To provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health-care-related information, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States’ rights.

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 Privacy and Security Act”.

IN THE SENATE OF THE UNITED STATES

MARCH 10, 1999

Mr. LEAHY (for himself, Mr. KENNEDY, Mr. DASCHLE, and Mr. DORGAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions
(b) **TABLE OF CONTENTS.**—The table of contents for this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Findings.
Sec. 3. Purposes.
Sec. 4. Definitions.

**TITLE I—INDIVIDUALS’ RIGHTS**

Subtitle A—Access to Protected Health Information by Subjects of the Information

Sec. 101. Inspection and copying of protected health information.
Sec. 102. Supplements to protected health information.
Sec. 103. Notice of privacy 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 disclosure of protected health information other than for treatment or payment.
Sec. 204. Emergency circumstances.
Sec. 205. Public health.
Sec. 206. Protection and advocacy agencies.
Sec. 207. Oversight.
Sec. 208. Disclosure for law enforcement purposes.
Sec. 209. Next of kin and directory information.
Sec. 211. Judicial and administrative purposes.
Sec. 212. Individual representatives.
Sec. 213. Prohibition against retaliation.

**TITLE III—OFFICE OF HEALTH INFORMATION PRIVACY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Subtitle A—Designation

Sec. 301. Designation.

Subtitle B—Enforcement

**CHAPTER 1—CRIMINAL PROVISIONS**

Sec. 311. Wrongful disclosure of protected health information.
Sec. 312. Debarment for crimes.

**CHAPTER 2—CIVIL SANCTIONS**

Sec. 321. Civil penalty.
SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Individuals have a right of privacy with respect to their protected health information and records.

(2) With respect to information about medical care and health status, the traditional right of confidentiality (between a health care provider and a patient) is at risk.

(3) An erosion of the right of privacy may reduce the willingness of patients to confide in physicians and other practitioners and may inhibit patients from seeking care.

(4) An individual’s privacy right means that the individual’s consent is needed to disclose his or her protected health information and that the individual has a right of access to that health information.

(5) Any disclosure of protected health information should be limited to that information or portion of the medical record necessary to fulfill the immediate and specific purpose of the disclosure.
(6) Health research often depends on access to both identifiable and de-identified patient health information and health research is critically important to the health and well-being of all people in the United States.

(7) The Supreme Court found in Jaffee v. Redmond (116 S.Ct. 1923 (1996)) that there is an imperative need for confidence and trust between a psychotherapist and a patient and that such trust can only be established by an assurance of confidentiality. This assurance serves the public interest by facilitating the provision of appropriate treatment for individuals.


SEC. 3. PURPOSES.

The purposes of this Act are as follows:

(1) To recognize that there is a right to privacy with respect to health information, including genetic information, and that this right must be protected.
(2) To create incentives to turn protected health information into de-identified health information, where appropriate.

(3) To designate an Office of Health Information Privacy within the Department of Health and Human Services to protect that right of privacy.

(4) To provide individuals with—

(A) access to health information of which they are the subject; and

(B) the opportunity to challenge the accuracy and completeness of such information by being able to file supplements to such information.

(5) To provide individuals with the right to limit the use and disclosure of protected health information.

(6) To establish strong and effective mechanisms to protect against the unauthorized and inappropriate use of protected health information.

(7) To invoke the sweep of congressional powers, including the power to enforce the 14th amendment, to regulate commerce, and to abrogate the immunity of the States under the 11th amendment, in order to address violations of the rights of individuals to privacy, to provide individuals with access to
their health information, and to prevent unauthorized use of protected health information that is genetic information.

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

(9) To protect the rights of States.

SEC. 4. DEFINITIONS.

In this Act:

(1) Administrative billing information.—The term “administrative billing information” means any of the following forms of protected health information:

(A) Date of service, policy, patient identifiers, and practitioner or facility identifiers.

(B) Diagnostic codes, in accordance with medicare billing codes, for which treatment is being rendered or requested.

(C) Complexity of service codes, indicating duration of treatment.

(D) Total billed charges.

(2) Agent.—The term “agent” means a person who represents and acts for another person (a principal) under a contract or relationship of agency, or whose function is to bring about, modify, affect, accept performance of, or terminate, contractual obli-
gations between the principal and a third person.

With respect to an employer, the term includes the employees of the employer.

(3) **De-Identified Health Information.**—

(A) **In General.**—The term “de-identified health information” means any protected health information, with respect to which—

(i) all personal identifiers, or other information that may be used by itself or in combination with other information which may be available to re-identify the subject of the information, have been removed; and

(ii) a good faith effort to evaluate the risks of re-identification of the subject of such information in the context in which it will be used or disclosed, has been made.

(B) **Examples.**—The term includes aggregate statistics, redacted health information, information in which random or fictitious alternatives have been substituted for personally identifiable information, and information in which personally identifiable information has been encrypted and the decryption key is maintained by a person otherwise authorized to have
access to such protected health information in an identifiable format.

(4) DISCLOSE.—The term “disclose” means to release, publish, share, transfer, transmit, disseminate, show, permit access to, re-identify, or otherwise divulge protected health information to any person other than the individual who is the subject of such information. The term includes the initial disclosure and any subsequent redisclosure of protected health information.

(5) DECRYPTION KEY.—The term “decryption key” means the variable information used in or produced by a mathematical formula, code, or algorithm, or any component thereof, used to encrypt or decrypt wire or electronic communications or electronically stored information.

(6) EMPLOYER.—The term “employer” means a person engaged in business affecting commerce who has employees.

(7) ENCRYPTION.—The term “encryption” means the scrambling of electronic or wire communications or electronically stored information using mathematical formulas or algorithms sufficient to preserve the confidentiality, integrity, and authenticity of such communications or information.
(8) **Health care.**—The term "health care" means—

(A) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, including appropriate assistance with disease or symptom management and maintenance, counseling, 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; and

(B) 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, pursuant to a prescription.

(9) **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 or State program that directly provides items or services that constitute health care to beneficiaries; or

(C) an officer or employee or agent of a person described in subparagraph (A) or (B) who is engaged in the provision of health care or who uses health information.

(10) HEALTH OR LIFE INSURER.—The term “health or life insurer” means a health insurance issuer (as defined in section 9805(b)(2) of the Internal Revenue Code of 1986) or a life insurance company (as defined in section 816 of such Code) and includes the employees and agents of such a person.

(11) HEALTH OVERSIGHT AGENCY.—The term “health oversight agency”—

(A) means a person who—

(i) performs or oversees the performance of an assessment, investigation, or prosecution relating to compliance with legal or fiscal standards relating to health
care fraud or fraudulent claims regarding health care, health services or equipment, or related activities and items; and

(ii) is a public executive branch agen-
cy, acting on behalf of a public executive branch agency, acting pursuant to a re-
quirement of a public executive branch agency, or carrying out activities under a Federal or State law governing an assess-
ment, evaluation, determination, investigation, or prosecution described in clause (i);

and

(B) includes the employees and agents of such a person.

(12) HEALTH PLAN.—The term “health plan” means any health insurance plan, including any hospital or medical service plan, dental or other health service plan or health maintenance organization plan, or other program providing or arranging for the provision of health benefits, whether or not fund-
ed through the purchase of insurance. The term in-
cludes employee welfare benefit plans and group plans (as defined in sections 3 and 607 of the Em-
(13) **Health Researcher.**—The term “health researcher” means a person who, with respect to a specific item of protected health information, receives the information—

(A) pursuant to section 210 (relating to health research); or

(B) while acting in whole or in part in the capacity of an officer, employee, or agent of a person who receives the information pursuant to such section.

(14) **Law Enforcement Inquiry.**—The term “law enforcement inquiry” means a lawful executive branch 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.

(15) **Office of Health Information Privacy.**—The term “Office of Health Information Privacy” means the Office of Health Information Privacy designated under section 301.

(16) **Person.**—The term “person” means a government, governmental subdivision of an executive branch agency or authority; corporation; company; association; firm; partnership; society; estate;
(17) PROTECTED HEALTH INFORMATION.—

(A) IN GENERAL.—The term “protected health information” means any information, including genetic information, demographic information, and tissue samples collected from an individual, whether oral or recorded in any form or medium, that—

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

(ii)(I) relates to the past, present, or future physical or mental health or condition of an individual (including individual cells and their components), the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and

(II)(aa) identifies an individual; or

(bb) with respect to which there is a reasonable basis to believe that the infor-
mation can be used to identify an individual; and

(B) Decryption key.—The term “protected health information” includes any information described in paragraph (5).

(18) Public health authority.—The term “public health authority” means an authority or instrumentality of the United States, a tribal government, a State, or a political subdivision of a State that is—

(A) primarily responsible for public health matters; and

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

(19) Re-identify.—The term “re-identify”, when used with respect to de-identified health information, means an attempt, successful or otherwise, to ascertain—

(A) the identity of the individual who is the subject of such information; or

(B) the decryption key with respect to the information (when undertaken with knowledge that such key would allow for the identification
of the individual who is the subject of such inform-

(20) School or University.—The term “school or university” means an institution or place 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 government.

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

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

(23) To the Maximum Extent Practicable.—The term “to the maximum extent practicable” means the level of compliance that a reasonable person would deem technologically feasible so long as such feasibility is periodically evaluated in light of scientific advances.

(24) Writing.—The term “writing” means writing in either a paper-based or computer-based form, including electronic and digital signatures.
TITLE I—INDIVIDUALS’ RIGHTS
Subtitle A—Access to Protected
Health Information by Subjects of the Information

SEC. 101. INSPECTION AND COPYING OF PROTECTED HEALTH INFORMATION.

(a) Right of Individual.—

(1) In general.—A health care provider, health plan, employer, health or life insurer, school, or university, or a person acting as the agent of any such person, shall permit an individual who is the subject of protected health information, or the individual’s designee, to inspect and copy protected health information concerning the individual, including records created under sections 102, 112, 202, 203, 208, and 211, that such person maintains.

(2) Procedures and fees.—A person described in paragraph (1) may set forth appropriate procedures to be followed for inspection and copying under such paragraph and may require an individual to pay fees associated with such inspection and copying in an amount that is not in excess of the actual costs of providing such copying. Such fees may not be assessed where such an assessment would have the effect of inhibiting an individual from gaining
access to the information described in paragraph (1).

(b) DEADLINE.—A person described in subsection (a)(1) shall comply with a request for inspection or copying of protected health information under this section not later than 15 business days after the date on which the person receives the request.

(c) RULES GOVERNING AGENTS.—A person acting as the agent of a person described in subsection (a) shall provide for the inspection and copying of protected health information if—

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

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

(d) SPECIAL RULE RELATING TO ONGOING CLINICAL TRIALS.—With respect to protected health information that is created as part of an individual’s participation in an ongoing clinical trial, access to the information shall be provided consistent with the individual’s agreement to participate in the clinical trial.

SEC. 102. SUPPLEMENTS TO PROTECTED HEALTH INFORMATION.

(a) IN GENERAL.—Not later than 45 days after the date on which a health care provider, health plan, em-
ployer, health or life insurer, school, or university, or a person acting as the agent of any such person, receives from an individual a request in writing to supplement protected health information concerning the individual, such person—

(1) shall add the supplement requested to the information;

(2) shall inform the individual that the supplement has been made; and

(3) shall make reasonable efforts to inform any person to whom the portion of the unsupplemented information was previously disclosed, of any substantive supplement that has been made.

(b) REFUSAL TO SUPPLEMENT.—If a person described in subsection (a) declines to make the supplement requested under such subsection, the person shall inform the individual in writing of—

(1) the reasons for declining to make the supplement;

(2) any procedures for further review of the declining of such supplement; and

(3) the individual’s right to file with the person a concise statement setting forth the requested supplement and the individual’s reasons for disagreeing with the declining person and the individual’s right
to include a copy of this refusal in his or her health record.

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

(1) shall include, at the individual’s request, a copy of the individual’s statement; and

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

(d) Rules Governing Agents.—A person acting as the agent of a person described in subsection (a) shall not be required to make a supplement to protected health information, except where—

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

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

SEC. 103. NOTICE OF PRIVACY PRACTICES.

(a) Preparation of Written Notice.—A health care provider, health plan, health oversight agency, public health authority, employer, health or life insurer, school, or university, or a person acting as the agent of any such person, shall prepare a written notice of the privacy prac-
of the person that provides information with respect
to the following:

(1) The procedures for an individual to author-
ize disclosures of protected health information, and
to object to, modify, and revoke such authorizations.

(2) The right of an individual to inspect, copy,
and supplement the protected health information.

(3) The right of an individual not to have em-
ployment or the receipt of services conditioned upon
the execution by the individual of an authorization
for disclosure.

(4) A description of the categories or types of
employees, by general category or by general job de-
scription, who have access to or use of protected
health information within the person.

(5) A simple, concise description of any infor-
mation systems used to store or transmit protected
health information, including a description of any
linkages made with other electronic systems or data-
bases outside the person.

(6) The right of the individual to request seg-
gregation of protected health information, and to re-
strict the use of such information by employees,
agents, and contractors of a person.
(7) The circumstances under which the information may be used or disclosed without an authorization executed by the individual.

(8) A statement that an individual may elect to pay for health care from the individual’s own funds and information on the right of such an individual to elect for identifying information not to be disclosed to anyone other than health care providers, unless such disclosure is required by mandatory reporting requirements or other similar information collection duties required by law.

(b) Provision and Posting of Written Notice.—

(1) Provision.—A person described in subsection (a) shall provide a copy of the written notice of privacy practices required under such subsection—

(A) at the time an authorization is sought for disclosure of protected health information;

and

(B) upon the request of an individual.

(2) Posting.—A person described in subsection (a) shall post, in a clear and conspicuous manner, a brief summary of the privacy practices of the person.
(c) Model Notice.—The Secretary, in consultation
with the Director of the Office of Health Information Pri-
vacy appointed under section 301, after notice and oppor-
tunity for public comment, shall develop and disseminate
model notices of privacy practices, and model summary
notices for posting, for use under this section. Use of such
a model notice shall be deemed to satisfy the requirements
of this section.

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, em-
ployer, health researcher, law enforcement official, health
or life insurer, school, or university, or a person acting
as the agent of any such person, shall establish and main-
tain appropriate administrative, organizational, technical,
and physical safeguards and procedures to ensure the con-
fidentiality, security, accuracy, and integrity of protected
health information created, received, obtained, main-
tained, used, transmitted, or disposed of by such person.

(b) Factors To Be Considered.—The policies and
safeguards under subsection (a) shall ensure that—

(1) protected health information is used or dis-
closed only when necessary;
(2) the categories of personnel who will have access to protected health information are identified; and

(3) the feasibility of limiting access to protected health information is considered.

(c) MODEL GUIDELINES.—The Secretary, in consultation with the Director of the Office of Health Information Privacy appointed under section 301, after notice and opportunity for public comment, shall develop and disseminate model guidelines for the establishment of safeguards and procedures for use under this section, such as, where appropriate, individual authentication of uses of computer systems, access controls, audit trails, encryption, physical security, protection of remote access points and protection of external electronic communications, periodic security assessments, incident reports, and sanctions. The director shall update and disseminate the guidelines, as appropriate, to take advantage of new technologies.

SEC. 112. ACCOUNTING FOR DISCLOSURES.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university, or a person acting as the agent of any such person, shall establish and maintain, with respect to any protected health information dis-
closure that is not related to payment or treatment, a
record of the disclosure in accordance with regulations
issued by the Secretary in consultation with the Director
of the Office of Health Information Privacy.

(b) MAINTENANCE OF RECORD.—A record estab-
lished under subsection (a) shall be maintained for not less
than 7 years.

(c) ELECTRONIC RECORDS.—A health care provider,
health plan, health oversight agency, public health author-
ity, employer, health researcher, law enforcement official,
health or life insurer, school, or university, or a person
acting as the agent of any such person, shall, to the maxi-
mum extent practicable, maintain an accessible electronic
record concerning each access, or attempt to access, whe-
ther authorized or unauthorized, successful or unsuc-
cessful, protected health information maintained by such
person in electronic form. The record shall include the
identity of the specific individual accessing or attempting
to gain such access (or a way to identify that individual
or information helpful in determining the identity of such
individual), information sufficient to identify the protected
health information sought or accessed, and other appro-
priate information.
TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

SEC. 201. GENERAL RULES REGARDING USE AND DISCLOSURE.

(a) Prohibition.—

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

(2) Rule of Construction.—Disclosure of de-identified health information shall not be construed as a disclosure of protected health information.

(b) Scope of Disclosure.—

(1) In general.—A disclosure of protected health information under this title shall be limited to the minimum amount of information necessary to accomplish the purpose for which the disclosure is made.

(2) Determination.—The determination as to what constitutes the minimum disclosure possible for purposes of paragraph (1) shall be made by a health care provider.
(c) Use or Disclosure for Purpose Only.—A recipient of information pursuant to this title may use or disclose such information solely to carry out the purpose for which the information was disclosed.

(d) No General Requirement To Disclose.—Nothing in this title permitting the disclosure of protected health information shall be construed to require such disclosure.

(e) Identification of Disclosed Information as Protected Health Information.—Protected health information disclosed pursuant to this title shall be clearly identified as protected health information that is subject to this Act.

(f) Disclosure by Agents.—An agent of a person described in subsection (a)(1), who receives protected health information from the person while acting within the scope of the agency, shall be subject to this title to the same extent as the person and for the duration of the period in which the agent holds the information.

(g) Creation of De-Identified Information.—Notwithstanding subsection (e), but subject to the other provisions of this section, a person described in subsection (a)(1) may disclose protected health information to an employee or other agent of the person for purposes of creating de-identified information.
(h) Unauthorized Use or Disclosure of the Decryption Key.—The unauthorized disclosure of a decryption key shall be deemed to be a disclosure of protected health information. The unauthorized use of a decryption key or de-identified health information in order to identify an individual is deemed to be disclosure of protected health information.

(i) No Waiver.—Except as provided in this Act, an authorization to disclose personally identifiable health information executed by an individual pursuant to section 202 or 203 shall not be construed as a waiver of any rights that the individual has under other Federal or State laws, the rules of evidence, or common law.

(j) Definitions.—For purposes of this title:

(1) Investigative or Law Enforcement Officer.—The term “investigative or law enforcement officer” means any officer of the United States or of a State or political subdivision thereof, who is empowered by law to conduct investigations of, or to make arrests for, criminal offenses, and any attorney authorized by law to prosecute or participate in the prosecution of such offenses.

(2) Segregate.—The term “segregate” means to place a designated subset of an individuals protected health information in a location or computer
file that is separate from the location or computer
file used to store protected health information and
where access to or use of any information so seg-
regated may be effectively limited to those persons
who are authorized by the individual to access or use
such information.

(3) Signed.—The term “signed” refers to both
signatures in ink and electronic signatures, and the
term “written” refers to both paper and computer-
ized formats.

SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-
TECTED HEALTH INFORMATION FOR TREAT-
MENT AND PAYMENT.

(a) Requirements Relating to Employers,
Health Plans, Health or Life Insurers, Unin-
sured Individuals, and Providers.—

(1) In general.—To satisfy the requirement
under section 201(a)(1), an employer, health plan,
health or life insurer, or health care provider that
seeks to disclose protected health information in con-
nection with treatment or payment shall obtain an
authorization that satisfies the requirements of this
section. The authorization may be a single author-
ization.
(2) Employers.—Every employer offering a health plan to its employees shall, at the time of an employee’s enrollment in the health plan, obtain a signed, written authorization that is a legal, informed authorization that satisfies the requirements of subsection (b) concerning the use and disclosure of protected health information for treatment or payment with respect to each individual who is eligible to receive care under the health plan.

(3) Health Plans, Health or Life Insurers.—Every health plan or health or life insurer offering enrollment to individual or nonemployer groups shall, at the time of enrollment in the plan or insurance, obtain a signed, written authorization that is a legal, informed authorization that satisfies the requirements of subsection (b) concerning the use and disclosure of protected health information with respect to each individual who is eligible to receive care under the plan or insurance.

(4) Uninsured.—An originating provider providing health care in other than a network plan setting, or providing health care to an uninsured individual, shall obtain a signed, written authorization that satisfies the requirements of subsection (b) to use protected health information in providing health
care or arranging for health care from other providers or seeking payment for the provision of health care services.

(5) PROVIDERS.—

(A) IN GENERAL.—Every health care provider providing health care to an individual who has not given the appropriate authorization under this section shall, at the time of providing such care, obtain a signed, written authorization that is a legal, informed authorization, that satisfies the requirements of subsection (b), concerning the use and disclosure of protected health information with respect to such individual.

(B) RULE OF CONSTRUCTION.—Subparagraph (A) shall not be construed to preclude the provision of health care to an individual who has not given appropriate authorization prior to receipt of such care if—

(i) the health care provider involved determines that such care is essential; and

(ii) the individual can reasonably be expected to sign an authorization for such care when appropriate.
(b) Requirements for Individual Authorization.—To satisfy the requirements of this subsection, an authorization to disclose protected health information—

(1) shall identify, by general job description or other functional description, persons authorized to disclose the information;

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

(3) shall identify, by general job description or other functional description, persons to whom the information is to be disclosed, including individuals employed by, or operating within, an entity to which information is authorized to be disclosed;

(4) shall describe the purpose of the disclosures;

(5) shall permit the executing individual to indicate that a particular individual listed on the authorization is not authorized to receive protected health information concerning the individual, except as provided for in subsection (c)(3);

(6) shall provide the means by which an individual may indicate that some of the individual’s protected health information should be segregated and to what persons such segregated information may be disclosed;
(7) shall be subject to revocation by the individual and indicate that the authorization is valid until revocation by the individual or until an event or date specified; and

(8)(A) shall be—

(i) in writing, dated, and signed by the individual; or

(ii) in electronic form, dated and authenticated by the individual using an authentication method approved by the Secretary; and

(B) shall not have been revoked under subparagraph (A).

(c) LIMITATION ON AUTHORIZATIONS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), a person described in subsection (a) who seeks an authorization under such subsection may not condition the delivery of treatment or payment for services on the receipt of such an authorization.

(2) RIGHT TO REQUIRE SELF PAYMENT.—If an individual has refused to provide an authorization for disclosure of administrative billing information to a person and such authorization is necessary for a health care provider to receive payment for services delivered, the health care provider may require the
individual to pay from their own funds for the services.

(3) Right of health care provider to require authorization for treatment purposes.—If a health care provider that is seeking an authorization for disclosure of an individual’s protected health information believes that the disclosure of such information is necessary so as not to endanger the health or treatment of the individual, the health care provider may condition the provision of services upon the execution of the authorization by the individual.

(d) Model Authorizations.—The Secretary, in consultation with the Director of the Office of Health Information Privacy, after notice and opportunity for public comment, shall develop and disseminate model written authorizations of the type described in this section and model statements of the limitations on authorizations. Any authorization obtained on a model authorization form under section 202 developed by the Secretary pursuant to the preceding sentence shall be deemed to satisfy the requirements of this section.

(e) Segregation of Files.—A person described in subsection (a)(1) shall comply, to the maximum extent
practicable, with the request of an individual who is the
subject of protected health information—

(1) to segregate any type or amount of pro-
tected health information, other than administrative
billing information, held by the entity; and

(2) to limit the use or disclosure of the seg-
regated health information within the entity to those
persons specifically designated by the subject of the
protected health information.

(f) Revocation of Authorization.—

(1) In general.—An individual may in writing
revoke or amend an authorization under this section
at any time, unless the disclosure that is the subject
of the authorization is required to effectuate pay-
ment for health care that has been provided to the
individual.

(2) Health plans.—With respect to a health
plan, the authorization of an individual is deemed to
be revoked at the time of the cancellation or non-re-
newal of enrollment in the health plan, except as
may be necessary to complete plan administration
and payment requirements related to the individual’s
period of enrollment.
(3) Actions.—An individual may not maintain an action against a person for disclosure of personally identifiable health information—

(A) if the disclosure was made based on a good faith reliance on the individual’s authorization under this section at the time disclosure was made;

(B) in a case in which the authorization is revoked, if the disclosing person had no actual or constructive notice of the revocation; or

(C) if the disclosure was for the purpose of protecting another individual from imminent physical harm, and is authorized under section 204.

(g) Record of Individual’s Authorizations and Revocations.—Each person collecting or storing personally identifiable health information shall maintain a record for a period of 7 years of each authorization of an individual and any revocation thereof, and such record shall become part of the personally identifiable health information concerning such individual.

(h) Rule of Construction.—Authorizations for the disclosure of protected health information for treatment or payment shall not authorize the disclosure of such information by an individual with the intent to sell, trans-
fer, or use protected health information for commercial adva-
vantage other than the revenues directly derived from the
provision of health care to that individual. For such disclo-
sures, a separate authorization that satisfies the require-
ments of section 203 is required.

SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-
TECTED HEALTH INFORMATION OTHER THAN
FOR TREATMENT OR PAYMENT.

(a) In General.—To satisfy the requirement under
section 201(a)(1), a health care provider, health plan,
health oversight agency, public health authority, employer,
health researcher, law enforcement official, health or life
insurer, school, or university that seeks to disclose pro-
tected health information for a purpose other than treat-
ment or payment may obtain an authorization that satis-
fies the requirements of subsections (b) and (g) of section
202. Such an authorization under this section shall be sep-
arate from an authorization provided under section 202.

(b) Limitation on Authorizations.—

(1) In General.—A person subject to section
202 may not condition the delivery of treatment, or
payment for services, on the receipt of an authoriza-
tion described in this section.

(2) Requirement for separate authoriza-
tion.—A person subject to section 202 may not dis-
close protected health information to any employees
or agents who are responsible for making employ-
ment, work assignment, or other personnel decisions
with respect to the subject of the information with-
out a separate authorization permitting such a dis-
closure.

(c) Model Authorizations.—The Secretary, in
consultation with the Director of the Office of Health In-
formation Privacy, after notice and opportunity for public
comment, shall develop and disseminate model written au-
thorizations of the type described in subsection (a). Any
authorization obtained on a model authorization form
under this section developed by the Secretary shall be
deemed to meet the authorization requirements of this sec-
tion.

(d) Requirement To Release Protected
Health Information to Coroners and Medical Ex-
aminers.—

(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 an individual’s death, the health
care provider, health plan, health oversight agency,
public health authority, employer, health researcher,
law enforcement officer, health or life insurer, school
or university involved shall provide that individual’s
protected health information to the Coroner or Medi-
cal Examiner or to the duly appointed deputies with-
out undue delay.

(2) Production of additional information.—If a Coroner or Medical Examiner or their
duly appointed deputies receives health information
from an entity referred to in paragraph (1), such
health information shall remain as protected health
information unless the health information is at-
tached 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 Medi-
cal Examiner’s official report, shall be exempt from
the provisions of this Act except as provided for in
this subsection.

(4) Reimbursement.—A Coroner or Medical
Examiner may require a person to reimburse their
Office for the reasonable costs associated with such
inspection or copying.
(e) Revocation or Amendment of Authorization.—An individual may, in writing, revoke or amend an authorization under this section at any time.

(f) Actions.—An individual may not maintain an action against a person for disclosure of protected health information—

(1) if the disclosure was made based on a good faith reliance on the individual’s authorization under this section at the time disclosure was made;

(2) in a case in which the authorization is revoked, if the disclosing person had no actual or constructive notice of the revocation; or

(3) if the disclosure was for the purpose of protecting another individual from imminent physical harm, and is authorized under section 204.

SEC. 204. EMERGENCY CIRCUMSTANCES.

(a) General Rule.—In the event of a threat of imminent physical or mental harm to the subject of protected health information, any person may, in order to allay or remedy such threat, disclose protected health information about such subject to a health care practitioner, health care facility, law enforcement authority, or emergency medical personnel.
(b) HARM TO OTHERS.—Any person may disclose protected health information about the subject of the information where—

(1) such subject has made an identifiable threat of serious injury or death with respect to an identifiable individual or group of individuals;

(2) the subject has the ability to carry out such threat; and

(3) the release of such information is necessary to prevent or significantly reduce the possibility of such threat being carried out.

SEC. 205. PUBLIC HEALTH.

(a) IN GENERAL.—A health care provider, health plan, public health authority, employer, health or life insurer, law enforcement official, school, or university may disclose protected health information to a public health authority or other person authorized by public health law when receipt of such information by the authority or other person—

(1) relates directly to a specified public health purpose;

(2) is reasonably likely to achieve such purpose; and
(3) is intended for a purpose that cannot be achieved through the receipt or use of de-identified health information.

(b) Public Health Purpose Defined.—For purposes of subsection (a), the term “public health purpose” means a population-based activity or individual effort, authorized by law, aimed at the prevention of injury, disease, or premature mortality, or the promotion of health, in a community, including—

(1) assessing the health needs and status of the community through public health surveillance and epidemiological research;

(2) developing public health policy;

(3) responding to public health needs and emergencies; and

(4) any other activities or efforts authorized by law.

SEC. 206. PROTECTION AND ADVOCACY AGENCIES.

Any person who creates protected health information or receives protected health information under this title may disclose that information to a protection and advocacy agency established under part C of title I of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.) or under the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C.
is probable cause to believe that an individual who is the subject of the protected health information is vulnerable to abuse and neglect by an entity providing health or social services to the individual.

SEC. 207. OVERSIGHT.

(a) IN GENERAL.—A health care provider, health plan, employer, law enforcement official, health or life insurer, public health authority, health researcher, school or university may disclose protected health information to a health oversight agency to enable the agency to perform a health oversight function authorized by law, if—

(1) the purpose for which the disclosure is to be made cannot reasonably be accomplished without protected health information;

(2) the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect on, or the risk to, the privacy of the individuals that additional exposure of the information might bring; and

(3) there is a reasonable probability that the purpose of the disclosure will be accomplished.

(b) USE AND MAINTENANCE OF PROTECTED HEALTH INFORMATION.—A health oversight agency that receives protected health information under this section—
(1) shall rely upon a method to scramble or otherwise safeguard, to the maximum extent practicable, the identity of the subject of the protected health information in all work papers and all documents summarizing the health oversight activity;

(2) shall maintain in its records only such information about an individual as is relevant and necessary to accomplish the purpose for which the protected health information was obtained;

(3) shall maintain such information securely and limit access to such information to those persons with a legitimate need for access to carry out the purpose for which the records were obtained; and

(4) shall remove or destroy the information that allows subjects of protected health information to be identified at the earliest time at which removal or destruction can be accomplished, consistent with the purpose of the health oversight activity.

(c) USE OF PROTECTED HEALTH INFORMATION IN JUDICIAL PROCEEDINGS.—

1. IN GENERAL.— The disclosure and use of protected health information in any judicial, administrative, court, or other public, proceeding or investigation relating to a health oversight activity shall
be undertaken in such a manner as to preserve the
confidentiality and privacy of individuals who are the
subject of the information, unless disclosure is re-
quired by the nature of the proceedings.

(2) LIMITING DISCLOSURE.—Whenever disclo-
sure of the identity of the subject of protected health
information is required by the nature of the proceed-
ings, or it is impracticable to redact the identity of
such individual, the agency shall request that the
presiding judicial or administrative officer enter an
order limiting the disclosure of the identity of the
subject to the extent possible, including the redact-
ing of the protected health information from publicly
disclosed or filed pleadings or records.

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

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

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

(2) a fraudulent claim related to health; or

(3) oversight of a public health authority or a health researcher.

SEC. 208. DISCLOSURE FOR LAW ENFORCEMENT PURPOSES.

(a) LAW ENFORCEMENT ACCESS TO PROTECTED HEALTH INFORMATION.—A health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school, university, a person acting as the agent of any such person, or a person who receives protected health information pursuant to section 204, may disclose protected health information to an investigative or law enforcement officer pursuant to a warrant issued under the Federal Rules of Criminal Procedure, an equivalent State warrant, a grand jury subpoena, or a court order under limitations set forth in subsection (b).

(b) REQUIREMENTS FOR COURT ORDERS FOR ACCESS TO PROTECTED HEALTH INFORMATION.—A court order for the disclosure of protected health information under subsection (a) may be issued by any court that is a court of competent jurisdiction and shall issue only if
the investigative or law enforcement officer submits a written application upon oath or equivalent affirmation demonstrating that there is probable cause to believe that—

(1) the protected health information sought is relevant and material to an ongoing criminal investigation, except in the case of a State government authority, such a court order shall not issue if prohibited by the law of such State;

(2) the investigative or evidentiary needs of the investigative or law enforcement officer cannot reasonably be satisfied by de-identified health information or by any other information; and

(3) the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains.

(e) Motions To Quash Or Modify.—A court issuing an order pursuant to this section, on a motion made promptly by the health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school, university, a person acting as the agent of any such person, or a person who receives protected health information pursuant to section 204, may quash or modify such order if the court finds that information or records requested are unreasonably voluminous or
if compliance with such order otherwise would cause an
unreasonable burden on such persons.

(d) Notice.—

(1) In general.—Except as provided in para-
graph (2), no order for the disclosure of protected
health information about an individual may be
issued by a court under this section unless prior no-
tice of the application for the order has been served
on the individual and the individual has been af-
forded an opportunity to oppose the issuance of the
order.

(2) Notice not required.—An order for the
disclosure of protected health information about an
individual may be issued without prior notice to the
individual if the court finds that notice would be im-
practical because—

(A) the name and address of the individual
are unknown; or

(B) notice would risk destruction or un-
availability of the evidence.

(e) Conditions.—Upon the granting of an order for
disclosure of protected health information under this sec-
tion, the court shall impose appropriate safeguards to en-
sure the confidentiality of such information and to protect
against unauthorized or improper use or disclosure.
(f) **Limitation on Use and Disclosure for Other Law Enforcement Inquiries.**—Protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual, unless the action or investigation arises out of, or is directly related to, the law enforcement inquiry for which the information was obtained.

(g) **Destruction or Return of Information.**—When the matter or need for which protected health information was disclosed to an investigative or law enforcement officer or grand jury has concluded, including any derivative matters arising from such matter or need, the law enforcement agency or grand jury shall either destroy the protected health information, or return it to the person from whom it was obtained.

(h) **Redactions.**—To the extent practicable, and consistent with the requirements of due process, a law enforcement agency shall redact personally identifying information from protected health information prior to the public disclosure of such protected information in a judicial or administrative proceeding.

(i) **Exception.**—This section shall not be construed to limit or restrict the ability of law enforcement authori-
ties to gain information while in hot pursuit of a suspect or if other exigent circumstances exist.

SEC. 209. NEXT OF KIN AND DIRECTORY INFORMATION.

(a) Next of Kin.—A health care provider, or a person who receives protected health information under section 204, may disclose protected health information about health care services provided to an individual to the individual’s next of kin, or to another person whom the individual has identified, if at the time of the treatment of the individual—

(1) the individual—

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

(B) is in a physical or mental condition such that the individual is not capable of objecting, and there are no prior indications that the individual would object; and

(2) the information disclosed relates to health care services currently being provided to that individual.

(b) Directory Information.—

(1) Disclosure.—

(A) In general.—Except as provided in paragraph (2), with respect an individual who is
admitted as an inpatient to a health care facility, a person described in subsection (a) may disclose information described in subparagraph (B) about the individual to any person if, at the time of the admission, the individual—

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

(ii) is in a physical or mental condition such that the individual is not capable of objecting 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 within the health care facility to which the individual is admitted.
(2) EXCEPTION.—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.

(c) DIRECTORY OR NEXT-OF-KIN INFORMATION.—A disclosure may not be made under this section if the disclosing person described in subsection (a) 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. 210. HEALTH RESEARCH.

(a) REGULATIONS.—

(1) IN GENERAL.—The requirements and protections provided for under part 46 of title 45, Code of Federal Regulations (as in effect on the date of enactment of this Act), shall apply to all health research.

(2) EFFECTIVE DATE.— Paragraph (1) shall not take effect until the Secretary has promulgated final regulations to implement such paragraph.

(b) EVALUATION.—Not later than 24 months after the date of enactment of this Act, the Secretary shall prepare and submit to Congress detailed recommendations on
whether written informed consent should be required, and
if so, under what circumstances, before protected health
information can be used for health research.

(c) RECOMMENDATIONS.—The recommendations re-
quired to be submitted under subsection (b) shall
include—

(1) a detailed explanation of current institu-
tional review board practices, including the extent to
which the privacy of individuals is taken into ac-
count as a factor before allowing waivers and under
what circumstances informed consent is being
waived;

(2) a summary of how technology could be used
to strip identifying data for the purposes of re-
search;

(3) an analysis of the risks and benefits of re-
quiring informed consent versus the waiver of in-
formed consent;

(4) an analysis of the risks and benefits of
using protected health information for research pur-
poses other than the health research project for
which such information was obtained; and

(5) an analysis of the risks and benefits of al-
lowing individuals to consent or to refuse to consent,
at the time of receiving medical treatment, to the
possible future use of records of medical treatments for research studies.

(d) Consultation.—In carrying out this section, the Secretary shall consult with individuals who have distinguished themselves in the fields of health research, privacy, related technology, consumer interests in health information, health data standards, and the provision of health services.

(e) Congressional Notice.—Not later than 6 months after the date on which the Secretary submits to Congress the recommendations required under subsection (b), the Secretary shall propose to implement such recommendations through regulations promulgated on the record after opportunity for a hearing, and shall advise the Congress of such proposal.

(f) Other Requirements.—

(1) Obligations of the recipient.—A person who receives protected health information pursuant to this section shall remove or destroy, at the earliest opportunity consistent with the purposes of the project involved, information that would enable an individual to be identified, unless—

(A) an institutional review board has determined that there is a health or research jus-
tification for the retention of such identifiers;
and
(B) there is an adequate plan to protect
the identifiers from disclosure consistent with
this section; and

(2) Periodic review and technical assistance.—

(A) Institutional review board.—Any
institutional review board that authorizes re-
search under this section shall provide the Sec-
retary with the names and addresses of the in-
stitutional review board members.

(B) Technical assistance.—The Sec-
retary may provide technical assistance to insti-
tutional review boards described in this sub-
section.

(C) Monitoring.—The Secretary shall pe-
riodically monitor institutional review boards
described in this subsection.

(D) Reports.—Not later than 3 years
after the date of enactment of this Act, the Sec-
retary shall report to Congress regarding the
activities of institutional review boards de-
scribed in this subsection.
(g) LIMITATION.—Nothing in this section shall be construed to permit protected health information that is received by a researcher under this section to be accessed for purposes other than research or as authorized by the individual.

SEC. 211. JUDICIAL AND ADMINISTRATIVE PURPOSES.

(a) IN GENERAL.—A health care provider, health plan, health oversight agency, employer, insurer, health or life insurer, school or university, a person acting as the agent of any such person, or a person who receives protected health information under section 204, may disclose protected health information—

(1) pursuant to the standards and procedures established in the Federal Rules of Civil Procedure or comparable rules of other courts or administrative agencies, in connection with litigation or proceedings to which an individual who is the subject of the information is a party and in which the individual has placed his or her physical or mental condition at issue;

(2) to a court, and to others ordered by the court, if in response to a court order issued by a court of competent jurisdiction in accordance with subsections (b) and (c); or
(3) if necessary to present to a court an application regarding the provision of treatment of an individual or the appointment of a guardian.

(b) Court Orders for Access to Protected Health Information.—A court order for the disclosure of protected health information under subsection (a) may be issued only if the person seeking disclosure submits a written application upon oath or equivalent affirmation demonstrating by clear and convincing evidence that—

(1) the protected health information sought is necessary for the adjudication of a material fact in dispute in a civil proceeding;

(2) the adjudicative need cannot be reasonably satisfied by de-identified health information or by any other information; and

(3) the need for the information outweighs the privacy interest of the individual to whom the information pertains.

(c) Notice.—

(1) In general.—Except as provided in paragraph (2), no order for the disclosure of protected health information about an individual may be issued by a court unless notice of the application for the order has been served on the individual and the
individual has been afforded an opportunity to op- 
oppose the issuance of the order.

(2) NOTICE NOT REQUIRED.—An order for the
disclosure of protected health information about an
individual may be issued without notice to the indi-
vidual if the court finds, by clear and convincing evi-
dence, that notice would be impractical because—

(A) the name and address of the individual 
are unknown; or 

(B) notice would risk destruction or un-
availability of the evidence.

(d) OBLIGATIONS OF RECIPIENT.—A person seeking
protected health information pursuant to subsection
(a)(1)—

(1) shall notify the individual or the individual’s
attorney of the request for the information;

(2) shall provide the health care provider,
health plan, health oversight agency, employer, in-
surer, health or life insurer, school or university,
agent, or other person involved with a signed docu-
ment attesting—

(A) that the individual has placed his or 
her physical or mental condition at issue in liti-
gation or proceedings in which the individual is 
a party; and
(B) the date on which the individual or the
individual’s attorney was notified under para-
graph (1); and
(3) shall not accept any requested protected
health information from the health care provider,
health plan, health oversight agency, employer, in-
surer, health or life insurer, school or university,
agent, or person until the termination of the 10-day
period beginning on the date notice was given under
paragraph (1).

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 an individual’s status as a minor), or
by an instrument recognized under law, to act as an agent,
attorney, proxy, or other legal representative of a individ-
ual, may, to the extent so authorized, exercise and dis-
charge 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 dis-
charge 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 physician or
other health care provider determines that an individual,
who has not been declared to be legally incompetent, suf-
fers 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 disclo-
sure under this Act may be exercised and discharged in
the best interest of the individual by—

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

(2) a person described in subsection (a) with re-
spect to the individual, but only if a person de-
scribed 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 per-
son described in paragraph (1), (2), or (3) cannot be
contacted after a reasonable effort.

(d) Rights of Minors.—

(1) Individuals who are 18 or legally ca-
pable.—In the case of an individual—
(A) who is 18 years of age or older, all rights of the individual under this Act shall be exercised by the individual; or

(B) who, acting alone, can obtain a type of health care without violating any applicable law, and who has sought such care, the individual shall exercise all rights of an individual under this Act with respect to protected health information relating to such health care.

(2) INDIVIDUALS UNDER 18.—Except as provided in paragraph (1)(B), in the case of an individual who is—

(A) under 14 years of age, all of the individual’s rights under this Act shall be exercised through the parent or legal guardian; or

(B) 14 through 17 years of age, the rights of inspection and supplementation, and the right to authorize use and disclosure of protected health information of the individual shall be exercised by the individual, or by the parent or legal guardian of the individual.

(e) DECEASED INDIVIDUALS.—

(1) APPLICATION OF ACT.—The provisions of this Act shall continue to apply to protected health information concerning a deceased individual.
(2) EXERCISE OF RIGHTS ON BEHALF OF A DECEASED INDIVIDUAL.—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. If no such designee has been authorized, the rights of the deceased individual may be exercised as provided for in subsection (e).

(3) IDENTIFICATION OF DECEASED INDIVIDUAL.—A person described in section 209(a) may disclose protected health information if such disclosure is necessary to assist in the identification of a deceased individual.

SEC. 213. PROHIBITION AGAINST RETALIATION.

A health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school or university, person acting as an agent of any such person, or person who receives protected health information under section 204 may not adversely affect another person, directly or indirectly, because such person has exercised a right under this Act, disclosed information relating to a possible violation of this Act, or associated
with, or assisted, a person in the exercise of a right under this Act.

TITLE III—OFFICE OF HEALTH INFORMATION PRIVACY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

Subtitle A—Designation

SEC. 301. DESIGNATION.

(a) IN GENERAL.—The Secretary shall designate an office within the Department of Health and Human Services to be known as the Office of Health Information Privacy. The Office shall be headed by a Director, who shall be appointed by the Secretary.

(b) DUTIES.—The Director of the Office of Health Information Privacy shall—

(1) receive and investigate complaints of alleged violations of this Act;

(2) provide for the conduct of audits where appropriate;

(3) provide guidance to the Secretary in the implementation of this Act;

(4) prepare and submit the report described in subsection (c);
(5) consult with, and provide recommendation to, the Secretary concerning improvements in the privacy and security of protected health information and concerning medical privacy research needs; and

(6) carry out any other activities determined appropriate by the Secretary.

(c) REPORT ON COMPLIANCE.—Not later than January 1 of the first calendar year beginning more than 1 year after the establishment of the Office under subsection (a), and every January 1 thereafter, the Secretary, in consultation with the Director of the Office of Health Information Privacy, shall prepare and submit to Congress a report concerning the number of complaints of alleged violations of this Act that are received during the year for which the report is being prepared. Such report shall describe the complaints and any remedial action taken concerning such complaints.

Subtitle B—Enforcement

CHAPTER 1—CRIMINAL PROVISIONS

SEC. 311. 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

Sec. 2801. 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 or attempts to obtain protected health information relating to an individual in violation of title II of the Medical Information Privacy and Security Act; or

(2) discloses or attempts to disclose protected health information to another person in violation of title II of the Medical Information Privacy and Security Act.

(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 $250,000, imprisoned not more than 5 years, or any combination of such penalties; or
“(3) if the offense is committed with the intent
to sell, transfer, or use protected health information
for commercial advantage, personal gain, or malici-
cious harm, be fined not more than $500,000, im-
prisoned not more than 10 years, excluded from par-
ticipation in any Federally funded health care pro-
grams, or any combination of such penalties.

“(c) SUBSEQUENT OFFENSES.—In the case of a per-
son described in subsection (a), the maximum penalties
described in subsection (b) shall be doubled for every sub-
sequent conviction for an offense arising out of a violation
or violations related to a set of circumstances that are dif-
f erent 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 follow-
ing new item:

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

SEC. 312. DEBARMENT FOR CRIMES.

(a) PURPOSE.—The purpose of this section is to pro-
mote the prevention and deterrence of instances of inten-
tional criminal actions which violate criminal laws which
are designed to protect the privacy of protected health in-
formation in a manner consistent with this Act.
(b) Debarment.—Not later than 270 days after the date of enactment of this Act, the Attorney General, in consultation with the Secretary, shall promulgate regulations and establish procedures to permit the debarment of health care providers, health researchers, health or life insurers, employers, or schools or universities from receiving benefits under any Federal health programs or other Federal procurement program if the managers or officers of such persons are found guilty of violating section 2801 of title 18, United States Code, have civil penalties imposed against such officers or managers under section 321 in connection with the illegal disclosure of protected health information, or are found guilty of making a false statement or obstructing justice related to attempting to conceal or concealing such illegal disclosure. Such regulations shall take into account the need for continuity of medical care and may provide for a delay of any debarment imposed under this section to take into account the medical needs of patients.

(c) Consultation.—Before publishing a proposed rule to implement subsection (b), the Attorney General shall consult with State law enforcement officials, health care providers, patient privacy rights’ advocates, and other appropriate persons, to gain additional information regarding the debarment of entities under subsection (b)
and the best methods to ensure the continuity of medical care.

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

(e) ASSISTANCE TO PREVENT CRIMINAL VIOLATIONS.—The Attorney General, in cooperation with any other appropriate individual, organization, or agency, may provide advice, training, technical assistance, and guidance regarding ways to reduce the incidence of improper disclosure of protected health information.

(f) RELATIONSHIP TO OTHER AUTHORITIES.—A debarment imposed under this section shall not reduce or diminish the authority of a Federal, State, or local governmental agency or court to penalize, imprison, fine, suspend, debar, or take other adverse action against a person, in a civil, criminal, or administrative proceeding.

CHAPTER 2—CIVIL SANCTIONS

SEC. 321. CIVIL PENALTY.

(a) VIOLATION.—A health care provider, health researcher, health plan, health oversight agency, public health agency, law enforcement agency, employer, health
or life insurer, school, or university, or a person acting
as the agent of any such 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 $5000 in the
aggregate for multiple violations;

(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; 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.

(b) Procedures for Imposition of Penalties.—
Section 1128A of the Social Security Act (42 U.S.C.
1320a-7a), other than subsections (a) and (b) and the sec-
ond sentence of subsection (f) of that section, shall apply
to the imposition of a civil, monetary, or exclusionary pen-
alty under this section in the same manner as such provi-
sions apply with respect to the imposition of a penalty under section 1128A of such Act.

SEC. 322. 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 321. The Secretary may not initiate an action under this section with respect to any violation described in section 321 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 HEARING.—The Secretary shall not make a determination adverse to any person under paragraph (1) until the person has been given written notice and an opportunity 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) **ESTOPPEL.**—In a proceeding under paragraph (1) that—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a crime under section 2801 of title 18, United States Code; and

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

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

(4) **SANCTIONS FOR FAILURE TO COMPLY.**—

The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct 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 permit discovery, drawing negative factual inferences 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 321, 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 against whom the claim is brought; and

(3) such other matters as justice may require.

(e) 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 para-
graph (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 conclu-
sive. 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 evi-
dence 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 re-
spect 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 chapter 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 Secretary hereunder, 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. Such attendance of witnesses and production of evidence at the designated place of such hearing, investigation, or other proceeding 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-
authorized 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 Obe[y.—In case of contumacy
by, or refusal to obey a subpoena duly served upon,
any person, 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 re-
sides or transacts business, upon application by the
Secretary, shall have jurisdiction to issue an order
requiring such person to appear and give testimony,
or to appear and produce evidence, or both. Any fail-
ure 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 en-
gaging, or is about to engage in any activity which makes
the person subject to a civil monetary penalty under sec-
tion 321, 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 jointly and severally liable with the principal’s agent for penalties under section 321 for the actions of the principal’s agent acting within the scope of the agency.

SEC. 323. CIVIL ACTION BY INDIVIDUALS.

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

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

(2) the greater of compensatory damages or liquidated damages of $5,000.

(b) PUNITIVE DAMAGES.—In any action brought under this section in which the individual has prevailed because of a knowing violation of a provision of this Act, the court may, in addition to any relief awarded under subsection (a), award such punitive damages as may be warranted.
(c) ATTORNEY’S FEES.—In the case of a civil action brought under subsection (a) in which the individual has substantially prevailed, the court may assess against the respondent a reasonable attorney’s fee and other litigation costs and expenses (including expert fees) reasonably incurred.

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

(e) AGENCY.—A principal is jointly and severally liable with the principal’s agent for damages under this section for the actions of the principal’s agent acting within the scope of the agency.

(f) ADDITIONAL REMEDIES.—The equitable relief or damages that may be available under this section shall be in additional to any other lawful remedy or award available.

TITLE IV—MISCELLANEOUS

SEC. 401. RELATIONSHIP TO OTHER LAWS.

(a) FEDERAL AND STATE LAWS.—Nothing in this Act shall be construed as preempting, superseding, or repealing, explicitly or implicitly, other Federal or State laws or regulations relating to protected health information or relating to an individual’s access to protected health infor-
mation or health care services, if such laws or regulations
provide protections for the rights of individuals to the pri-
vacy of, and access to, their health information that are
greater than those provided for in this Act.

(b) PRIVILEGES.—Nothing in this Act shall be con-
strued to preempt or modify any provisions of State statu-
tory 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 section 202 shall not be construed as a waiver of any
such privilege.

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

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

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

(3) regulates the disclosure or reporting of in-
formation concerning an individual’s mental health;
or
(4) governs a minor’s rights to access protected
health information or health care services.

(d) **Federal Privacy Act.**—

(1) **Medical exemptions.**—Section 552a of
title 5, United States Code, is amended by adding
at the end the following:

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(w) Certain Protected Health Information.—The head of an agency that is a health care pro-
vider, health plan, health oversight agency, employer, ins-
surer, health or life insurer, school or university, or person
who receives protected health information under section
204 of the Medical Information Privacy and Security Act
shall promulgate rules, in accordance with the require-
ments (including general notice) of subsections (b)(1),
(b)(2), (b)(3), (c), (e) of section 553 of this title, to ex-
empt a system of records within the agency, to the extent
that the system of records contains protected health infor-
mation (as defined in section 4 of such Act), from all pro-
visions of this section except subsections (b)(6), (d),
(e)(1), (e)(2), subparagraphs (A) through (C) and (E)
through (I) of subsection (e)(4), and subsections (e)(5),
(e)(6), (e)(9), (e)(12), (l), (n), (o), (p), , (r), and (u)).”.
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(2) **Technical amendment.**—Section

552a(f)(3) of title 5, United States Code, is amend-
ed by striking “pertaining to him,” and all that fol-
laws through the semicolon and inserting “pertaining to the individual.”

(c) CONSTITUTION.—Nothing in this Act shall be construed to alter, diminish, or otherwise weaken existing legal standards under the Constitution regarding the confidentiality of protected health information.

SEC. 402. EFFECTIVE DATE.

(a) EFFECTIVE DATE.—Unless specifically provided for otherwise, this Act shall take effect on the date that is 12 months after the date of the promulgation of the regulations required under subsection (b), or 30 months after the date of enactment of this Act, whichever is earlier.

(b) REGULATIONS.—Not later than 12 months after the date of enactment of this Act, or as specifically provided for otherwise, the Secretary shall promulgate regulations implementing this Act.