 (9) public health uses of personal health data
4 are critical to both personal health as well as public
5 health; and

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

12 **SEC. 3. PURPOSES.**

13 The purpose of this Act is to—

14 (1) establish strong and effective mechanisms
15 to protect against the unauthorized and inappropri-
16 ate use of protected health information that is cre-
17 ated or maintained as part of health care treatment,
18 diagnosis, enrollment, payment, plan administration,
19 testing, or research processes;

20 (2) promote the efficiency and security of the
21 health information infrastructure so that members
22 of the health care community may more effectively
23 exchange and transfer health information in a man-
24 ner that will ensure the confidentiality of protected

1 health information without impeding the delivery of
2 high quality health care;

3 (3) create incentives to turn personal health in-
4 formation into nonidentifiable health information for
5 oversight, health research, public health, law en-
6 forcement, judicial, and administrative purposes,
7 where appropriate; and

8 (4) establish strong and effective remedies for
9 violations of this Act.

10 **SEC. 4. DEFINITIONS.**

11 As used in this Act:

12 (1) ACCREDITING BODY.—The term “accredit-
13 ing body” means a national body, committee, organi-
14 zation, or institution (such as the Joint Commission
15 on Accreditation of Health Care Organizations or
16 the National Committee for Quality Assurance) that
17 has been authorized by law or is recognized by a
18 health care regulating authority as an accrediting
19 entity or any other entity that has been similarly au-
20 thorized or recognized by law to perform specific ac-
21 creditation, licensing or credentialing activities.

22 (2) AGENT.—The term “agent” means a person
23 who represents and acts for another under the con-
24 tract or relation of agency, or whose function is to
25 bring about, modify, affect, accept performance of,

1 or terminate contractual obligations between the
2 principal and a third person, including a contractor.

3 (3) ANONYMOUS LINK.—

4 (A) IN GENERAL.—The term “anonymous
5 link” means a number assigned to nonidentifi-
6 able health information which, by itself, con-
7 tains no information about an individual, but
8 which, under specific, controlled conditions, can
9 be used to link to additional health information
10 about the same individual which may be used to
11 identify that individual.

12 (B) DISCLOSURE.—Any subsequent disclo-
13 sure of an anonymous link with any information
14 which, together with information previously dis-
15 closed with the same link might reasonably be
16 used to identify an individual, shall be consid-
17 ered to be a disclosure of protected health infor-
18 mation. Such a disclosure shall convert any pre-
19 viously disclosed, nonidentifiable information
20 with the same link into protected health infor-
21 mation.

22 (4) COMMON RULE.—The term “common rule”
23 means the Federal policy for the protection of
24 human subjects from research risks originally pub-
25 lished as 56 Federal Register 28.012 (et seq) (June

1 18, 1991) as adopted and implemented by a Federal
2 department or agency.

3 (5) DISCLOSE.—The term “disclose” means to
4 release, transfer, provide access to, or otherwise di-
5 vulge protected health information to any person
6 other than the individual who is the subject of such
7 information. Such term includes the initial disclosure
8 and any subsequent redisclosures of protected health
9 information.

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

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

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

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

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

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

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

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

15 (A) conducting quality assurance activities
16 or outcomes assessments;

17 (B) reviewing the competence or qualifica-
18 tions of health care professionals;

19 (C) performing accreditation, licensing, or
20 credentialing activities;

21 (D) analysis of health plan claims or
22 health care records data;

23 (E) evaluating health plan and provider
24 performance;

1 (F) carrying out utilization review,
2 precertification or preauthorization of services;

3 (G) underwriting or experience rating of
4 health plans; or

5 (H) conducting or arranging for auditing
6 services.

7 (9) 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, or employer spon-
19 sored program that directly provides items or
20 services that constitute health care to bene-
21 ficiaries; or

22 (C) an officer, employee, or agent of a per-
23 son described in subparagraph (A) or (B).

24 (10) 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 (11) 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, or credentialing of health
14 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, or payment
23 for, health care; 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 (12) 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, whether or not funded through the
13 purchase of insurance.

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

21 (14) INDIVIDUAL REPRESENTATIVE.—The term
22 “individual representative” means a person who is
23 authorized by law (based on grounds other than the
24 individual being a minor), or by an instrument rec-
25 ognized under law, to act as an agent, attorney,

1 proxy, or other legal representative of a protected
2 individual. Such term includes a health care power
3 of attorney.

4 (15) INSTITUTIONAL REVIEW BOARD.—The
5 term “institutional review board” means a review
6 panel, that is generally associated with a particular
7 university or other research institution, that is re-
8 sponsible for implementing Federal human subject
9 protection requirements for research conducted at or
10 supported by the university or institution involved.

11 (16) LAW ENFORCEMENT INQUIRY.—The term
12 “law enforcement inquiry” means a lawful investiga-
13 tion conducted by an appropriate government agency
14 or official inquiring into a violation of, or failure to
15 comply with, any criminal or civil statute or any reg-
16 ulation, rule, or order issued pursuant to such a
17 statute.

18 (17) NETWORK PLAN.—The term “network
19 plan” means health care coverage provided under a
20 health plan under which the financing and delivery
21 of health care are provided, in whole or in part,
22 through a defined set of health care providers under
23 contract with the health plan.

24 (18) NONIDENTIFIABLE HEALTH INFORMA-
25 TION.—The term “nonidentifiable health informa-

1 tion” means any information that would otherwise
2 be protected health information except that such in-
3 formation does not reveal the identity of the individ-
4 ual whose health or health care is the subject of the
5 information and there is no reasonable basis to be-
6 lieve that such information could be used, either
7 alone or with other information that is, or should
8 reasonably be known to be, available to predictable
9 recipients of such information, to reveal the identity
10 of that individual.

11 (19) ORIGINATING PROVIDER.—The term “orig-
12 inating provider” means a health care provider who
13 creates or originates medical information that is or
14 that becomes protected health information.

15 (20) PAYMENT.—The term “payment”
16 means—

17 (A) the activities undertaken by—

18 (i) or on behalf of a health plan to de-
19 termine its responsibility for coverage
20 under the plan and the actual payment
21 under such plan; and

22 (ii) a health care provider to obtain
23 payment for items or services provided
24 under a health plan or provided based on
25 a determination by the health plan of re-

1 sponsibility for coverage under the plan;
2 and

3 (B) activities undertaken as described in
4 subparagraph (A) including—

5 (i) billing, claims management, medi-
6 cal data processing or other administrative
7 services;

8 (ii) determinations of coverage or ad-
9 judication of health benefit claims; and

10 (iii) review of health care services with
11 respect to medical necessity, coverage
12 under a health plan, appropriateness of
13 care, or justification of charges.

14 (21) PERSON.—The term “person” means a
15 government, governmental subdivision, agency or au-
16 thority; corporation; company; association; firm;
17 partnership; society; estate; trust; joint venture; indi-
18 vidual; individual representative; tribal government;
19 and any other legal entity.

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

24 (A) that relates to the past, present or fu-
25 ture—

1 (i) physical or mental health or condi-
2 tion of an individual (including the condi-
3 tion or other attributes of individual cells
4 or their components);

5 (ii) provision of health care to an indi-
6 vidual; or

7 (iii) payment for the provision of
8 health care to an individual;

9 (B) that is created by a health care pro-
10 vider, health plan, health researcher, health
11 oversight agency, public health authority, em-
12 ployer, law enforcement official, health or life
13 insurer, school or university; and

14 (C) that is not nonidentifiable health infor-
15 mation.

16 (23) PUBLIC HEALTH AUTHORITY.—The term
17 “public health authority” means an authority or in-
18 strumentality of the United States, a tribal govern-
19 ment, a State, or a political subdivision of a State
20 that is—

21 (A) primarily responsible for public health
22 matters; and

23 (B) primarily engaged in activities such as
24 injury reporting, public health surveillance, and
25 public health investigation or intervention.

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

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

10 (26) STATE.—The term “State” includes the
11 District of Columbia, Puerto Rico, the Virgin Is-
12 lands, Guam, American Samoa, and the Northern
13 Mariana Islands.

14 (27) TREATMENT.—The term “treatment”
15 means the provision of health care by, or the coordi-
16 nation of health care among, health care providers,
17 or the referral of a patient from one provider to an-
18 other, or coordination of health care or other serv-
19 ices among health care providers and third parties
20 authorized by the health plan or the plan member.

21 (28) WRITING.—The term “writing” means
22 writing in either a paper-based or computer-based
23 form, including electronic signatures.

1 **TITLE I—INDIVIDUAL’S RIGHTS**
 2 **Subtitle A—Review of Protected**
 3 **Health Information by Subjects**
 4 **of the Information**

5 **SEC. 101. INSPECTION AND COPYING OF PROTECTED**
 6 **HEALTH INFORMATION.**

7 (a) **IN GENERAL.**—At the request of an individual
 8 and except as provided in subsection (b), a health care
 9 provider, health plan, employer, health or life insurer,
 10 school, or university shall permit an individual who is the
 11 subject of protected health information or the individual’s
 12 designee, to inspect and copy protected health information
 13 concerning the individual, including records created under
 14 section 102, that such entity maintains. The entity may
 15 set forth appropriate procedures to be followed for such
 16 inspection or copying and may require an individual to pay
 17 reasonable costs associated with such inspection or copy-
 18 ing.

19 (b) **EXCEPTIONS.**—Unless ordered by a court of com-
 20 petent jurisdiction, an entity described in subsection (a)
 21 is not required to permit the inspection or copying of pro-
 22 tected health information if any of the following conditions
 23 are met:

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

1 formation could reasonably be expected to endanger
2 the life or physical safety of, or cause substantial
3 mental harm to, the individual who is the subject of
4 the record.

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

10 (3) INFORMATION COMPILED IN ANTICIPATION
11 OF LITIGATION.—The information is compiled prin-
12 cipally—

13 (A) in the reasonable anticipation of a
14 civil, criminal, or administrative action or pro-
15 ceeding; or

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

17 (4) RESEARCH PURPOSES.—The information
18 was collected for or during a clinical trial monitored
19 by an institutional review board, such trial is not
20 complete, and the researcher reasonably believes that
21 access would harm the conduct of the trial.

22 (c) DENIAL OF A REQUEST FOR INSPECTION OR
23 COPYING.—If an entity described in subsection (a) denies
24 a request for inspection or copying pursuant to subsection
25 (b), the entity shall inform the individual in writing of—

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

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

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

8 (d) STATEMENT REGARDING REQUEST.—If an indi-
9 vidual has filed a statement under subsection (c)(3), the
10 entity in any subsequent disclosure of the portion of the
11 information requested under subsection (a) shall include—

12 (1) a copy of the individual's statement; and

13 (2) a concise statement of the reasons for deny-
14 ing the request for inspection or copying.

15 (e) INSPECTION AND COPYING OF SEGREGABLE POR-
16 TION.—An entity described in subsection (a) shall permit
17 the inspection and copying under subsection (a) of any
18 reasonably segregable portion of a record after deletion of
19 any portion that is exempt under subsection (b).

20 (f) DEADLINE.—An entity described in subsection (a)
21 shall comply with or deny, in accordance with subsection
22 (c), a request for inspection or copying of protected health
23 information under this section not later than 30 days after
24 the date on which the entity receives the request.

1 (g) RULES GOVERNING AGENTS.—An agent of an en-
 2 tity described in subsection (a) shall not be required to
 3 provide for the inspection and copying of protected health
 4 information, except where—

5 (1) the protected health information is retained
 6 by the agent; and

7 (2) the agent has received in writing a request
 8 from the entity involved to fulfill the requirements of
 9 this section;

10 at which time such information shall be provided to the
 11 requesting entity. Such requesting entity shall comply with
 12 subsection (f) with respect to any such information.

13 (h) RULE OF CONSTRUCTION.—This section shall not
 14 be construed to require an entity described in subsection
 15 (a) to conduct a formal, informal, or other hearing or pro-
 16 ceeding concerning a request for inspection or copying of
 17 protected health information.

18 **SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-**
 19 **TION.**

20 (a) IN GENERAL.—Except as provided in subsection
 21 (b), not later than 45 days after the date on which a
 22 health care provider, health plan, employer, health or life
 23 insurer, school, or university receives from an individual
 24 a request in writing to amend information, and the record
 25 involved is in fact inaccurate, such entity shall—

1 (1) make the amendment requested;

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

4 (3) make reasonable efforts to inform any per-
5 son to whom the unamended portion of the informa-
6 tion was previously disclosed, of any nontechnical
7 amendment that has been made.

8 (b) REFUSAL TO AMEND.—If an entity described in
9 subsection (a) refuses to make the amendment requested
10 under such subsection, the entity shall inform the individ-
11 ual in writing of—

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

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

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

20 (c) STATEMENT OF DISAGREEMENT.—If an individ-
21 ual has filed a statement of disagreement under subsection
22 (b)(3), the entity involved, in any subsequent disclosure
23 of the disputed portion of the information—

24 (1) shall include a copy of the individual's
25 statement; and

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

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

7 (1) the protected health information is retained
8 by the agent; and

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

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

14 (e) REPEATED REQUESTS FOR AMENDMENTS.—If an
15 entity described in subsection (a) receives a request for
16 an amendment of information as provided for in such sub-
17 section and a statement of disagreement has been filed
18 pursuant to subsection (c), the entity shall inform the indi-
19 vidual of such filing and shall not be required to carry
20 out the procedures required under this section.

21 (f) RULES OF CONSTRUCTION.—This section shall
22 not be construed to—

23 (1) require that an entity described in sub-
24 section (a) conduct a formal, informal, or other

1 hearing or proceeding concerning a request for an
2 amendment to protected health information; or

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

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

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

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

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

18 (3) the procedures for authorizing disclosures of
19 protected health information and for revoking such
20 authorizations;

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

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

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

6 **Subtitle B—Establishment of**
7 **Safeguards**

8 **SEC. 111. ESTABLISHMENT OF SAFEGUARDS.**

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

18 (b) REGULATIONS.—The Secretary shall have the au-
19 thority to promulgate regulations for the implementation
20 of subsection (a).

21 (c) RULE OF CONSTRUCTION.—Safeguards to protect
22 the security of protected health information under sub-
23 section (a) shall include the implementation of policies or
24 procedures to consider whether protected health informa-

1 tion is essential for a use or disclosure undertaken by an
2 entity described in such subsection.

3 **SEC. 112. ACCOUNTING FOR DISCLOSURES.**

4 (a) IN GENERAL.—

5 (1) HEALTH RELATED ENTITIES.—Except as
6 provided in paragraph (3), a health care provider,
7 health plan, health oversight agency, public health
8 authority, employer, health or life insurer, health re-
9 searcher, law enforcement official, school, or univer-
10 sity shall establish and maintain, with respect to any
11 protected health information disclosure, a record of
12 such disclosure in accordance with regulations issued
13 by the Secretary.

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

17 (3) EXCEPTION.—A record of disclosures under
18 this subsection is not required with respect to disclo-
19 sures made to officers or employees of the entity
20 that maintains the record involved who, in the per-
21 formance of their duties, have a need for the pro-
22 tected health information.

23 (b) RECORD OF DISCLOSURE.—A record established
24 under subsection (a) shall be maintained for not less than
25 7 years.

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

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

5 (a) PROHIBITION.—

6 (1) GENERAL RULE.—A health care provider,
7 health plan, health oversight agency, public health
8 authority, employer, health or life insurer, health re-
9 searcher, law enforcement official, school, or univer-
10 sity may not disclose protected health information
11 except as authorized under this title.

12 (2) RULE OF CONSTRUCTION.—Disclosure of
13 health information in the form of nonidentifiable
14 health information shall not be construed as a dis-
15 closure of protected health information.

16 (b) USE OR DISCLOSURE OF PROTECTED HEALTH
17 INFORMATION WITHIN AN ENTITY.—

18 (1) IN GENERAL.—An entity described in sub-
19 section (a) may use protected health information or
20 disclose such information within the entity if such
21 use or disclosure is made pursuant to an authoriza-
22 tion under section 202 or 203 and consistent with
23 the limitations under subsection (d) on the scope of
24 disclosure.

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

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

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

12 (e) NO GENERAL REQUIREMENT TO DISCLOSE.—
13 Nothing in this title permitting the disclosure of protected
14 health information shall be construed to require such dis-
15 closure.

16 (f) IDENTIFICATION OF DISCLOSED INFORMATION AS
17 PROTECTED INFORMATION.—Except as otherwise pro-
18 vided in this title, protected health information may not
19 be disclosed unless such information is clearly identified
20 as protected health information that is subject to this Act.

21 (g) CREATION OF NONIDENTIFIABLE INFORMA-
22 TION.—An entity described in subsection (a) may disclose
23 protected health information to an employee or agent of
24 the entity for purposes of creating nonidentifiable infor-
25 mation, if the entity prohibits the employee or agent of

1 the entity from using or disclosing the protected health
2 information for purposes other than the sole purpose of
3 creating nonidentifiable information as specified by the en-
4 tity.

5 (h) DEEMED DISCLOSURES OF PROTECTED HEALTH
6 INFORMATION.—

7 (1) IN GENERAL.—Any individual or entity who
8 manipulates a nonidentifiable database in order to
9 identify an individual shall be deemed to have dis-
10 closed protected health information.

11 (2) DISCLOSURE OR TRANSMISSION OF AN
12 ANONYMOUS LINK.—The disclosure or transmission
13 of an anonymous link with any information which,
14 together with information previously disclosed with
15 the same link, might reasonably be used to identify
16 an individual, shall be deemed to be a disclosure of
17 protected health information. Such a disclosure shall
18 have the effect of converting any previously dis-
19 closed, nonidentifiable information with the same
20 link into the protected health information.

1 **SEC. 202. PROCUREMENT OF AUTHORIZATIONS FOR DIS-**
2 **CLOSURE OF PROTECTED HEALTH INFORMA-**
3 **TION FOR TREATMENT, PAYMENT, OR**
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 form must be secured for each individual
12 in connection with treatment, payment and health
13 care 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, or 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 individual 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 with respect to each individual who is el-
4 igible to receive care under the plan.

5 (4) UNINSURED.—An originating provider pro-
6 viding health care in other than a network plan set-
7 ting, or providing health care to an uninsured indi-
8 vidual, shall obtain a signed, written authorization to
9 use protected health information in providing health
10 care or arranging for health care from other provid-
11 ers or seeking payment for the provision of health
12 care services.

13 (5) PROVIDERS.—Every health care provider
14 providing health care to an individual who has not
15 given the appropriate authorization under this sec-
16 tion shall, at the time of providing such care, obtain
17 a signed, written authorization that is a legal, in-
18 formed authorization concerning the use and disclo-
19 sure of protected health information with respect to
20 such individual.

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 paragraph (c).

16 (c) REVOCATION OF AUTHORIZATION.—

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

24 (2) HEALTH PLANS.—With respect to a health
25 plan, the authorization of an individual is deemed to

1 be revoked at the time of the cancellation or non-re-
2 newal of enrollment in the health plan, except as
3 may be necessary to complete health care operations
4 and payment requirements related to the individual's
5 period of enrollment.

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

11 (d) RECORD OF INDIVIDUAL'S AUTHORIZATIONS AND
12 REVOCATIONS.—Each person collecting or storing pro-
13 tected health information shall maintain a record for a pe-
14 riod of 7 years of each authorization of an individual and
15 revocation thereof.

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

21 (f) RULE OF CONSTRUCTION.—Authorizations for
22 the disclosure of protected health information for treat-
23 ment, payment, and health care operations shall not au-
24 thorize the disclosure of such information by an individual
25 with the intent to sell, transfer, or use protected health

1 information for commercial advantage. For such dislo-
2 sures a separate authorization is required under section
3 203.

4 **SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-**
5 **TECTED HEALTH INFORMATION OTHER THAN**
6 **FOR TREATMENT, PAYMENT, OR HEALTH**
7 **CARE OPERATIONS.**

8 (a) WRITTEN AUTHORIZATIONS.—A health care pro-
9 vider, health plan, health oversight, health researcher,
10 public health authority, law enforcement official agency,
11 public health authority, employer, health or life insurer,
12 health researcher, law enforcement official, school, or uni-
13 versity may disclose protected health information, for pur-
14 poses other than those authorized under section 202, pur-
15 suant to an authorization executed by the individual who
16 is the subject of the information that meets the require-
17 ments of section 202(b). Such an authorization shall be
18 separate from an authorization provided under section
19 202.

20 (b) LIMITATION ON AUTHORIZATIONS.—An entity
21 described in section 202 may not condition the delivery
22 of treatment or payment for services on the receipt of an
23 authorization described in this section.

24 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-
25 TION.—

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

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

11 (d) REQUIREMENT TO RELEASE PROTECTED
12 HEALTH INFORMATION TO CORONERS AND MEDICAL EX-
13 AMINERS.—

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

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

10 (3) EXEMPTION.—Health information attached
11 to or otherwise made a part of a Coroner’s or Medi-
12 cal Examiner’s official report, shall be exempt from
13 the provisions of this Act except as provided for in
14 this subsection.

15 (4) REIMBURSEMENT.—A Coroner or Medical
16 Examiner may require a person to reimburse their
17 Office for the reasonable costs associated with such
18 inspection or copying.

19 (e) DISCLOSURE FOR PURPOSE ONLY.—A recipient
20 of information pursuant to an authorization under this
21 section may use or disclose such information solely to
22 carry out the purpose for which the information was au-
23 thorized for release.

24 (f) MODEL AUTHORIZATIONS.—The Secretary, after
25 notice and opportunity for public comment, shall develop

1 and disseminate model written authorizations of the type
2 described in subsection (a). Any authorization obtained on
3 a model authorization form developed by the Secretary
4 shall be deemed to meet the authorization requirements
5 of this section.

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

7 (a) NEXT OF KIN.—A health care provider, or a per-
8 son who receives protected health information under sec-
9 tion 205, may disclose protected health information re-
10 garding an individual to the individual’s next of kin, an
11 individual’s representative, or to another person whom the
12 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), an entity 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 (c) IDENTIFICATION OF DECEASED INDIVIDUAL.—

21 An entity described in subsection (a) may disclose pro-
22 tected health information if such disclosure is necessary
23 to assist in the identification or safe handling of a de-
24 ceased individual.

25 (d) RIGHTS OF MINORS.—

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

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

6 (B) who, acting alone, can obtain a type of
7 health care without violating any applicable
8 Federal or State law, and who has sought such
9 care, the individual shall exercise all rights of
10 the individual under this title with respect to
11 protected health information relating to such
12 health care.

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

16 (A) under 14 years of age, all of the indi-
17 vidual's rights under this title shall be exercised
18 through the parent or legal guardian; or

19 (B) at least 14 but under 18 years of age,
20 the rights of inspection and amendment, and
21 the right to authorize use and disclosure of pro-
22 tected health information of the individual shall
23 be exercised by the individual, or by the parent
24 or legal guardian of the individual.

1 **SEC. 205. EMERGENCY CIRCUMSTANCES.**

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

11 **SEC. 206. OVERSIGHT.**

12 (a) **IN GENERAL.**—A health care provider, health
13 plan, employer, health or life insurer, law enforcement of-
14 ficial, school, or university may disclose protected health
15 information to a health oversight agency for purposes of
16 an oversight function authorized by law.

17 (b) **PUBLIC HEALTH AND HEALTH RESEARCH.**—A
18 public health authority or health researcher may disclose
19 protected health information to a health oversight agency
20 for purposes of an oversight function of the public health
21 authority or health researcher authorized by law.

22 (c) **AUTHORIZATION BY A SUPERVISOR.**—For pur-
23 poses of this section, the individual with authority to au-
24 thorize the oversight function involved shall provide to the
25 entity described in subsection (a) or (b) a statement that

1 the protected health information is being sought for a le-
2 gally authorized oversight function.

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

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

12 (2) an action involving a fraudulent claim relat-
13 ed to health; or

14 (3) an action involving oversight of a public
15 health authority or a health researcher.

16 **SEC. 207. PUBLIC HEALTH.**

17 A health care provider, health plan, public health au-
18 thority, employer, health or life insurer, law enforcement
19 official, school, or university may disclose protected health
20 information to a public health authority or other person
21 authorized by law for use in a legally authorized—

22 (1) disease or injury report;

23 (2) public health surveillance; or

24 (3) public health investigation or intervention.

1 **SEC. 208. HEALTH RESEARCH.**

2 (a) IN GENERAL.—A health care provider, health
3 plan, public health authority, employer, health or life in-
4 surer, school, or university may disclose protected health
5 information to a health researcher if—

6 (1) the research involves human subjects con-
7 ducted or supported by any Federal department or
8 agency and the researcher complies with the com-
9 mon rule;

10 (2) the research is a clinical investigation in-
11 volving human subjects and the researcher follows
12 the regulations of the Food and Drug Administra-
13 tion governing confidentiality procedures; or

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

16 (b) OBLIGATIONS OF THE RECIPIENT.—A person
17 who receives protected health information pursuant to this
18 section—

19 (1) shall remove or destroy, at the earliest op-
20 portunity consistent with the purposes of the project
21 involved, information that would enable an individual
22 to be identified, unless—

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

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

4 (2) may disclose or use the protected health in-
5 formation solely for the purposes of the health re-
6 search project for which such information was ob-
7 tained, except that the health researcher may also
8 disclose such information pursuant to sections 205
9 and 206(b).

10 (c) PERIODIC REVIEW AND TECHNICAL ASSIST-
11 ANCE.—

12 (1) INSTITUTIONAL REVIEW BOARD.—Any in-
13 stitutional review board that authorizes research
14 under this section shall keep records of the names
15 and addresses of all members who participate in
16 such authorizations for possible review or audit.

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

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

23 (4) REPORTS.—Not later than 3 years after the
24 date of enactment of this Act, the Secretary shall re-

1 port to Congress regarding the activities of institu-
2 tional review boards described in this section.

3 (d) RECOMMENDATIONS WITH RESPECT TO PRI-
4 VACY.—

5 (1) IN GENERAL.—Not later than the date that
6 is 12 months after the date of the enactment of this
7 Act, the Secretary shall submit to the Committee on
8 Labor and Human Resources of the Senate detailed
9 recommendations on standards with respect to the
10 privacy of individually identifiable health information
11 in research described in subsection (a)(3).

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

18 (3) REGULATIONS.—If legislation governing
19 standards with respect to the privacy of individually
20 identifiable health information transmitted in con-
21 nection with research described in subsection (a)(3)
22 is not enacted by the date that is 24 months after
23 the date of the enactment of this Act, the Secretary
24 shall promulgate final regulations containing such

1 standards not later than the date that is 30 months
2 after the date of the enactment of this Act.

3 (e) PERIODIC REVIEW AND TECHNICAL ASSIST-
4 ANCE.—

5 (1) INSTITUTIONAL REVIEW BOARD.—Any in-
6 stitucional review board that authorizes research
7 under this section shall keep records of the names
8 and addresses of all members who participate in
9 such authorizations for possible review or audit.

10 (2) TECHNICAL ASSISTANCE.—The Secretary
11 may provide technical assistance to institutional re-
12 view boards described in this section.

13 (3) MONITORING.—The Secretary shall periodi-
14 cally monitor institutional review boards described in
15 this section.

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

20 **SEC. 209. DISCLOSURE IN CIVIL, JUDICIAL, AND ADMINIS-**
21 **TRATIVE PROCEDURES.**

22 (a) IN GENERAL.—A health care provider, health
23 plan, public health authority, employer, health or life in-
24 surer, law enforcement official, school, or university may
25 disclose protected health information pursuant to a discov-

1 ery request or subpoena in a civil action brought in a Fed-
2 eral or State court or a request or subpoena related to
3 a Federal or State administrative proceeding, but only if
4 the disclosure is made pursuant to a court order as pro-
5 vided for in subsection (b).

6 (b) COURT ORDERS.—

7 (1) STANDARD FOR ISSUANCE.—In considering
8 a request for a court order regarding the disclosure
9 of protected health information under subsection (a),
10 the court shall issue such order if the court deter-
11 mines that without the disclosure of such informa-
12 tion, the person requesting the order would be im-
13 paired from establishing a claim or defense.

14 (2) REQUIREMENTS.—An order issued under
15 paragraph (1) shall—

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

18 (B) specify to whom the information may
19 be disclosed;

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

22 (D) meet any other requirements that the
23 court determines are needed to protect the con-
24 fidentiality of the information.

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

4 (1) is nonidentifiable health information;

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

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

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

13 **SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PUR-**
14 **POSES.**

15 (a) IN GENERAL.—A health care provider, health
16 plan, health oversight agency, employer, health or life in-
17 surer, school, university, or person who receives protected
18 health information pursuant to sections 203 through 208,
19 may disclose protected health information under this sec-
20 tion, except to a health oversight agency governed by sec-
21 tion 206, if the disclosure is pursuant to—

22 (1) a subpoena issued under the authority of a
23 grand jury;

24 (2) an administrative subpoena or summons or
25 judicial subpoena or warrant; or

1 (3) a request otherwise authorized by State or
2 Federal law.

3 (b) PROBABLE CAUSE.—A subpoena or summons for
4 a disclosure under paragraph (1) or (2) of subsection (a)
5 shall only be issued if the law enforcement agency involved
6 shows that there is probable cause to believe that the in-
7 formation is relevant to a legitimate law enforcement in-
8 quiry.

9 (c) DESTRUCTION OR RETURN OF INFORMATION.—
10 When the matter or need for which protected health infor-
11 mation was disclosed to a law enforcement agency or
12 grand jury under subsection (a) has concluded, including
13 any derivative matters arising from such matter or need,
14 the law enforcement agency or grand jury shall either de-
15 stroy the protected health information, or return it to the
16 person from whom it was obtained.

17 (d) REDACTIONS.—To the extent practicable, and
18 consistent with the requirements of due process, a law en-
19 forcement agency shall redact personally identifying infor-
20 mation from protected health information prior to the
21 public disclosure of such protected information in a judi-
22 cial or administrative proceeding.

23 (e) USE OF INFORMATION.—Protected health infor-
24 mation obtained by a law enforcement agency pursuant

1 to this section may only be used for purposes of a legiti-
2 mate law enforcement activity.

3 (f) EXCLUSION OF EVIDENCE.—If protected health
4 information is obtained without meeting the requirements
5 of paragraphs (1), (2), and (3) of subsection (a), any such
6 information that is unlawfully obtained shall be excluded
7 from court proceedings unless the defendant requests oth-
8 erwise.

9 **SEC. 211. DISCLOSURES FOR POSTMARKETING ADVERSE**
10 **EXPERIENCE REPORTING FOR HUMAN DRUG**
11 **AND LICENSED BIOLOGICAL PRODUCTS.**

12 (a) ADVERSE EXPERIENCE REPORTS.—

13 (1) IN GENERAL.—Pursuant to the regulations
14 of the Food and Drug Administration at sections
15 310.305, 314.80, and 600.80 of title 21, Code of
16 Federal Regulations, manufacturers, packers, and
17 distributors of approved new drug applications, ab-
18 breviated new drug applications, antibiotic applica-
19 tions, marketed prescription of drugs for human use,
20 and approved biologic product license applications
21 shall report adverse experiences in accordance with
22 such section.

23 (2) NO IDENTIFICATION OF PATIENTS.—In ac-
24 cordance with the August 1997 Guidance for Indus-
25 try of the Food and Drug Administration, patients

1 shall not be identified by name or address in any re-
2 port described in paragraph (1). The manufacturer,
3 packer, or distributor involved shall assign a code
4 for a patient in each such report.

5 (3) NON LIABILITY UNDER ACT.—A manufac-
6 turer, packer, or distributor who submits an adverse
7 report in accordance with this subsection and the
8 regulations described in paragraph (1) shall not be
9 liable under this Act.

10 (b) RULE OF CONSTRUCTION.—An adverse experi-
11 ence report written in accordance with the regulations de-
12 scribed in subsection (a)(1) shall be deemed to be a dislo-
13 sure of non-identifiable information under this Act.

14 **SEC. 212. PAYMENT CARD AND ELECTRONIC PAYMENT**
15 **TRANSACTION.**

16 (a) PAYMENT FOR HEALTH CARE THROUGH CARD
17 OR ELECTRONIC MEANS.—If an individual pays for health
18 care by presenting a debit, credit, or other payment card
19 or account number, or by any other electronic payment
20 means, the entity receiving payment may disclose to a per-
21 son described in subsection (b) only such protected health
22 information about the individual as is necessary for the
23 processing of the payment transaction or the billing or col-
24 lection of amounts charged to, debited from, or otherwise

1 paid by, the individual using the card, number, or other
2 electronic means.

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

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

17 (2) the transfer of receivables, accounts, or in-
18 terest therein;

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

21 (4) compliance with Federal, State, or local law,
22 or

23 (5) compliance with a properly authorized civil,
24 criminal, or regulatory investigation by Federal,

1 State, or local authorities as governed by the re-
2 quirements of this section.

3 **SEC. 213. STANDARDS FOR ELECTRONIC DISCLOSURES.**

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

7 **SEC. 214. INDIVIDUAL REPRESENTATIVES.**

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

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

24 (c) NO COURT DECLARATION.—If a health care pro-
25 vider determines that an individual, who has not been de-

1 clared to be legally incompetent, suffers from a medical
2 condition that prevents the individual from acting know-
3 ingly or effectively on the individual's own behalf, the right
4 of the individual to authorize disclosure under this Act
5 may be exercised and discharged in the best interest of
6 the individual by—

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

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

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

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

19 (d) APPLICATION TO DECEASED INDIVIDUALS.—The
20 provisions of this Act shall continue to apply to protected
21 health information concerning a deceased individual for a
22 period of 2-years following the death of that individual.

23 (e) EXERCISE OF RIGHTS ON BEHALF OF A DE-
24 CEASED INDIVIDUAL.—A person who is authorized by law
25 or by an instrument recognized under law, to act as an

1 executor of the estate of a deceased individual, or other-
2 wise to exercise the rights of the deceased individual, may,
3 to the extent so authorized, exercise and discharge the
4 rights of such deceased individual under this Act for a pe-
5 riod of 2-years following the death of that individual. If
6 no such designee has been authorized, the rights of the
7 deceased individual may be exercised as provided for in
8 subsection (c).

9 **SEC. 215. LIMITED LIABILITY FOR LAW ENFORCEMENT OF-**
10 **FICERS.**

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

17 **SEC. 216. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.**

18 A health care provider, health plan, health oversight
19 agency, health researcher, public health authority, law en-
20 forcement official, employer, health or life insurer, school,
21 or university who makes a disclosure of protected health
22 information about an individual that is permitted by this
23 Act shall not be liable to the individual for such disclosure
24 under common law.

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**

 “Sec.
 “2801. Wrongful disclosure 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 tentionally—

14 “(1) obtains protected health information relat-
 15 ing to an individual in violation of title II of the
 16 Health Care PIN Act; or

17 “(2) discloses protected health information to
 18 another person in violation of title II of the Health
 19 Care PIN Act.

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

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

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

5 “(3) if the offense is committed with the intent
6 to sell, transfer, or use protected health information
7 for commercial advantage, personal gain, or mali-
8 cious harm, be fined not more than \$500,000, im-
9 prisoned not more than 10 years, excluded from par-
10 ticipation in any federally funded health care pro-
11 grams, or any combination of such penalties.

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

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

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

23 **SEC. 302. DEBARMENT FOR CRIMES.**

24 (a) PURPOSE.—The purpose of this section is to pro-
25 mote the prevention and deterrence of instances of inten-

1 tional criminal actions which violate criminal laws which
2 are designed to safeguard the protected health information
3 in a manner consistent with this Act.

4 (b) DEBARMENT.—Not later than 270 days after the
5 effective date of this Act, the Attorney General, in con-
6 sultation with the Secretary, shall promulgate regulations
7 and establish procedures to permit the debarment of
8 health care providers, health researchers, health or life in-
9 surers, or schools or universities from receiving benefits
10 under any Federal health programs if the managers or
11 officers of such entities are found guilty of violating sec-
12 tion 2801 of title 18, United States Code, have civil pen-
13 alties imposed against such officers or managers under
14 section 311 in connection with the illegal disclosure of pro-
15 tected health information, or are found guilty of making
16 a false statement or obstructing justice related to attempt-
17 ing to conceal or concealing such illegal disclosure. Such
18 regulations shall take into account the need for continuity
19 of medical care and may provide for a delay of any debar-
20 ment imposed under this section to take into account the
21 medical needs of patients.

22 (c) CONSULTATION.—Before publishing a proposed
23 rule to implement subsection (b), the Attorney General
24 shall consult with State law enforcement officials, health
25 care providers, patient privacy rights' advocates, and other

1 appropriate individuals and entities, to gain additional in-
2 formation regarding the debarment of entities under sub-
3 section (b) and the best methods to ensure the continuity
4 of medical care.

5 (d) REPORT.—The Attorney General shall annually
6 prepare and submit to the Committee on the Judiciary of
7 the House of Representatives and the Committee on the
8 Judiciary of the Senate a report concerning the activities
9 and debarment actions taken by the Attorney General
10 under this section.

11 (e) ASSISTANCE TO PREVENT CRIMINAL VIOLA-
12 TIONS.—The Attorney General, in cooperation with any
13 other appropriate individual, organization, or agency, may
14 provide advice, training, technical assistance, and guid-
15 ance regarding ways to reduce the incidence of improper
16 disclosure of protected health information.

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

1 **Subtitle B—Civil Sanctions**

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

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

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

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

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

24 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.—
25 Section 1128A of the Social Security Act, other than sub-

1 sections (a) and (b) and the second sentence of subsection
2 (f) of that section, shall apply to the imposition of a civil,
3 monetary, or exclusionary penalty under this section in the
4 same manner as such provisions apply with respect to the
5 imposition of a penalty under section 1128A of such Act.

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

7 (a) INITIATION OF PROCEEDINGS.—

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

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

1 to be represented by counsel, to present witnesses,
2 and to cross-examine witnesses against the person.

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

5 (A) is against a person who has been con-
6 victed (whether upon a verdict after trial or
7 upon a plea of guilty or nolo contendere) of a
8 crime under section 2801 of title 18, United
9 States Code; and

10 (B) involves the same conduct as in the
11 criminal action;

12 the person is estopped from denying the essential
13 elements of the criminal offense.

14 (4) SANCTIONS FOR FAILURE TO COMPLY.—

15 The official conducting a hearing under this section
16 may sanction a person, including any party or attor-
17 ney, for failing to comply with an order or proce-
18 dure, failing to defend an action, or other mis-
19 conduct as would interfere with the speedy, orderly,
20 or fair conduct of the hearing. Such sanction shall
21 reasonably relate to the severity and nature of the
22 failure or misconduct. Such sanction may include—

23 (A) in the case of refusal to provide or per-
24 mit discovery, drawing negative factual infer-
25 ences or treating such refusal as an admission

1 by deeming the matter, or certain facts, to be
2 established;

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

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

7 (D) staying the proceedings;

8 (E) dismissal of the action;

9 (F) entering a default judgment;

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

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

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

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

21 (2) the degree of culpability, history of prior of-
22 fenses, and financial condition of the person present-
23 ing the claims; and

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

25 (c) REVIEW OF DETERMINATION.—

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

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

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

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

1 for the modification or setting aside of the original
2 order, shall be conclusive.

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

10 (d) RECOVERY OF PENALTIES.—

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

21 (2) DEDUCTION FROM AMOUNTS OWING.—The
22 amount of any penalty, when finally determined
23 under this section, or the amount agreed upon in
24 compromise under paragraph (1), may be deducted
25 from any sum then or later owing by the United

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

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

11 (f) SUBPOENA AUTHORITY.—

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

1 United States or in any Territory or possession
2 thereof.

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

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

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

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

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

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

15 **SEC. 313. REPORT ON USE OF EXISTING ENFORCEMENT**
16 **MECHANISMS.**

17 In addition to the criminal and civil penalties that
18 may be applied under this title, the Secretary shall prepare
19 and submit to Congress a report regarding the use of ex-
20 isting Federal, State and other licensure, certification and
21 regulatory mechanisms, including State insurance regula-
22 tions, for the imposition of sanctions or penalties for the
23 wrongful disclosure of protected health information.

1 **SEC. 314. CIVIL ACTION BY INDIVIDUALS.**

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

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

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

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

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

21 (d) LIMITATION.—No action may be commenced
22 under this section more than 3 years after the date on
23 which the violation was or should reasonably have been
24 discovered.

1 **TITLE IV—MISCELLANEOUS**

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

3 (a) STATE LAW.—Except as provided in subsections
4 (b) and (c), the provision of this Act shall preempt any
5 State law that directly relates to matters covered by this
6 Act. This Act shall not be construed as repealing, explicitly
7 or implicitly, other Federal laws or regulations relating to
8 protected health information or relating to an individual's
9 access to protected health information or health care serv-
10 ices.

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

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

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

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

3 (3) relates to public or mental health and that
4 prevents or otherwise restricts disclosure of informa-
5 tion otherwise permissible under this Act;

6 (4) governs a minor's right to access protected
7 health information or health care services; or

8 (5) authorizes the collecting, analysis, or dis-
9 semination of information from an entity described
10 in section 201(a) for the purpose of developing use,
11 cost effectiveness, performance, or quality data.

12 (d) FEDERAL PRIVACY ACT.—

13 (1) MEDICAL EXEMPTIONS.—Sections 552a of
14 title 5, United States Code, is amended by adding
15 at the end thereof the following: “The head of an
16 agency that is an entity described in section 311(a)
17 of the Health Care PIN Act shall promulgate rules,
18 in accordance with the requirements (including gen-
19 eral notice) of subsections (b)(1), (b)(2), (b)(3), (c),
20 and (e) of section 553 of this title, to exempt a sys-
21 tem of records within an agency, to the extent that
22 the system of records contains protected health in-
23 formation (as defined in section 4(20) of such Act),
24 from all provisions of this section except subsections
25 (b)(6), (d), (e)(1), (e)(2), subparagraphs (A) and

1 (C) and (E) through (I) of subsection (e)(4), and
2 subsections (e)(5), (e)(6), (e)(9), (e)(12), (l), (n),
3 (o), (p), (r), and (u).”.

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

9 (e) APPLICATION TO CERTAIN FEDERAL AGEN-
10 CIES.—

11 (1) DEPARTMENT OF DEFENSE.—

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

23 (B) APPLICATION TO CIVILIAN EMPLOY-
24 EES.—The Secretary of Defense may, by regu-
25 lation, establish for civilian employees of the

1 Department of Defense and employees of De-
2 partment of Defense contractors, limitations on
3 the right of such persons to revoke or amend
4 authorizations for disclosures under section 203
5 when such authorizations were provided by such
6 employees as a condition of employment and
7 the disclosure is determined necessary by the
8 Secretary of Defense to the proper conduct of
9 national defense functions by such employees.

10 (2) DEPARTMENT OF TRANSPORTATION.—

11 (A) EXCEPTIONS.—The Secretary of
12 Transportation may, with respect to members
13 of the Coast Guard, exercise the same powers
14 as the Secretary of Defense may exercise under
15 paragraph (1)(A).

16 (B) APPLICATION TO CIVILIAN EMPLOY-
17 EES.—The Secretary of Transportation may,
18 with respect to civilian employees of the Coast
19 Guard and Coast Guard contractors, exercise
20 the same powers as the Secretary of Defense
21 may exercise under paragraph (1)(B).

22 (3) DEPARTMENT OF VETERANS AFFAIRS.—

23 The limitations on use and disclosure of protected
24 health information under this Act shall not be con-
25 strued to prevent any exchange of such information

1 within and among components of the Department of
2 Veterans Affairs that determine eligibility for or en-
3 titlement to, or that provide, benefits under laws ad-
4 ministered by the Secretary of Veteran Affairs.

5 **SEC. 402. STUDY BY GAO.**

6 Not later than 6 months after the date of enactment
7 of the Act, the General Accounting Office shall report the
8 results of a study examining research issues relating to
9 protected health information, including the quality and
10 uniformity of institutional review boards with respect to
11 the confidentiality of such information, the extent to which
12 health research is research described in section 208(a)(3),
13 the extent to which health researchers conducting research
14 described in section 208(a)(3) have established and main-
15 tained safeguards described in section 111, and the need
16 for personally identifiable information in various research
17 settings.

18 **SEC. 403. EFFECTIVE DATE.**

19 (a) EFFECTIVE DATE.—Except as provided in sub-
20 section (b), this Act shall take effect on the date that is
21 18 months after the date of enactment of this Act.

22 (b) REGULATIONS.—The Secretary shall promulgate
23 regulations implementing this Act not later than 12
24 months after the date of enactment of this Act.

○