H. R. 1215

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

IN THE HOUSE OF REPRESENTATIVES

MARCH 27, 2001

Mr. GREENWOOD introduced the following bill; which was referred to the Committee on Energy and 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the “Medical Information Protection and Research Enhancement Act of 2001”.

(b) Table of Contents.—The table of contents for 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. 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.
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TITLE III—SANCTIONS

Subtitle A—Criminal Provisions

Sec. 301. Wrongful disclosure of protected health information.

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TITLE IV—MISCELLANEOUS

Sec. 401. Relationship to other laws.
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Sec. 403. Study by Institute of Medicine.
Sec. 404. Effective date.

1 SEC. 2. DEFINITIONS.

2 As used in this Act:
(1) ACCREDITING BODY.—The term “accrediting body” means a national body, committee, organization, or institution (such as the Joint Commission on Accreditation of Health Care Organizations or the National Committee for Quality Assurance) that has been authorized by law or is recognized by a health care regulating authority as an accrediting entity or any other entity that has been similarly authorized or recognized by law to perform specific accreditation, licensing or credentialing activities.

(2) AGENT.—The term “agent” means a person, including a contractor, who represents and acts for another under the contract or relation of agency, or whose function is to bring about, modify, effect, accept performance of, or terminate contractual obligations between the principal and a third person.

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

(4) DISCLOSE/DISCLOSURE.—The term “disclose” means to release, transfer, provide access to, or otherwise divulge protected health information to any person other than the individual who is the sub-
ject of such information. The term “disclosure” re-
fers to such a release, transfer, provisions for access
to, or communication of such information. The use
of protected health information by an authorized
person and its agents shall not be considered a dis-
closure for purposes of this Act, provided that the
use is consistent with the purposes for which the in-
formation was lawfully obtained. Using or providing
access to health information in the form of non-
identifiable health information shall not be construed
as a disclosure of protected health information.

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

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

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

(i) with respect to the physical or
mental condition of an individual; or
(ii) affecting the structure or function
of the human body or any part of the
human body, including the banking of
blood, sperm, organs, or any other tissue;
or
(B) pursuant to a prescription or medical
order any sale or dispensing of a drug, device,
equipment, or other health care related item to
an individual, or for the use of an individual.

(7) Health care operations.—The term
“health care operations” means services provided by
or on behalf of a health plan or health care provider
for the purpose of carrying out the management
functions of a health care provider or health plan, or
implementing the terms of a contract for health plan
benefits, including—

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

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

(C) reviewing the competence or qualifica-
tions of health care professionals, evaluating
provider performance, and conducting health care education, accreditation, certification, licensing, or credentialing activities;

(D) carrying out utilization review activities, including precertification and preauthorization of services, and health plan rating and insurance activities, including underwriting, experience rating and reinsurance; and

(E) conducting or arranging for auditing services, including fraud detection and compliance programs.

(8) Health care provider.—The term “health care provider” means a person, who with respect to a specific item of protected health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—

(A) a person who is licensed, certified, registered, or otherwise authorized by Federal or State law to provide an item or service that constitutes health care in the ordinary course of business, or practice of a profession;

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

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

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

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

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

(B) a person who—

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

(ii) is a public agency, acting on behalf of a public agency, acting pursuant to a requirement of a public agency, or carrying out activities under a Federal or State law governing the assessment, evaluation, determination, investigation, or prosecution described in subparagraph (A).

(10) HEALTH PLAN.—The term “health plan” means has the meaning given such term in section 1171(5) of the Social Security Act (42 U.S.C. 1320d(5)) and includes any health insurance issuer, health insurance plan (including any hospital or medical service plan, dental or other health service plan, or health maintenance organization plan), provider sponsored organization, or other program providing or arranging for the provision of health benefits. Such term does not include any policy, plan, or program to the extent that it provides, arranges, supports, or administers any excepted benefits (as defined in section 2791(e)(1) of the Public Health Service Act (42 U.S.C. 300gg–91(e)(1))).
(11) Health Research/Health Researcher.—The term “health research” means a systematic investigation of health (including but not limited to basic biological processes and structures), health care, or its delivery and financing, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge concerning human health, health care, or health care delivery. The term “health researcher” means a person involved in health research, or an officer, employee, or agent of such person.

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

(13) Law Enforcement Inquiry.—The term “law enforcement inquiry” means a lawful investigation or official proceeding inquiring into a violation of, or failure to comply with, any criminal or civil statute or any regulation, rule, or order issued pursuant to such a statute.

(14) Life Insurer.—The term “life insurer” means life insurance company as defined in section 816 of the Internal Revenue Code of 1986.
(15) Nonidentifiable health information.—The term “nonidentifiable health information” means protected health information from which personal identifiers, that directly reveal the identity of the individual who is the subject of such information or provide a direct means of identifying the individual (such as name, address, and social security number), have been removed, encrypted, or replaced with a code, such that the identity of the individual is not evident without (in the case of encrypted or coded information) use of key.

(16) Originating provider.—The term “originating provider” means a health care provider who initiates a treatment episode, such as prescribing a drug, ordering a diagnostic test, or admitting an individual to a health care facility. A hospital or nursing facility is the originating provider with respect to protected health information created or received as part of inpatient or outpatient treatment provided in such settings.

(17) Payment.—The term “payment” means—

(A) the activities undertaken by—
(i) or on behalf of a health plan to determine its responsibility for coverage under the plan; or

(ii) a health care provider to obtain payment for items or services provided to an individual, provided under a health plan, or provided based on a determination by the health plan of responsibility for coverage under the plan; and

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

(i) billing, claims management, medical data processing, other administrative services, and actual payment;

(ii) determinations of coverage or adjudication of health benefit or subrogation claims; and

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

(18) PERSON.—The term “person” means a government, governmental subdivision, agency or authority; corporation; company; association; firm; partnership; society; estate; trust; joint venture; indi-
individual; 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 individual, whether oral or recorded in any form or medium, 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 individual (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 information.

(20) Public health authority.—The term “public health authority” means an authority or in-
strumentality of the United States, a tribal govern-
ment, a State, or a political subdivision of a State
that is—

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

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

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

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

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

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

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

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

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.

(a) General Rules.—

(1) Compliance with section.—At the request of an individual who is the subject of protected health information and except as provided in subsection (c), a health care provider, a health plan, employer, life insurer, school, or university shall arrange for inspection or copying of protected health information concerning the individual, including
records created under section 102, as provided for in this section.

(2) **AVAILABILITY OF INFORMATION THROUGH ORIGINATING PROVIDER.**—Protected health information that is created or received by a health plan or health care provider as part of treatment or payment shall be made available for inspection or copying as provided for in this title through the originating provider.

(3) **OTHER ENTITIES.**—An employer, life insurer, school, or university that creates or receives protected health information in performing any function other than providing treatment, payment, or health care operations with respect to the individual who is the subject of such information, shall make such information available for inspection or copying as provided for in this title, or through any provider designated by the individual.

(4) **PROCEDURES.**—The person providing access to information under this title may set forth appropriate procedures to be followed for such inspection or copying and may require an individual to pay reasonable costs associated with such inspection or copying.
(b) **Special Circumstances.**—If an originating provider, its agent, or contractor no longer maintains the protected health information sought by an individual pursuant to subsection (a), a health plan or another health care provider that maintains such information shall arrange for inspection or copying.

(c) **Exceptions.**—Unless ordered by a court of competent jurisdiction, a person acting pursuant to subsection (a) or (b) is not required to permit the inspection or copying of protected health information if any of the following conditions are met:

1. **Endangerment to Life or Safety.**—The person determines that the disclosure of the information could reasonably be expected to endanger the life or physical safety of any individual.

2. **Confidential Source.**—The information identifies, or could reasonably lead to the identification of, a person who provided information under a promise of confidentiality to a health care provider concerning the individual who is the subject of the information.

3. **Information Compiled in Anticipation of or in Connection with a Fraud Investigation or Litigation.**—The information is compiled principally—
(A) in anticipation of or in connection with a fraud investigation, an investigation of material misrepresentation in connection with an insurance policy, a civil, criminal, or administrative action or proceeding; or

(B) for use in such action or proceeding.

(4) INVESTIGATIONAL INFORMATION.—The protected health information was created, received or maintained by a health researcher as provided in section 208.

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

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

(2) the availability of procedures for further review of the denial; and

(3) the individual’s right to file with the person a concise statement setting forth the request for inspection or copying.

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

(1) shall include a notation concerning the individual’s statement; and

(2) may include a concise statement of the reasons for denying the request for inspection or copying.

(f) Inspection and Copying of Segregable Portion.—A person described in subsection (a) or (b) shall permit the inspection and copying of any reasonably segregable portion of a record after deletion of any portion that is exempt under subsection (c).

(g) Deadline.—A person described in subsection (a) or (b) shall comply with or deny, in accordance with subsection (d), a request for inspection or copying of protected health information under this section not later than 60 days after the date on which the person receives the request.

(h) Rules of Construction.—

(1) Agents.—An agent of a person described in subsection (a) or (b) shall not be required to provide for the inspection and copying of protected health information, except where—

(A) the protected health information is retained by the agent; and
(B) the agent has been asked in writing by
the person involved to fulfill the requirements of
this section.

(2) No requirement for hearing.—This
section shall not be construed to require a person
described in subsection (a) or (b) to conduct a for-
mal, informal, or other hearing or proceeding con-
cerning a request for inspection or copying of pro-
tected health information.

SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-
TION.

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

(1) make the amendment requested;

(2) inform the individual of the amendment
that has been made; and
(3) inform any person identified by the individual in the request for amendment and—

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

(B) to whom the unamended portion of the information was disclosed within the previous year by sending a notice to the individual’s last known address that there has been a substantive amendment to the protected health information of such individual.

(b) Special Circumstances.—If an originating provider, its agent, or contractor no longer maintains the protected health information sought to be amended by an individual pursuant to subsection (a), a health plan or another health care provider that maintains such information may arrange for amendment consistent with this section.

(c) Refusal to Amend.—If a person described in subsection (a) refuses to make the amendment requested under such subsection, the person shall inform the individual in writing of—

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

(2) the availability of procedures for further review of the refusal; and
(3) the procedures by which the individual may file with the person a concise statement setting forth the requested amendment and the individual's reasons for disagreeing with the refusal.

(d) **Statement of Disagreement.**—If an individual has filed a statement of disagreement under subsection (c)(3), the person involved, in any subsequent disclosure of the disputed portion of the information—

(1) shall include a notation concerning the individual's statement; and

(2) may include a concise statement of the reasons for not making the requested amendment.

(e) **Rules Governing Agents.**—The agent of a person described in subsection (a) shall not be required to make amendments to protected health information, except where—

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

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

(f) **Repeated Requests for Amendments.**—If a person described in subsection (a) receives a request for an amendment of information as provided for in such subsection and a statement of disagreement has been filed pursuant to subsection (d), the person shall inform the

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

(g) Rules of Construction.—This section shall not be construed to—

(1) require that a person described in subsection (a) conduct a formal, informal, or other hearing or proceeding concerning a request for an amendment to protected health information;

(2) require a provider to amend an individual’s protected health information as to the type, duration, or quality of treatment the individual believes he or she should have been provided; or

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

SEC. 103. NOTICE OF CONFIDENTIALITY PRACTICES.

(a) Preparation of Written Notice.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, school, or university shall post or provide, in writing and in a clear and conspicuous manner, notice of the person’s confidentiality practices, that shall include—

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

(2) the uses and disclosures of protected health information authorized under this Act;
(3) the procedures for authorizing disclosures of protected health information and for revoking such authorizations;

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

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

(b) Model Notice.—The Secretary, after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices, using the advice of the National Committee on Vital Health Statistics, for use under this section. Use of the model notice shall serve as an absolute defense against claims of receiving inappropriate notice.

Subtitle B—Establishment of Safeguards

SEC. 111. ESTABLISHMENT OF SAFEGUARDS.

(a) In General.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of protected health information created, re-
received, obtained, maintained, used, transmitted, or disposed of by such person.

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

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

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

(3) The categories of personnel who will have access to protected health information and appropriate training, supervision and sanctioning of such persons with respect to their use of protected health information and adherence to established safeguards.

(4) Appropriate limitations on access to individual identifiers.

(5) Appropriate mechanism for limiting disclosures to the protected health information necessary to respond to the request for disclosure.

(6) Procedures for handling requests for protected health information by persons other than the individual who is the subject of such information, in-
including but not limited to relatives and affiliates of such individual, law enforcement officials, parties in civil litigation, health care providers, and health plans.

SEC. 112. ACCOUNTING FOR DISCLOSURES.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university shall establish and maintain a process for documenting its disclosures of protected health information by recording the name and address or other means of contacting the recipient, and the purpose of the disclosure.

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

(c) IDENTIFICATION OF DISCLOSED INFORMATION AS PROTECTED HEALTH INFORMATION.—Except as otherwise provided in this title, protected health information shall be clearly identified as protected health information that is subject to this Act.
TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

SEC. 201. GENERAL RULES REGARDING USE AND DISCLOSURE.

(a) Disclosure Prohibited.—A health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university, or any of their agents may not disclose protected health information except as authorized under this Act or as authorized by the individual who is the subject of such information.

(b) Applicability to Agents.—A person described in subsection (a) may use an agent, including a contractor, to carry out an otherwise lawful activity using protected health information maintained by such person, provided that the person specifies the activities for which the agent is authorized and prohibits the agent from using or disclosing protected health information for purposes other than carrying out the specified activities.

(1) Notwithstanding any other provision of this Act, a person who has limited the activities of an agent as provided in this subsection, shall not be liable for the actions or disclosures of the agent that are not in fulfillment of the agent’s specified activities.
(2) An agent who receives protected health information from a person described in subsection (a) shall in its own right be subject to the applicable provisions of this Act.

(c) Creation of Nonidentifiable Health Information.—A person described in subsection (a) may use protected health information for the purpose of creating nonidentifiable health information.

(d) Individual Authorization.—To be valid, an authorization to disclose protected health information under this title shall—

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

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

(3) identify the type of person to whom the information is to be disclosed;

(4) describe the purpose of the disclosure;

(5) be subject to revocation by the individual and indicate that the authorization is valid until revocation by the individual; and

(6) be in writing, dated, and signed by the individual, a family member or other authorized representative.
(c) MANIPULATION OF NONIDENTIFIABLE HEALTH INFORMATION.—Any person who manipulates nonidentifiable health information in order to identify an individual, or uses a key to identify an individual without authorization, is deemed to have disclosed protected health information.

SEC. 202. GENERAL RULES REGARDING USE AND DISCLOSURE OF HEALTH CARE INFORMATION.

(a) IN GENERAL.—An individual who furnishes protected health information in the context of obtaining health care or health care benefits has a justifiable expectation that such information will not be misused and that its confidentiality will be maintained. Protected health information in possession or control of a health care provider or health plan shall be available—

(1) for use by a health plan or a health care provider in furnishing health care to an individual who is the subject of such information, including arrangements for treatment, payment, and health care operations; and

(2) for use in health research that is not inconsistent with the requirements of other applicable Federal laws.

(3) LIMITATION.—For purposes of subsection (b), use of protected health information in activities
described in this subsection is not a disclosure of such information by persons lawfully engaged in such activities.

(b) Prohibition.—A health care provider, health plan, health oversight agency, public health authority, employer, health or life insurer, health researcher, law enforcement official, school, or university may not disclose protected health information except as authorized under this title.

(1) Rules of construction.—

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

(B) Arrangements by a person and its agents for carrying out an authorized use of protected health information, including uses authorized under subsection (a), shall not be considered disclosures for purposes of this Act, provided that the use is consistent with the purposes for which the information was lawfully obtained by such person.

(C) Nothing in this title shall be construed to require disclosure by a health care provider or a health plan.
(2) Disclosure by agents.—An agent who receives protected health information from a person described in subsection (b) shall be subject to all rules of disclosure and safeguard requirements under this title.

(c) Scope of disclosure.—Every disclosure of protected health information by a person under this title shall be limited to the information necessary to accomplish the purpose for which the information is disclosed.

(d) Identification of disclosed information as protected health information.—Except as otherwise provided in this title, protected health information may not be disclosed unless such information is clearly identified as protected health information that is subject to this Act.

(e) Creation of nonidentifiable health information.—A person described in subsection (b) may use protected health information for the purpose of creating nonidentifiable health information, if the person prohibits the employee or agent creating the nonidentifiable health information from using or disclosing the protected health information for purposes other than the sole purpose of creating nonidentifiable health information as specified by the person.
(f) Disclosure Using the Key.—Any person who manipulates nonidentifiable health information in order to identity an individual, without lawfully using the key, is deemed to have disclosed protected health information.

SEC. 203. Authorizations for Use or Disclosure of Protected Health Information Other Than for Treatment, Payment, Health Care Operations, or Health Research.

(a) In General.—An individual who is the subject of protected health information may authorize any person to disclose or use such information for any purpose. An authorization under this section is not valid if its signing by the individual is a prerequisite for signing an authorization under section 202.

(b) Written Authorizations.—A person may disclose and use protected health information, for purposes other than those authorized under section 202, pursuant to a written authorization signed by the individual who is the subject of the information that meets the requirements of section 201(d). An authorization under this section shall be separate from any authorization provided under section 202.

(e) Limitation on Authorizations.—Notwithstanding any other provision of Federal law, life insurers, and other entities issuing disability income or long-term
care insurance under the laws of any State, shall meet
the requirements of section 201(a) with respect to an indi-
vidual for purposes of life, disability income or long-term
care insurance, by obtaining authorization of such indi-
vidual under this section 203.

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

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

(d) Revocation or Amendment of Authoriza-
tion.—

(1) In general.—Except as otherwise pro-
vided in this section, an individual may revoke or
amend an authorization described in this section by
providing written notice to the person who obtained
such authorization unless the disclosure that is the
subject of the authorization is related to the evaluation of an application for life insurance coverage or a claim for life insurance benefits.

(2) **NOTICE OF REVOCATION.**—A person that discloses protected health information pursuant to an authorization that has been revoked under paragraph (1) shall not be subject to any liability or penalty under this title if that person had no actual notice of the revocation.

(e) **DISCLOSURE FOR PURPOSE ONLY.**—A recipient of protected health information pursuant to an authorization under section 203(b) may disclose such information only to carry out the purposes for which the information was authorized to be disclosed.

(f) **MODEL AUTHORIZATIONS.**—

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

(2) Notwithstanding paragraph (1), the insurance commissioner of the State of domicile of a life insurer may exercise exclusive authority in devel-
oping and disseminating model written authoriza-

tions for purposes of subsection (e).

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

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

SEC. 204. NEXT OF KIN AND DIRECTORY INFORMATION.

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

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

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

(B) is in a physical or mental condition
such that the individual is not capable of object-
ing, and there are no prior indications that the
individual would object;
(2) the information disclosed relates to health care currently being provided to that individual; and

(3) the disclosure of the protected health information is consistent with good medical or professional practice.

(b) DIRECTORY INFORMATION.—

(1) Disclosure.—

(A) In general.—Except as provided in paragraph (2), a person described in subsection (a) may disclose the information described in subparagraph (B) to any person if the individual who is the subject of the information—

(i) has been notified of the individual’s right to object and the individual has not objected to the disclosure; or

(ii) is in a physical or mental condition such that the individual is not capable of objecting, the individual’s next of kin has not objected, and there are no prior indications that the individual would object.

(B) Information.—Information described in this subparagraph is information that consists only of 1 or more of the following items:

(i) The name of the individual who is the subject of the information.
(ii) The general health status of the individual, described as critical, poor, fair, stable, or satisfactory or in terms denoting similar conditions.

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

(2) EXCEPTION.—

(A) LOCATION.—Paragraph (1)(B)(iii) shall not apply if disclosure of the location of the individual would reveal specific information about the physical or mental condition of the individual, unless the individual expressly authorizes such disclosure.

(B) DIRECTORY OR NEXT OF KIN INFORMATION.—A disclosure may not be made under this section if the health care provider involved has reason to believe that the disclosure of directory or next of kin information could lead to the physical or mental harm of the individual, unless the individual expressly authorizes such disclosure.

SEC. 205. EMERGENCY CIRCUMSTANCES.

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

SEC. 206. OVERSIGHT.

(a) In General.—Any person may disclose pro-
tected health information to an accrediting body or public
health authority, a health oversight agency, or a State ins-
surance department, for purposes of an oversight function
authorized by law.

(b) Protection From Further Disclosure.—
Protected health information disclosed under this section
shall not be further disclosed by an accrediting body or
public health authority, a health oversight agency, a State
insurance department, or their agents for any purpose un-
related to the authorized oversight function. Notwith-
standing any other provision of law, protected health in-
formation disclosed under this section shall be protected
from further disclosure by an accrediting body or public
health authority, a health oversight agency, a State insur-
ance department, or their agents pursuant to a subpoena,
discovery request, introduction as evidence, testimony, or
otherwise.
(c) Authorization by a Supervisor.—For purposes of this section, the individual with authority to authorize the oversight function involved shall provide to the person described in subsection (a) a statement that the protected health information is being sought for a legally authorized oversight function.

(d) Use in Action Against Individuals.—Protected health information about an individual that is disclosed under this section may not be used by the recipient in, or disclosed by the recipient to any person for use in, an administrative, civil, or criminal action or investigation directed against the individual who is the subject of the protected health information unless the action or investigation arises out of and is directly related to—

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

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

SEC. 207. PUBLIC HEALTH.

(a) In General.—A health care provider, health plan, public health authority, health researcher, employer, life insurer, law enforcement official, school, or university may disclose protected health information to a public
health authority or other person authorized by law for use
in a legally authorized—

(1) disease or injury report;

(2) public health surveillance;

(3) public health investigation or intervention;

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

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

(6) report of information concerning a commu-
nicable disease status.

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

(e) REQUIREMENT TO RELEASE PROTECTED
HEALTH INFORMATION TO CORONERS AND MEDICAL
EXAMINERS.—

(1) IN GENERAL.—When a Coroner or Medical
Examiner or their duly appointed deputies seek pro-
tected health information for the purpose of inquiry
into and determination of, the cause, manner, and
circumstances of a death, the health care provider,
health plan, health oversight agency, public health
authority, employer, life insurer, health researcher,
law enforcement official, school, or university involved shall provide the protected health information to the Coroner or Medical Examiner or to the duly appointed deputies without undue delay.

(2) Production of Additional Information.—If a Coroner or Medical Examiner or their duly appointed deputies receives health information from a person referred to in paragraph (1), such health information shall remain as protected health information unless the health information is attached to or otherwise made a part of a Coroner’s or Medical Examiner’s official report, in which case it shall no longer be protected.

(3) Exemption.—Health information attached to or otherwise made a part of a Coroner’s or Medical Examiner’s official report, shall be exempt from the provisions of this Act.

SEC. 208. HEALTH RESEARCH.

(a) In General.—A person lawfully in possession of protected health information may disclose such information to a health researcher under any of the following arrangements:

(1) Research Governed by the Common Rule.—A person identified in subsection (a) may disclose protected health information to a health re-
searcher if the research project has been approved by an institutional review board pursuant to the requirements of the common rule as implemented by a Federal agency.

(2) **Analyses of Health Care Records and Medical Archives.**—A person identified in subsection (a) may disclose protected health information to a health researcher if—

(A) consistent with the safeguards established pursuant to section 111 and the person’s policies and procedures established under this section, the health research has been reviewed by a board, committee, or other group formally designated by such person to review research programs;

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

(C) the person that maintains the protected health information to be used in the analyses has in place a written policy and procedure to assure the security and confidentiality of protected health information and to specify permissible and impermissible uses of such information for health research;
(D) the person that maintains the protected health information to be used in the analyses enters into a written agreement with the recipient health researcher that specifies the permissible and impermissible uses of the protected health information and provides notice to the researcher that any misuse or further disclosure of the information to other persons is prohibited and may provide a basis for action against the health researcher under this Act; and

(E) the person keeps a record of health researchers to whom protected health information has been disclosed.

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

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

(c) Statutory Assurance of Confidentiality.—

(1) Protected health information obtained by a
health researcher pursuant to this section shall be
used and maintained in confidence, consistent with
the confidentiality practices established by the health
researcher pursuant to section 111.

(2) A recipient health researcher may not be
compelled in any Federal, State, or local civil, crimi-
nal, administrative, legislative, or other proceeding
to disclose protected health information created,
maintained or received under this section, provided
that nothing in this paragraph shall be construed to
prevent an audit or lawful investigation pursuant to
the authority of a Federal department or agency, of
a research project conducted, supported or subject to
regulation by such department or agency.

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

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

(a) In General.—A health care provider, health
plan, public health authority, employer, life insurer, law
enforcement official, school, or university may disclose
protected health information—

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

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

(b) Court Orders.—

(1) Standard for Issuance.—In considering
a request for a court order regarding the disclosure
of protected health information under subsection (a),
the court shall issue such order if the court determines that without the disclosure of such information, the person requesting the order would be impaired from establishing a claim or defense.

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

(A) provide that the protected health information involved is subject to court protection;

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

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

(D) meet any other requirements that the court determines are needed to protect the confidentiality of the information.

(e) APPLICABILITY.—This section shall not apply in a case in which the protected health information sought under such discovery request or subpoena relates to a party to the litigation or an individual whose medical condition is at issue.

(d) EFFECT OF SECTION.—This section shall not be construed to supersede any grounds that may apply under Federal or State law for objecting to turning over the protected health information.
SEC. 210. DISCLOSURE FOR LAW ENFORCEMENT PURPOSES.

(a) Disclosure.—

(1) In general.—A person who receives protected health information pursuant to sections 202 through 207, may disclose such information to a State or Federal law enforcement agency if such disclosure is pursuant to—

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

(B) an administrative subpoena or summons or a judicial subpoena or warrant if the determination described in paragraph (2) has been made;

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

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

(E) a written consent or waiver of privilege by an individual allowing access to the individual’s protected health information; or

(F) by other court order if the determination described in paragraph (2) has been made.
(2) Higher standard for disclosure of certain information.—The determination under this paragraph is a determination, by the court or administrative body issuing the subpoena, summons, warrant, or order involved, that the need of the person requesting the disclosure for the information substantially outweighs the privacy interest of each individual whose health or health care is the subject of the information.

(b) Redactions.—To the extent practicable and consistent with the requirements of due process, in the case of information disclosed under subsection (a) the State or Federal law enforcement agency to which the information is disclosed shall react personal identifiers from protected health information prior to the public disclosure of such information in a judicial or administrative proceeding.

(c) Use of Information.—Protected health information obtained by a State or Federal law enforcement agency under subsection (a) may only be used for purposes of a legitimate law enforcement activity.

(d) Exception in Exigent Circumstances.—Subsection (a) shall not be construed to limit or restrict the ability of State or Federal law enforcement agencies to
gain protected health information if exigent circumstances exist.

SEC. 211. PAYMENT CARD AND ELECTRONIC PAYMENT TRANSACTION.

(a) Payment for Health Care Through Card or Electronic Means.—If an individual pays for health care by presenting a debit, credit, or other payment card or account number, or by any other payment means, the person receiving the payment may disclose to a person described in subsection (b) only such protected health information about the individual as is necessary in connection with activities described in subsection (b), including the processing of the payment transaction or the billing or collection of amounts charged to, debited from, or otherwise paid by, the individual using the card, number, or other means.

(b) Transaction Processing.—A person who is a debit, credit, or other payment card issuer, a payment system operator, a financial institution participant in a payment system or is an entity assisting such an issuer, operator, or participant in connection with activities described in this subsection, may use or disclose protected health information about an individual in connection with—

(1) the authorization, settlement, billing, processing, clearing, transferring, reconciling, or collect-
tion of amounts charged, debited or otherwise paid
using a debit, credit, or other payment card or ac-
count number, or by other payment means;

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

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

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

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

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

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

(d) Scope.—

(1) In general.—The use of protected health information by a person described in subsection (b) and its agents shall not be considered a disclosure for purposes of this Act, so long as the use involved is consistent with the activities authorized in subsection (b) or other purposes for which the information was lawfully obtained.

(2) Regulated institutions.—A person who is subject to enforcement pursuant to section 8 of the Federal Deposit Insurance Act or who is a Federal credit union or State credit union as defined in the Federal Credit Union Act or who is registered pursuant to the Securities and Exchange Act, or who is an entity assisting such a person—

(A) shall not be subject to this Act to the extent that such person or entity is described in subsection (b) and to the extent that such person or entity is engaged in activities authorized in that subsection; and

(B) shall be subject to enforcement exclusively under section 8 of the Federal Deposit Insurance Act, the Federal Credit Union Act,
or the Securities and Exchange Act, as applicable, to the extent that such person or entity is engaged in activities other than those permitted under subsection (b).

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be deemed to exempt entities described in paragraph (2) from the prohibition set forth in subsection (c).

SEC. 212. INDIVIDUAL REPRESENTATIVES.

(a) IN GENERAL.—Except as provided in subsections (b) and (c), a person who is authorized by law (based on grounds other than the individual being a minor), or by an instrument recognized under law, to act as an agent, attorney, proxy, or other legal representative of a protected individual, may, to the extent so authorized, exercise and discharge the rights of the individual under this Act.

(b) HEALTH CARE POWER OF ATTORNEY.—A person who is authorized by law (based on grounds other than being a minor), or by an instrument recognized under law, to make decisions about the provision of health care to an individual who is incapacitated, may exercise and discharge the rights of the individual under this Act to the extent necessary to effectuate the terms or purposes of the grant of authority.
(c) No Court Declaration.—If a health care provider determines that an individual, who has not been declared to be legally incompetent, suffers from a medical condition that prevents the individual from acting knowingly or effectively on the individual’s own behalf, the right of the individual to authorize disclosure under this Act may be exercised and discharged in the best interest of the individual by—

(1) a person described in subsection (b) with respect to the individual;

(2) a person described in subsection (a) with respect to the individual, but only if a person described in paragraph (1) cannot be contacted after a reasonable effort;

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

(4) the health care provider, but only if a person described in paragraph (1), (2), or

(5) cannot be contacted after a reasonable effort.

(d) Application to Deceased Individuals.—The provisions of this Act shall continue to prevent disclosure of protected health information concerning a deceased individual.
(c) Exercise of Rights on Behalf of a Deceased Individual.—

(1) In General.—A person who is authorized by law or by an instrument recognized under law, to act as an executor of the estate of a deceased individual, or otherwise to exercise the rights of the deceased individual, may, to the extent so authorized, exercise and discharge the rights of such deceased individual under this Act for a period of 2 years following the death of such individual. If no such designee has been authorized, the rights of the deceased individual may be exercised as provided for in subsection (c).

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

(f) Rights of Minors.—The rights of minors under this Act shall be exercised by a parent, the minor or other person as provided under applicable state law.

SEC. 213. NO LIABILITY FOR PERMISSIBLE DISCLOSURES.

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

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

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

(b) No Further Disclosure.—A person or per-
sons who receive protected health information under this
section shall make no further use or disclosure of such
information unless otherwise authorized under this Act.

TITLE III—SANCTIONS
Subtitle A—Criminal Provisions

SEC. 301. WRONGFUL DISCLOSURE OF PROTECTED
HEALTH INFORMATION.

(a) In General.—Part I of title 18, United States
Code, is amended by adding at the end the following:
"CHAPTER 124—WRONGFUL DISCLOSURE
OF PROTECTED HEALTH INFORMATION

§ 2801. Wrongful disclosure of protected health information

(a) Offense.—The penalties described in subsection (b) shall apply to a person that knowingly and intentionally—

"(1) obtains protected health information relating to an individual from a health care provider, health plan, health oversight agency, public health authority, employer, life insurer, health researcher, law enforcement official, school, or university except as provided in title II of the Medical Information Protection Act of 2001; or

"(2) discloses protected health information to another person in a manner other than that which is permitted under title II of the Medical Information Protection Act of 2001.

(b) Penalties.—A person described in subsection (a) shall—

"(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

"(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; or
“(3) if the offense is committed with the intent to sell, transfer, or use protected health information for monetary gain or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

“(c) Subsequent Offenses.—In the case of a person described in subsection (a), the maximum penalties described in subsection (b) shall be doubled for every subsequent conviction for an offense arising out of a violation or violations related to a set of circumstances that are different from those involved in the previous violation or set of related violations described in such subsection (a).”.

(b) Clerical Amendment.—The table of chapters for part I of title 18, United States Code, is amended by inserting after the item relating to chapter 123 the following new item:

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

Subtitle B—Civil Sanctions

SEC. 311. CIVIL PENALTY VIOLATION.

A person who the Secretary, in consultation with the Attorney General, determines has substantially and materially failed to comply with this Act shall be subject, in addition to any other penalties that may be prescribed by law—

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

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

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

SEC. 312. PROCEDURES FOR IMPOSITION OF PENALTIES.

(a) INITIATION OF PROCEEDINGS.—

(1) IN GENERAL.—The Secretary, in consultation with the Attorney General, may initiate a proceeding to determine whether to impose a civil money penalty under section 311. The Secretary may not initiate an action under this section with respect to any violation described in section 311 after the expiration of the 6-year period beginning on the date on which such violation was alleged to have occurred. The Secretary may initiate an action under this section by serving notice of the action in any
manner authorized by Rule 4 of the Federal Rules
of Civil Procedure.

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

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

(A) in the case of refusal to provide or per-
mit discovery, drawing negative factual infer-
ences or treating such refusal as an admission
by deeming the matter, or certain facts, to be
established;
(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

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

(D) staying the proceedings;

(E) dismissal of the action;

(F) entering a default judgment;

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

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(b) Scope of Penalty.—In determining the amount or scope of any penalty imposed pursuant to section 311, the Secretary shall take into account—

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

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims;

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

(4) such other matters as justice may require.
(c) **Review of Determination.**

(1) **In General.**—Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim was presented, by filing in such court (within 60 days following the date the person is notified of the determination of the Secretary) a written petition requesting that the determination be modified or set aside.

(2) **Filing of Record.**—A copy of the petition filed under paragraph (1) shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court the record in the proceeding as provided in section 2112 of title 28, United States Code. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary.
and enforcing the same to the extent that such order is affirmed or modified.

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

(4) FINDINGS.—The findings of the Secretary with respect to questions of fact in an action under this subsection, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and shall file with the court such modified or new findings, and such findings with respect to questions of fact, if supported by substan-
tial evidence on the record considered as a whole, and the recommendations of the Secretary, if any, for the modification or setting aside of the original order, shall be conclusive.

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

(d) RECOVERY OF PENALTIES.—

(1) IN GENERAL.—Civil money penalties imposed under this subtitle may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim was presented, or where the claimant resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and deposited as miscellaneous receipts of the Treasury of the United States.

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

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

(f) SUBPOENA AUTHORITY.—

(1) IN GENERAL.—For the purpose of any hearing, investigation, or other proceeding authorized or directed under this section, or relative to any other matter within the jurisdiction of the Attorney General hereunder, the Attorney General, acting through the Secretary shall have the power to issue subpoenas requiring the attendance and testimony of witnesses and the production of any evidence that relates to any matter under investigation or in question before the Secretary. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other pro-
ceeding may be required from any place in the
United States or in any Territory or possession
thereof.

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

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

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

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

(g) INJUNCTIVE RELIEF.—Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under section 311, the Secretary may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

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

SEC. 313. ENFORCEMENT BY STATE INSURANCE COMMISSIONERS.

(a) State Penalties.—Subject to section 401, and notwithstanding any other provision of this title, a state insurance commissioner of the State of domicile of a life insurer may exercise exclusive authority to impose any penalties on a life insurer for violations of this Act pursuant to the administrative procedures provided under that State’s insurance laws.
(b) Fail-Safe Federal Authority.—In the case of a State that fails to substantially enforce the requirements of Title I and Title II of this Act with respect to life insurers regulated by such State, the provisions of this title shall apply with respect to a life insurer in the same way that they apply to other persons subject to the Act.

TITLE IV—MISCELLANEOUS

SEC. 401. RELATIONSHIP TO OTHER LAWS.

(a) State and Federal Law.—Except as provided in this section—

(1) the provisions of this Act shall preempt any State law that relates to matters covered by this Act;

(2) this Act shall not be construed to preempt, modify, repeal, or affect the interpretation of a provision of State or Federal law that relates to the disclosure of protected health information or any other information about a minor to a parent or guardian of such minor; and

(3) this Act shall not be construed as repealing, explicitly or implicitly, other Federal laws or regulations relating to protected health information or relating to an individual’s access to protected health information or health care services.
(b) Relationship to Other Regulations.—This Act is legislation described in section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 2033) and the regulations issued under such section as of December 28, 2000, shall be of no effect.

(c) Privileges.—Nothing in this Act shall be construed to preempt or modify any provisions of State statutory or common law to the extent that such law concerns a privilege of a witness or person in a court of that State. This Act shall not be construed to supersede or modify any provision of Federal statutory or common law to the extent such law concerns a privilege of a witness or person in a court of the United States. Authorizations pursuant to sections 202 and 203 shall not be construed as a waiver of any such privilege.

(d) Reports Concerning Federal Privacy Act.—Not later than 1 year after the date of the enactment of this Act, the head of each Federal agency shall prepare and submit to Congress a report concerning the effect of this Act on each such agency. Such reports shall include recommendations for legislation to address concerns relating to the Federal Privacy Act.

(e) Application to Certain Federal Agencies.—
(1) DEPARTMENT OF DEFENSE.—

(A) EXCEPTIONS.—The Secretary of Defense may, by regulation, establish exceptions to the disclosure requirements of this Act to the extent such Secretary determines that disclosure of protected health information relating to members of the armed forces from systems of records operated by the Department of Defense is necessary under circumstances different from those permitted under this Act for the proper conduct of national defense functions by members of the armed forces.

(B) APPLICATION TO CIVILIAN EMPLOYEES.—The Secretary of Defense may, by regulation, establish for civilian employees of the Department of Defense and employees of Department of Defense contractors, limitations on the right of such persons to revoke or amend authorizations for disclosures under section 203 when such authorizations were provided by such employees as a condition of employment and the disclosure is determined necessary by the Secretary of Defense to the proper conduct of national defense functions by such employees.

(2) DEPARTMENT OF TRANSPORTATION.—
(A) **Exceptions.**—The Secretary of Transportation may, with respect to members of the Coast Guard, exercise the same powers as the Secretary of Defense may exercise under paragraph (1)(A).

(B) **Application to Civilian Employees.**—The Secretary of Transportation may, with respect to civilian employees of the Coast Guard and Coast Guard contractors, exercise the same powers as the Secretary of Defense may exercise under paragraph (1)(B).

(3) **Department of Veterans Affairs.**—The limitations on use and disclosure of protected health information under this Act shall not be construed to prevent any exchange of such information within and among components of the Department of Veterans Affairs that determine eligibility for or entitlement to, or that provide, benefits under laws administered by the Secretary of Veteran Affairs.

**SEC. 402. CONFORMING AMENDMENT.**

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

“(6) **Individually Identifiable Health Information.**—The term ‘individually identifiable health information’ has the same meaning given the
term ‘protected health information’ by section 2 of the Medical Information Protection Act of 2001.’’.

SEC. 403. STUDY BY INSTITUTE OF MEDICINE.

Not later than 2 years after the date of enactment of this Act, the National Research Council in conjunction with the Institute of Medicine of the National Academy of Sciences shall conduct a study to examine research issues relating to protected health information, such as the quality and uniformity of institutional review boards and their practices with respect to data management for both researchers and institutional review boards, as well as current and proposed protection of health information in relation to the legitimate needs of law enforcement. The Council shall prepare and submit to Congress a report concerning the results of such study.

SEC. 404. EFFECTIVE DATE.

(a) Effective Date.—Except as provided in subsection (b), this Act shall take effect on the date that is 12 months after the date on which regulations are promulgated as required under subsection (c).

(b) Applicability.—The provisions of this Act shall only apply to protected health information collected and disclosed 12 months after the date on which regulations are promulgated as required under subsection (c).
(c) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, the Secretary shall, in consultation with the National Committee on Vital and Health Statistics, promulgate regulations implementing this Act.

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