## 105TH CONGRESS 1ST SESSION

# H. R. 1815

To protect the privacy of health information in the age of genetic and other new technologies, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

June 5, 1997

Mr. McDermott (for himself, Mr. Nadler, Mr. Dellums, Ms. Lofgren, Mr. Rush, Mr. Barrett of Wisconsin, Mrs. Mink of Hawaii, Mr. Frost, Mr. Miller of California, and Mr. Torres) introduced the following bill; which was referred to the Committee on Commerce, and in addition to the Committee on Government Reform and Oversight, 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 protect the privacy of health information in the age of genetic and other new technologies, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Medical Privacy in the Age of New Technologies Act of
- 6 1997".

## 1 (b) Table of Contents for

### 2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings and purposes.
- Sec. 3. Definitions.

#### TITLE I—INDIVIDUALS' RIGHTS

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

- Sec. 101. Inspection and copying of protected health information.
- Sec. 102. Correction or amendment of protected health information.
- Sec. 103. Notice of information practices.

#### Subtitle B—Establishment of Safeguards

- Sec. 111. Establishment of safeguards.
- Sec. 112. Accounting for disclosures.
- Sec. 113. Prohibition against retaliation.

#### TITLE II—RESTRICTIONS ON USE AND DISCLOSURE

- Sec. 201. General rules regarding use and disclosure.
- Sec. 202. Authorizations for disclosure of protected health information for treatment or payment.
- Sec. 203. Authorizations for disclosure of protected health information for purposes other than treatment or payment.
- Sec. 204. Creation of nonidentifiable and coded information.
- Sec. 205. Next of kin and directory information.
- Sec. 206. Emergency circumstances.
- Sec. 207. Oversight.
- Sec. 208. Accreditation.
- Sec. 209. Public health.
- Sec. 210. Health research.
- Sec. 211. Judicial and administrative purposes.
- Sec. 212. General requirements governing subpoenas.
- Sec. 213. Additional requirements for law enforcement access.

#### TITLE III—SANCTIONS

#### Subtitle A—Civil Sanctions

- Sec. 301. Civil penalty.
- Sec. 302. Civil action.

#### Subtitle B—Criminal Sanctions

Sec. 311. Wrongful disclosure of protected health information.

#### TITLE IV—MISCELLANEOUS

- Sec. 401. Regulations.
- Sec. 402. Relationship to other laws.
- Sec. 403. Effective dates.
- Sec. 404. Applicability.

#### 1 SEC. 2. FINDINGS AND PURPOSES.

2 (a) FINDINGS.—The Congress finds as	,	(a) FINDINGS	.—The Con	gress finds	as follows:
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- (1) Health information plays a vital role in every aspect of an individual's life. It includes some of the most sensitive information available about an individual.
- (2) An individual's health information is currently accessible to many people who do not need the information to provide health care to the individual, often without the individual's knowledge or consent.
- (3) Individuals will be deterred from using the health care system unless they are assured that the confidentiality of their health information will be respected.
- (4) There exists little Federal protection of the confidentiality of an individual's health information.
- (5) While health information often is transferred across State lines, protection of the confidentiality of health information varies greatly from State to State, with little protection in some States.
- (6) New technologies increase the importance of addressing new threats to the confidentiality of health information. For example, technologies that permit an individual's health information to be computerized increase the possibility of unauthorized electronic access to the information. Technologies

1	that provide genetic information provide information
2	not just about an individual's current health but also
3	about the individual's potential future health and the
4	health of the individual's relatives. This creates po-
5	tential new uses and abuses of genetic health infor-
6	mation that need to be addressed by legislation.
7	(7) The potential benefits from new genetic
8	technologies will not be realized if individuals cannot
9	trust that their health information is safe from un-
10	authorized uses.
11	(b) Purposes.—The purposes of this Act are as fol-
12	lows:
13	(1) To recognize that there is a right to privacy
14	with respect to health information, including genetic
15	information, and that this right must be protected
16	accordingly.
17	(2) To ensure that an individual's interest in
18	the privacy of their health information cannot be

- overridden without meaningful notice and informed consent, except in limited circumstances where there is a compelling public interest.
- 22 (3) To provide individuals—
- 23 (A) access to health information of which 24 they are the subject; and

- 1 (B) the power to challenge the accuracy 2 and completeness of, and amend or correct, 3 records containing such information.
  - (4) To establish a minimum Federal standard for the protection of health information which will promote confidentiality while allowing efficient transfer of health information between States.
- 8 (5) To help ensure the confidentiality of com-9 puterized or electronically transferred health infor-10 mation.
- To restrict the gathering of aggregate 12 health information for financial gain or other pur-13 poses without each subject's knowledge or consent.
- 14 (7) To establish strong and effective remedies 15 for violations of this Act.

#### 16 SEC. 3. DEFINITIONS.

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- 17 As used in this Act:
- 18 (1) Accrediting Body.—The term "accredit-19 ing body" means a body, committee, organization, or 20 institution that has been authorized by law, or is 21 recognized by a health care regulating authority, 22 with respect to accreditation, licensing, 23 credentialing of health care providers or health care facilities. 24

1	(2) CODED HEALTH INFORMATION.—The term
2	"coded health information" means any protected
3	health information—

- (A) in which all identifying information has been replaced by a unique identifier, and where neither the remaining information nor the unique identifier, on its face, identifies an individual;
- (B) which cannot easily be used or manipulated in a manner that reveals the identity of an individual; and
- (C) which can only be linked or matched to other information in a manner that reveals the identity of an individual by a person authorized to carry out such functions under section 204.
- (3) DISCLOSE.—The term "disclose" when used with respect to protected health information that is held by a health information trustee, means to release, transfer, provide access to, or otherwise divulge the information to any person other than an individual who is the subject of the information. Such term includes the placement of protected health information into a computerized data base, networked computer system, or any other electronic or magnetic data system, that more than one person

1	may access by any means. Such term does not in-
2	clude oral communication between an individual who
3	is the subject of protected health information and a
4	health care provider delivering health care to such
5	individual.
6	(4) Electronic.—The term "electronic", when
7	used with reference to information, means—
8	(A) in electronic or magnetic form;
9	(B) in an optical storage form;
10	(C) computer-based;
11	(D) computer-associated; or
12	(E) in some other form that—
13	(i) is appropriate for non-paper-based
14	information processing or storage; and
15	(ii) exists on the date of the enact-
16	ment of this Act or is developed subse-
17	quent to such date.
18	(5) HEALTH CARE.—The term "health care"
19	means—
20	(A) any sale or dispensing of a drug, de-
21	vice, equipment, or other item to an individual,
22	or for the use of an individual, pursuant to a
23	prescription: and

1	(B) any preventive, predictive, diagnostic,
2	therapeutic, rehabilitative, maintenance, or pal-
3	liative care, counseling, service, or procedure—
4	(i) with respect to the physical or
5	mental condition of an individual; or
6	(ii) affecting the structure or function
7	of the human body or any part of the
8	human body, including individual cells and
9	their components.
10	(6) HEALTH CARE PROVIDER.—The term
11	"health care provider" means a person who, with re-
12	spect to a specific item of protected health informa-
13	tion, receives, creates, uses, maintains, or discloses
14	the information while acting in whole or in part in
15	the capacity of—
16	(A) a person who is licensed, certified, reg-
17	istered, or otherwise authorized by law to pro-
18	vide an item or service that constitutes health
19	care, in the ordinary course of business or prac-
20	tice of a profession; or
21	(B) a Federal or State program that di-
22	rectly provides items or services that constitute
23	health care to beneficiaries.
24	(7) HEALTH INFORMATION TRUSTEE.—The
25	term "health information trustee" means—

1	(A) a person who is a health care provider.
2	health plan, health oversight agency, public
3	health authority, health researcher, employer,
4	insurer, school, institution of higher education,
5	or insurance support organization, insofar as
6	the person creates, receives, obtains, maintains,
7	uses, or transmits protected health information
8	$\operatorname{or}$
9	(B) any employee, agent, or contractor of
10	a person described in subparagraph (A), insofar
11	as the employee, agent, or contractor creates,
12	receives, obtains, maintains, uses, or transmits
13	protected health information.
14	(8) Health oversight agency.—The term
15	"health oversight agency" means a person who—
16	(A) performs or oversees the performance
17	of an assessment, investigation, or prosecution
18	relating to—
19	(i) compliance with legal or fiscal
20	standards pertinent to health care fraud
21	including fraudulent claims regarding
22	health care, health services or equipment
23	or related activities and items; or
24	(ii) the protection of individuals from
25	harm, abuse, neglect, or exploitation; and

- 1 (B) is a public agency, acting on behalf of 2 a public agency, acting pursuant to a require-3 ment of a public agency, or carrying out activi-4 ties under a Federal or State law governing an 5 assessment, investigation, or prosecution de-6 scribed in subparagraph (A).
  - (9) 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 payment for health care, whether or not funded through the purchase of insurance.
  - (10) Health researcher.—The term "health researcher" means a person who conducts, using protected health information, a systematic investigation, or research development, testing, or evaluation, to develop or contribute to scientific or medical knowledge.
  - (11) Individual representative" means any individual legally empowered to make decisions concerning the provision of health care to an individual (where the individual lacks the legal capacity under State law to

1 make such decisions) or the administrator or execu-2 tor of the estate of a deceased individual. 3 (12) Insurance support organization.— (A) In General.—Subject to subparagraph (B), the term "insurance support organi-6 zation" means any person who regularly en-7 gages, in whole or in part, in the practice of as-8 sembling and providing information about indi-9 viduals to an insurer or health plan for insur-10 ance transactions, including— 11 (i) the furnishing of consumer reports 12 or investigative consumer reports to an in-13 surer or health plan for use in connection 14 with an insurance transaction; or 15 (ii) the collection of personal informa-16 tion from insurers, health plans, or other 17 insurance support organizations for the 18 purpose of detecting or preventing fraud or 19 material misrepresentation in connection 20 with insurance underwriting or insurance 21 claim activity. 22 (B) Persons EXCLUDED.—Such term 23 does not include any person who is treated as 24 a health information trustee under any other 25 provision of this Act.

1	(13) Law enforcement inquiry.—The term
2	"law enforcement inquiry" means an official law en-
3	forcement investigation or proceeding inquiring into
4	a violation of, or failure to comply with, any law.
5	(14) Nonidentifiable health informa-
6	TION.—The term "nonidentifiable health informa-
7	tion" means information that would be protected
8	health information, except that—
9	(A) it is impossible to ascertain, based on
10	the information, or on any codes or identifiers
11	related to the information, the identity of any
12	individual whose health or condition is the sub-
13	ject of the information; and
14	(B) it cannot be linked or matched by a
15	foreseeable method to any other information
16	that pertains to any such individual.
17	(15) Person.—The term "person" means any
18	of the following:
19	(A) An individual.
20	(B) A government.
21	(C) A governmental subdivision, agency or
22	authority.
23	(D) A corporation.
24	(E) A company.
25	(F) An association.

1	(G) A firm.
2	(H) A partnership.
3	(I) A society.
4	(J) An estate.
5	(K) A trust.
6	(L) A joint venture.
7	(M) An individual representative.
8	(N) Any other legal entity.
9	(16) PROTECTED HEALTH INFORMATION.—The
10	term "protected health information" means any in-
11	formation, including information derived from a bio-
12	logical sample from the human body and demo-
13	graphic information about an individual, whether
14	oral or recorded in any form or medium, that—
15	(A) is created or received by a health infor-
16	mation trustee or an accrediting body;
17	(B) relates to—
18	(i) the past, present, or future phys-
19	ical or mental health, predisposition, or
20	condition of an individual, or individuals
21	related by blood to the individual;
22	(ii) the provision of health care to an
23	individual; or

1	(iii) the past, present, or future pay-
2	ment for the provision of health care to an
3	individual; and
4	(C)(i) identifies such individual;
5	(ii) with respect to which there is a reason-
6	able basis to believe that the information can be
7	used to identify such individual; or
8	(iii) could be linked or matched by a fore-
9	seeable method to any other information which
10	pertains to such individual.
11	(17) PROTECTED HEALTH INFORMATION
12	SUBFILE.—The term "protected health information
13	subfile" means any amount of protected health in-
14	formation which is segregated pursuant to section
15	201(e).
16	(18) Public Health Authority.—The term
17	"public health authority" means an authority or in-
18	strumentality of the United States, a State, or a po-
19	litical subdivision of a State that—
20	(A) is charged by statute with responsibil-
21	ity for public health matters; and
22	(B) is engaged in such activities as injury
23	reporting, public health surveillance, and public
24	health investigation or intervention.

1	(19) Secretary.—The term "Secretary"
2	means the Secretary of Health and Human Services.
3	(20) State.—The term "State" includes the
4	District of Columbia, Puerto Rico, the Virgin Is-
5	lands, Guam, American Samoa, and the Northern
6	Mariana Islands.
7	(21) Writing.—The term "writing" means
8	writing in either a paper-based or electronic form.
9	TITLE I—INDIVIDUALS' RIGHTS
10	Subtitle A—Review of Protected
11	Health Information by Subjects
12	of the Information
13	SEC. 101. INSPECTION AND COPYING OF PROTECTED
13 14	HEALTH INFORMATION.
14	HEALTH INFORMATION.
14 15	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee shall permit an
14 15 16 17	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee shall permit an
14 15 16 17	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee shall permit an individual who is the subject of protected health informa-
14 15 16 17	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee 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, in-
14 15 16 17 18	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee 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, in-
14 15 16 17 18 19 20	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee 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 section 102, that the trustee
14 15 16 17 18 19 20	HEALTH INFORMATION.  (a) IN GENERAL.—Except as provided in subsections (b) and (h), a health information trustee 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 section 102, that the trustee maintains. A health information trustee may require an

- 1 (1) In GENERAL.—A health care provider who
  2 is delivering, or has delivered, health care to an indi3 vidual who is the subject of protected health infor4 mation relating to such health care is not required
  5 by this section to permit inspection or copying of the
  6 information, where such inspection or copying rea7 sonably could be expected to endanger the life or
  8 physical or mental safety of any individual.
- 9 (2) ALTERNATIVE DISCLOSURE.—In any case
  10 where a health care provider determines that the
  11 provider, pursuant to paragraph (1), will not permit
  12 an individual to inspect or copy protected health in13 formation, the provider may permit inspection or
  14 copying by the individual's designee.
- 15 (c) Denial of a Request for Inspection or 16 Copying.—If a health information trustee denies a re-17 quest for inspection or copying under subsection (b), the 18 trustee shall inform the individual in writing of—
- 19 (1) the reasons for the denial of the request;
- 20 (2) any procedures for further review of the de-21 nial; and
- 22 (3) the individual's right to file with the trust-23 ee, if the individual so wishes, a concise statement 24 setting forth the request for inspection or copying.

- 1 (d) STATEMENT REGARDING REQUEST.—If an indi-
- 2 vidual has filed a statement under subsection (c)(3) set-
- 3 ting forth the request, the health information trustee in
- 4 any subsequent disclosure of the portion of the informa-
- 5 tion requested shall include—
- 6 (1) a copy of the individual's statement; and
- 7 (2) a concise statement of the reasons for deny-
- 8 ing the request for inspection or copying.
- 9 (e) Rule of Construction.—This section shall not
- 10 be construed to require a health information trustee to
- 11 conduct a formal, informal, or other hearing or proceeding
- 12 concerning a request for inspection or copying of protected
- 13 health information.
- 14 (f) Inspection and Copying of Segregable Por-
- 15 Tion.—A health information trustee shall permit inspec-
- 16 tion and copying under subsection (a) of any reasonably
- 17 segregable portion of a record after deletion of any portion
- 18 that is exempt under subsection (b).
- 19 (g) Deadline.—A health information trustee shall
- 20 comply with or deny, in accordance with subsection (c),
- 21 a request for inspection or copying of protected health in-
- 22 formation under this section within the 30-day period be-
- 23 ginning on the date on which the trustee receives the re-
- 24 quest.

- 1 (h) Rules Governing Agents and Contrac-2 TORS.—
- 3 (1) IN GENERAL.—A person acting in the capacity of an agent or contractor of a health care 5 provider, health plan, health oversight agency, public 6 health authority, health researcher, employer, in-7 surer, school, institution of higher education, or in-8 surance support organization is not responsible for 9 providing for the inspection or copying of protected 10 health information under this section, except when the agent or contractor has been notified by their 12 principal that a request for inspection or copying 13 has been made to the principal under section (a) and 14 has not been denied under section (b).
  - (2) Coded Health Information.—In any case where a person acting in the capacity of an agent or contractor of a health care provider, health plan, health oversight agency, public health authority, health researcher, employer, insurer, school, institution of higher education, or insurance support organization is requested to provide for the inspection or copying of coded health information under this section, the person shall inform the individual making the request that the individual should contact a person authorized under section 204 to link

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1	or match the coded health information to reveal the
2	identity of the individual who is the subject of the
3	information.
4	SEC. 102. CORRECTION OR AMENDMENT OF PROTECTED
5	HEALTH INFORMATION.
6	(a) In General.—Unless proceeding under sub-
7	section (b), and except as provided in subsection (f), a
8	health information trustee, within the 45-day period be-
9	ginning on the date on which the trustee receives from
10	an individual a written request to correct or amend pro-
11	tected health information about the individual—
12	(1) shall make the correction or amendment re-
13	quested;
14	(2) shall inform the individual of the correction
15	or amendment that has been made; and
16	(3) shall make reasonable efforts to inform any
17	person who is identified by the individual, and to
18	whom the uncorrected or unamended portion of the
19	information was previously disclosed, of the correc-
20	tion or amendment that has been made.
21	(b) Refusal To Correct or Amend.—If the
22	health information trustee refuses to make the correction
23	or amendment, the trustee shall inform the individual
24	within the 45-day period beginning on the date on which
25	the trustee receives the individual's request of—

1	(1) the reasons for the refusal to make the cor-
2	rection or amendment;
3	(2) any procedures for further review of the re-
4	fusal; and
5	(3) the individual's right to file with the trust-
6	ee, if the individual so wishes, a concise statement
7	setting forth the requested correction or amendment
8	and the individual's reasons for disagreeing with the
9	refusal.
10	(c) Statement of Disagreement.—If an individ-
11	ual has filed a statement of disagreement under subsection
12	(b)(3), the health information trustee in any subsequent
13	disclosure of the disputed portion of the information—
14	(1) shall include a copy of the individual's
15	statement; and
16	(2) shall include a concise statement of the rea-
17	sons for not making the requested correction or
18	amendment.
19	(d) Rule of Construction.—This section shall not
20	be construed to require a health information trustee to
21	conduct a formal, informal, or other hearing or proceeding
22	concerning a request for a correction or amendment to
23	protected health information.
24	(e) Correction.—For purposes of subsection (a), a

25 correction is deemed to have been made to protected

- 1 health information when information that has been dis-
- 2 puted by an individual has been corrected, clearly marked
- 3 as incorrect, or supplemented by correct information.
- 4 (f) Rules Governing Agents and Contrac-
- 5 TORS.—A person acting in the capacity of an agent or con-
- 6 tractor of a health care provider, health plan, health over-
- 7 sight agency, public health authority, health researcher,
- 8 employer, insurer, school, institution of higher education,
- 9 or insurance support organization is not authorized to
- 10 make corrections or amendments to protected health infor-
- 11 mation received from their principal, except when the
- 12 agent or contractor has been asked by the principal to ful-
- 13 fill the principal's obligations under this section.
- 14 SEC. 103. NOTICE OF INFORMATION PRACTICES.
- 15 (a) Preparation of Written Notice.—A health
- 16 information trustee shall prepare and provide, in accord-
- 17 ance with subsection (b), a written notice containing the
- 18 following:
- 19 (1) Individuals' rights.—A description of
- the following rights of an individual who is a subject
- of protected health information maintained by the
- trustee:
- 23 (A) The right of the individual to request
- segregation of protected health information, and
- to restrict the use of such information by em-

1	ployees, agents, and contractors of the trustee,
2	under section 201(c).
3	(B) The right of the individual to inspect,
4	copy, amend, and correct the protected health
5	information under sections 101 and 102.
6	(C) The right of the individual to object to
7	the disclosure of the information to next of kin
8	or in directory information under section 205.
9	(D) The circumstances under which the in-
10	formation may be used or disclosed without an
11	authorization executed by the individual.
12	(E) The right of the individual not to have
13	employment or the receipt of services condi-
14	tioned upon the execution by the individual of
15	an authorization for disclosure or use for any
16	purpose other than treatment or payment.
17	(F) The procedures the individual must
18	follow in order to exercise the foregoing rights.
19	(2) Trustee information practices.—A de-
20	scription of the trustee's health information prac-
21	tices, including the safeguards and practices used to
22	protect such information.
23	(b) Availability of Notice to Subjects.—A
24	health information trustee shall provide a copy of a notice

1	prepared under this section to an individual who is a sub-
2	ject of protected health information—
3	(1) along with any request for authorization to
4	use or disclose the information created pursuant to
5	section 202 or 203 and presented by the trustee to
6	the individual for execution;
7	(2) at the first practicable opportunity after the
8	trustee uses or discloses the information without an
9	authorization executed by the individual;
10	(3) at the first practicable opportunity after a
11	health information trustee commences the collection
12	of the information; or
13	(4) when the individual requests to inspect,
14	copy, correct, or amend their protected health infor-
15	mation pursuant to section 101 or 102.
16	Subtitle B—Establishment of
17	Safeguards
18	SEC. 111. ESTABLISHMENT OF SAFEGUARDS.
19	(a) In General.—A health information trustee shall
20	establish and maintain appropriate administrative, tech-
21	nical, and physical safeguards to ensure the confidential-
22	ity, security, accuracy, and integrity of protected health
23	information created, received, obtained, maintained, used
24	or transmitted by the trustee.
25	(b) Safeguards for Electronic Information.—

1	(1) Application and construction.—
2	(A) APPLICATION.—This subsection ap-
3	plies only with respect to protected health infor-
4	mation that is electronic.
5	(B) Construction.—Nothing in this Act
6	shall be construed to require that protected
7	health information be created, received, main-
8	tained, used, or disclosed in electronic form.
9	(2) Requirements for electronic mainte-
10	NANCE, USE, AND DISCLOSURE.—The Secretary
11	shall develop, and by regulation impose on health in-
12	formation trustees, requirements for the electronic
13	maintenance, use, and disclosure of protected health
14	information. Such requirements shall include the fol-
15	lowing:
16	(A) CONTROL OF ACCESS TO PROTECTED
17	HEALTH INFORMATION.—
18	(i) In general.—A health informa-
19	tion trustee shall implement controls with
20	respect to access to electronic protected
21	health information. The trustee may grant
22	a request by any person for access to such
23	information for use by the health informa-
24	tion trustee, or for disclosure to another

1	health information trustee, only after veri-
2	fying that—
3	(I) the person making the re-
4	quest can prove their identity; and
5	(II) the proposed use of the pro-
6	tected health information, or the re-
7	quested disclosure, is authorized
8	under this Act.
9	(ii) Authentication of identity
10	of requesters.—A health information
11	trustee shall use a method of verification
12	to verify the identity of persons requesting
13	access to electronic protected health infor-
14	mation. A health information trustee who
15	issues a device that verifies the identity of
16	a person making a request for information
17	for purposes of this clause shall instruct
18	the person in the proper care and use of
19	the device and shall require the person to
20	protect the device from misuse. Any system
21	used by a health information trustee to
22	maintain verification information collected
23	under this clause shall prevent the disclo-
24	sure of such verification information to any
25	person other than a person who is specifi-

cally authorized to receive such information.

> (B) Access for use by health information trustmation trustee.—A health information trustee shall limit the persons who may use protected health information created or maintained by the trustee in electronic form to persons specifically authorized by the trustee to use such information consistent with this Act.

## (C) Disclosure to others.—

- (i) Protection of requests for Disclosure and responses.—A health information trustee who requests, using electronic means, to receive protected health information, or who responds, using electronic means, to such a request, shall implement procedures to prevent the interception of such request or response by persons who are not authorized to intercept it.
- (ii) IDENTIFICATION OF SUBJECT.—A health information trustee who receives, using electronic means, a request for protected health information from another health information trustee may not provide such information in response to the request

unless the request contains sufficient details to uniquely identify one individual who is the subject of the request.

## (D) Audit trail.—

- (i) Access to information maintain an electronic trustee shall maintain an electronic record concerning each attempt that is made by the trustee, whether authorized or unauthorized, successful or unsuccessful, to access protected health information that is maintained by any other health information trustee in electronic form. The record shall include the identity of the specific individual attempting to gain such access and information sufficient to identify the information sought.
- (ii) Access to information maintain an electronic record concerning each attempt that is made by the trustee, or by any other person, whether authorized or unauthorized, successful or unsuccessful, to access protected health information maintained by

the trustee in electronic form. The record shall include the identity of the specific individual attempting to gain such access and information sufficient to identify the information sought.

(3) Review of requirements.—The Secretary from time to time shall review the requirements developed and imposed under paragraph (2), to determine whether technological advances or other factors make necessary changes to the requirements. If the Secretary determines that such changes are necessary, the Secretary shall make them.

#### 13 SEC. 112. ACCOUNTING FOR DISCLOSURES.

### (a) In General.—

- (1) Persons not acting as agents or contractors.—Except as provided in paragraph (2), a health information trustee shall create and maintain, with respect to any protected health information disclosure made by the trustee that is not related to treatment, a record of the disclosure in accordance with regulations promulgated by the Secretary.
- (2) AGENTS AND CONTRACTORS.—A person acting in the capacity of an agent or contractor of a health care provider, health plan, health oversight agency, public health authority, health researcher,

- 1 employer, insurer, school, institution of higher edu-
- 2 cation, or insurance support organization shall cre-
- 3 ate and maintain, with respect to any protected
- 4 health information disclosure made by the person
- 5 that is authorized under one of section 202, 203,
- 6 204, or 206 through 213, a record of the disclosure
- 7 in accordance with regulations promulgated by the
- 8 Secretary.
- 9 (b) Record of Disclosure Part of Protected
- 10 HEALTH INFORMATION.—A record created and main-
- 11 tained under subsection (a) shall be maintained as pro-
- 12 tected health information for not less than 7 years.

#### 13 SEC. 113. PROHIBITION AGAINST RETALIATION.

- 14 A health information trustee may not adversely affect
- 15 another person, directly or indirectly, because such person
- 16 has exercised a right under this Act, disclosed information
- 17 relating to a possible violation of this Act, or associated
- 18 with, or assisted a person in the exercise of a right under
- 19 this Act.

## TITLE II—RESTRICTIONS ON 1 **USE AND DISCLOSURE** 2 3 SEC. 201. GENERAL RULES REGARDING USE AND DISCLO-4 SURE. 5 (a) General Rule.—A health information trustee may not use or disclose protected health information ex-7 cept as authorized under this title. (b) Scope of Use and Disclosure.— 8 9 (1) Compatibility with purpose for ob-10 TAINING INFORMATION.—A health information 11 trustee may not use, or disclose to any person, pro-12 tected health information unless the use or disclo-13 sure is compatible with and directly related to— 14 (A) the purposes for which the information 15 was obtained by the health information trustee; 16 and 17 (B) in the case where an individual has ex-18 ecuted an authorization, for the specific purpose 19 authorized by the individual. 20 LIMITATION ON AMOUNT OF INFORMA-(2)21 TION.— 22 (A) Use and disclosure.— 23 (i) IN GENERAL.—Every use and dis-

closure of protected health information by

a health information trustee shall be lim-

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ited to the minimum amount of information necessary to accomplish the purpose for which the information is used or disclosed.

- (ii) Nonidentifiable information.—A health information trustee shall use and disclose nonidentifiable health information, in lieu of protected health information, to the maximum extent possible, consistent with the purpose for the use or disclosure.
- (iii) Coded Health Information.—
  A health information trustee shall use and disclose coded health information, in lieu of any other kind of protected health information, to the maximum extent possible, consistent with the purpose for the use or disclosure.
- (B) Collection, Creation, and Requests.—A health information trustee may not collect, create, or request the disclosure of, more protected health information than is necessary to accomplish the purpose for which the information is collected, created, or requested.

1	(c) Special Rules for Protected Health In-
2	FORMATION SUBFILES.—
3	(1) Segregation.—A health information trust-
4	ee shall, upon creating or obtaining protected health
5	information, comply with the request of a subject of
6	such information—
7	(A) to segregate any amount or type of
8	protected health information; and
9	(B) to maintain such protected health in-
10	formation as one or more protected health in-
11	formation subfiles.
12	(2) Disclosure and use.—
13	(A) In general.—Subject to subpara-
14	graph (B), a person, other than a health care
15	provider who is otherwise authorized to access
16	or use protected health information about an
17	individual contained in a protected health infor-
18	mation subfile for purposes of delivering health
19	care to the individual, may not use or disclose
20	any information that is in the subfile, except as
21	authorized under section 202, 203, or 206.
22	(B) Employees, agents, contrac-
23	TORS.—A health information trustee, with re-
24	spect to a protected health information subfile
25	created pursuant to paragraph (1), shall limit

- use of the subfile to those employees, contractors, or agents of the trustee, described by name or job title, who, with respect to the subfile are authorized, pursuant to section 202 or 203, to use or obtain such information.
- 6 (C) Information on existence of
  7 Subfiles.—A health information trustee may
  8 not disclose information about the existence of
  9 a health information subfile to any person who
  10 is not authorized to obtain, access, or use the
  11 subfile.
- 12 (d) No General Requirement To Disclose.—
  13 Nothing in this title that permits a disclosure of protected
  14 health information shall be construed to require such dis-
- 16 (e) Limitations on Disclosure and Use Within 17 a Trustee.—
- 18 (1) CONDITION OF TREATMENT OR PAYMENT.—
  19 A health information trustee may not condition de20 livery of health care, or payment for services, on the
  21 receipt of an authorization described in section 202
  22 or 203 that authorizes the disclosure of protected
  23 health information to any employee, agent, or con24 tractor who does not perform a legitimate and nec-

closure.

- essary function with respect to the purpose for which the information was obtained or created.
- 2) EMPLOYMENT.—A health information trustee may not condition employment on the receipt of
  an authorization described in section 202 or 203
  that authorizes the disclosure of protected health information to any employee, agent, or contractor who
  does not perform a legitimate and necessary function
  with respect to the purpose for which the information was obtained or created.
- 11 (f) IDENTIFICATION OF DISCLOSED INFORMATION AS
  12 PROTECTED INFORMATION.—Except as provided in this
  13 title, a health information trustee may not disclose pro14 tected health information unless such information is clear15 ly identified as protected health information that is subject
  16 to this title.
- 17 (g) Information Identifying Providers.—The 18 Secretary shall issue regulations protecting information 19 identifying health care providers in order to promote the 20 availability of health care services.
- 21 (h) USE OF SOCIAL SECURITY NUMBER.—A Social Security account number, or a derivative of a Social Security account number, may not be used by a health information trustee for any purpose relating to protected health information or the use or disclosure of such information.

- 1 (i) Multiple Records.—No person may aggregate,
  2 compile, link, or match protected health information held
  3 by two or more different health information trustees, or
  4 two or more protected health information subfiles pertain5 ing to an individual, without obtaining specific authoriza6 tion under section 202 or 203 for such use.
  7 (j) No Effect of Agency on Duty or Liability
  8 of Principal.—An agreement or relationship between a
  9 trustee and an agent or contractor does not relieve a
- 12 SEC. 202. AUTHORIZATIONS FOR DISCLOSURE OF PRO-

health information trustee of any duty or liability under

- 13 TECTED HEALTH INFORMATION FOR TREAT-
- 14 MENT OR PAYMENT.
- 15 (a) Written Authorizations.—A health informa-
- 16 tion trustee may disclose protected health information for
- 17 purposes of treatment or payment pursuant to an author-
- 18 ization executed by an individual who is the subject of the
- 19 information (or a person acting for the individual pursu-
- 20 ant to State law) if each of the following requirements is
- 21 met:

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this Act.

- 22 (1) Writing.—The authorization is in written
- or electronic form, signed or electronically authenti-
- cated by the individual, and dated.

- 1 (2) SEPARATE FORMS.—Separate forms author-2 izing disclosures for treatment and separate forms 3 authorizing disclosures for payment processes are 4 provided to the individual.
  - (3) Information described.—The information to be disclosed is specified, or is described, in the authorization.
  - (4) Trustee Described.—The trustee who is authorized to disclose such information is specifically identified, or is described, in the authorization.
  - (5) RECIPIENT DESCRIBED.—The person to whom the information is to be disclosed is specifically identified, or is described, in the authorization.
  - (6) RIGHT TO REVOKE OR AMEND.—The authorization contains an acknowledgement that the individual who is executing the authorization has the right to revoke or amend the authorization, subject to subsection (b).
  - (7) PURPOSE DESCRIBED.—The authorization describes in detail the purpose for which the information will be used.
  - (8) STATEMENT OF INTENDED DISCLOSURES.—
    The authorization contains an acknowledgment that
    the individual who is executing the authorization has
    read a statement of any disclosures of the protected

1	health information that the recipient intends to
2	make.
3	(9) Use and disclosure restricted.—The
4	authorization includes a statement that the informa-
5	tion will be used and disclosed solely for one or more
6	purposes specified in the authorization.
7	(10) Expiration date specified.—The au-
8	thorization specifies a date on which, or event upon
9	which, the authorization expires, which shall be no
10	later than one year after the date on which the au-
11	thorization is executed.
12	(b) REVOCATION OR AMENDMENT OF AUTHORIZA-
13	TION.—
14	(1) In general.—An authorization under sub-
15	section (a) shall be subject to revocation and amend-
16	ment at any time by the individual who executed the
17	authorization, except that—
18	(A) the revocation or amendment shall be
19	in writing; and
20	(B) an authorization executed for the pur-
21	pose of validation of expenditures for health
22	care that the individual has authorized to be
23	rendered may not be revoked.
24	(2) Notice of Revocation.—A health infor-
25	mation trustee who discloses protected health infor-

- 1 mation pursuant to an authorization described in
- 2 subsection (a) that has been revoked shall not be
- 3 subject to any liability or penalty under this Act if
- 4 the trustee has no actual or constructive notice of
- 5 the revocation at the time the trustee makes the dis-
- 6 closure.
- 7 (c) Model Authorizations.—The Secretary, after
- 8 providing notice and opportunity for public comment, shall
- 9 develop and disseminate model written authorizations of
- 10 the type described in subsection (a) and model statements
- 11 of intended disclosures of the type described in subsection
- 12 (a)(7).
- 13 (d) Copy.—A health information trustee who dis-
- 14 closes protected health information pursuant to an author-
- 15 ization under this section shall maintain a copy of the au-
- 16 thorization for not less than 7 years.
- 17 SEC. 203. AUTHORIZATIONS FOR DISCLOSURE OF PRO-
- 18 TECTED HEALTH INFORMATION FOR PUR-
- 19 POSES OTHER THAN TREATMENT OR PAY-
- 20 MENT.
- 21 (a) Written Authorizations.—A health informa-
- 22 tion trustee may disclose protected health information for
- 23 a purpose other than treatment or payment pursuant to
- 24 an authorization executed by an individual who is the sub-
- 25 ject of the information (or a person acting for the individ-

ual pursuant to State law) if each of the following requirements is met: 3 (1) General requirements.—The requirements of paragraphs (1) through (7) of section 202(a). 5 6 (2) Statement of intended disclosures.— 7 The statement of intended disclosure shall be in 8 writing, and shall be received by the individual au-9 thorizing the disclosure on or before the date the au-10 thorization is executed. 11 (3) Expiration date specified.—The au-12 thorization specifies a date on which, or an event 13 upon which, the authorization expires, which shall 14 not occur more than 1 year from the date of the exe-15 cution of the authorization. 16 (b) Limitation on Requests for Authoriza-17 TIONS.— 18 (1) Condition of treatment or payment.— 19 A health information trustee may not condition de-20 livery of treatment, or payment for services, on the 21 receipt of an authorization described in subsection 22 (a). (2) Employment.—A health information trust-23

ee may not adversely affect, or condition, the em-

ployment of any person based on the agreement or

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- 1 refusal of the person to execute or provide an au-
- 2 thorization described in subsection (a).
- 3 (c) REVOCATION OR AMENDMENT OF AUTHORIZA-
- 4 TION.—
- 5 (1) In general.—An individual may in writing
- 6 revoke or amend an authorization described in sub-
- 7 section (a).
- 8 (2) Notice of Revocation.—A health infor-
- 9 mation trustee who discloses protected health infor-
- mation pursuant to an authorization described in
- subsection (a) that has been revoked shall not be
- subject to any liability or penalty under this Act if
- the trustee has no actual or constructive notice of
- the revocation at the time the trustee makes the dis-
- 15 closure.
- 16 (d) Model Authorizations.—The Secretary, after
- 17 notice and opportunity for public comment, shall develop
- 18 and disseminate model written authorizations of the type
- 19 described in subsection (a) and model statements of the
- 20 intended disclosures of the type described in subsection
- 21 (a)(2).
- 22 SEC. 204. CREATION OF NONIDENTIFIABLE AND CODED IN-
- FORMATION.
- 24 (a) Creation of Nonidentifiable Informa-
- 25 TION.—A health information trustee may disclose pro-

tected health information about an individual to an employee, agent, or contractor for the purpose of creating nonidentifiable health information if— 3 4 (1) the individual is informed of the purpose for 5 the creation of the nonidentifiable information; 6 (2) the individual is given the option to prohibit 7 any specific uses of the nonidentifiable information, 8 such as use of the information for marketing pur-9 poses; and 10 (3) the health information trustee does not con-11 dition the delivery of health care, payment for serv-12 ices, or employment, on the granting by the individ-13 ual of permission to create the nonidentifiable infor-14 mation. 15 (b) Creation of Coded Health Information.— A health care provider may create coded health informa-16 17 tion, or disclose protected health information about an in-18 dividual to an employee, agent, or contractor for the purpose of creating coded health information, if— 19 20 (1) the individual is informed of the purpose for 21 the creation of the coded information; 22 (2) the individual is informed of which persons 23 will have the authority to link or match the coded

health information to reveal the identity of the indi-

vidual;

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- 1 (3) the individual gives written authorization 2 for a disclosure for this purpose in accordance with 3 subsections (a)(1) through (a)(3), (c), and (d) of 4 section 203;
- 5 (4) the health care provider does not condition 6 the delivery of health care, payment for services, em-7 ployment, or the terms of employment on the grant-8 ing by the individual of permission to create the 9 coded health information; and
- 10 (5) agents and contractors who receive pro-11 tected health information for the purpose of creating 12 coded health information use the information exclu-13 sively for such purpose.

## 14 SEC. 205. NEXT OF KIN AND DIRECTORY INFORMATION.

- (a) NEXT OF KIN.—Except as provided in subsection (c), a health care provider, or a person who receives protected health information under section 206, may disclose protected health information regarding an individual who is an inpatient in a health care facility to the individual's next of kin, to an individual representative of the individual, or to an individual with whom the individual has a
- 23 (1) the individual who is the subject of the in-24 formation—

significant personal relationship if—

1	(A) has been notified of the individual's
2	right to object at the time of admission to the
3	facility and has not objected to the disclosure;
4	or
5	(B) is in a physical or mental condition
6	such that it would not be possible to notify the
7	individual of the right to object and there are
8	no prior indications that the individual would
9	object; and
10	(2) the information relates to health care cur-
11	rently being provided to the individual at the time
12	of the disclosure.
13	(b) Directory Information.—
14	(1) Disclosure.—Except as provided in sub-
15	section (c), a health information trustee may disclose
16	to any person protected health information concern-
17	ing an individual if the information is described in
18	paragraph (2) and the individual who is the subject
19	of the information—
20	(A) has been notified of the individual's
21	right to object and has not objected to the dis-
22	closure; or
23	(B) is in a physical or mental condition
24	such that it would not be possible to notify the
25	individual of the right to object and there are

1	no prior indications that the individual would
2	object.
3	(2) Information described.—The informa-
4	tion referred to in paragraph (1) is any one or more
5	of the following:
6	(A) The name of the individual who is the
7	subject of the information.
8	(B) The general health status of the indi-
9	vidual, described as critical, poor, fair, stable,
10	or satisfactory, or in terms denoting similar
11	conditions.
12	(C) The location of the individual, if on a
13	premises controlled by a health care provider.
14	(c) Exception.—A health care provider may not dis-
15	close protected health information without specific author-
16	ization pursuant to section 203—
17	(1) in the case of a disclosure under subsection
18	(b), if disclosure of the location of the individual
19	would reveal specific information about the physical
20	or mental condition of the individual; or
21	(2) in the case of a disclosure under subsection
22	(a) or (b), if the provider has reason to believe that
23	the disclosure could lead to physical, mental, or emo-
24	tional harm to the individual.
25	(d) Deceased Individual.—

- 1 (1) IDENTIFICATION.—A health information 2 trustee may disclose protected health information if 3 necessary to assist in the identification of a deceased 4 individual.
- 5 (2) Regulations.—The Secretary shall de-6 velop and establish through regulation a procedure 7 for obtaining protected health information relating 8 to a deceased individual when there is no individual 9 representative for such individual.

### 10 SEC. 206. EMERGENCY CIRCUMSTANCES.

- 11 (a) Disclosure When Subject of Information
- 12 Is in Danger.—A health information trustee who re-
- 13 ceives protected health information under this title may
- 14 disclose such protected health information to a health care
- 15 provider or emergency medical personnel, or use such in-
- 16 formation in emergency medical circumstances, to the ex-
- 17 tent necessary to protect the health or safety of an individ-
- 18 ual who is a subject of such information from serious im-
- 19 minent harm.
- 20 (b) Disclosure When Another Individual Is in
- 21 Danger.—A health information trustee may disclose pro-
- 22 tected health information, to the extent necessary, where
- 23 such trustee determines that—

1	(1) there is an identifiable threat of serious in-
2	jury or death to an identifiable individual or group
3	of individuals; and
4	(2) the disclosure of the information to the per-
5	son is necessary to prevent or significantly reduce
6	the possibility of such threat.
7	SEC. 207. OVERSIGHT.
8	(a) In General.—A health information trustee,
9	other than a public health authority or a health re-
10	searcher, may disclose protected health information to—
11	(1) a health oversight agency for any function
12	of the agency authorized by law, if—
13	(A) there is probable cause to believe fraud
14	has been committed;
15	(B) the oversight agency is investigating
16	the fraud;
17	(C) the oversight agency has obtained a
18	subpoena for purposes of obtaining the informa-
19	tion; and
20	(D)(i) a subject of the information is be-
21	lieved to have committed the fraud; or
22	(ii) the information is necessary to permit
23	the agency to investigate the fraud; or
24	(2) a health oversight agency charged by law to
25	protect individuals from harm, abuse, neglect, or ex-

1	ploitation, if the information is necessary to inves-
2	tigate whether abuse, neglect, or exploitation of an
3	individual has occurred.
4	(b) Use of Coded Health Information.—The
5	health oversight agency shall receive exclusively coded
6	health information under subsection (a) whenever the pur-
7	pose of the agency may be accomplished using only such
8	information.
9	(c) Notice to Subjects.—In any case where an in-
10	dividual who is a subject of protected health information
11	disclosed under subsection (a) is not believed to have com-
12	mitted fraud, the individual shall be notified, at the first
13	practical opportunity—
14	(1) that an investigation described in such sub-
15	section is being conducted;
16	(2) of the reason why disclosure of the informa-
17	tion is necessary; and
18	(3) of all intended subsequent disclosures of the
19	information that the agency intends to make.
20	(d) USE IN ACTION AGAINST INDIVIDUALS.—
21	(1) In General.—Subject to paragraph (2),
22	protected health information about an individual
23	that is disclosed under this section may not be used
24	in, or disclosed to any person for use in, an adminis-

trative, civil, or criminal action or investigation di-

- 1 rected against the individual, unless the action or in-
- 2 vestigation arises out of and is directly related to the
- 3 purpose for which the disclosure was authorized
- 4 under subsection (a).
- 5 (2) Special rule.—A health oversight agency
- 6 may not disclose protected health information re-
- 7 ceived by the agency under subsection (a)(2) for any
- 8 purpose other than protecting individuals from
- 9 harm, abuse, neglect, or exploitation.
- 10 (e) Public Health and Health Research.—A
- 11 public health authority may disclose protected health in-
- 12 formation to a health oversight agency only if such infor-
- 13 mation is necessary for use in an investigation of whether
- 14 the authority has committed fraud. A health researcher
- 15 may disclose protected health information to a health over-
- 16 sight agency only if such information is necessary for use
- 17 in an investigation of whether the researcher has commit-
- 18 ted fraud.
- 19 SEC. 208. ACCREDITATION.
- 20 (a) In General.—A health information trustee may
- 21 disclose protected health information to an accrediting
- 22 body for the exclusive purpose of permitting the accredit-
- 23 ing body to carry out accreditation, licensing, or
- 24 credentialing activities.

1	(b) Use of Coded Health Information.—The
2	accrediting body shall receive exclusively coded health in
3	formation under subsection (a) whenever the purpose of
4	the body may be accomplished using only such informa-
5	tion.
6	(c) RESTRICTION ON USE AND DISCLOSURE.—A per-
7	son to whom protected health information is disclosed
8	under subsection (a) may not use or disclose the informa-
9	tion for any purpose other than the purpose for which the
10	information was disclosed to the person.
11	SEC. 209. PUBLIC HEALTH.
12	(a) Disclosures by Providers.—A health care
13	provider may disclose protected health information about
14	an individual to a public health authority where—
15	(1) the information is disclosed for the purpose
16	of permitting the authority to ascertain the identity
17	of such individual;
18	(2) there is a specific nexus between such indi-
19	vidual's identity and a threat of death or injury to
20	any person; and
21	(3) knowledge of such individual's identity
22	would allow the public health authority to prevent or
23	significantly reduce the possibility of injury or death
24	to any person.

- 1 (b) Limitation on Liability.—A health informa-
- 2 tion trustee shall not be liable to any person for a disclo-
- 3 sure of protected health information under this section
- 4 that is made based upon a good faith belief by the trustee
- 5 of a representation made by a public health authority that
- 6 such disclosure satisfies the requirements of subsection
- 7 (a).
- 8 (c) Limitation on Use and Disclosure by Pub-
- 9 LIC HEALTH AUTHORITIES.—A public health authority
- 10 may not use or disclose protected health information for
- 11 any purpose other than for public health reporting, sur-
- 12 veillance, protection, investigation, or intervention.

#### 13 SEC. 210. HEALTH RESEARCH.

- 14 (a) IN GENERAL.—A health information trustee may
- 15 disclose protected health information, other than coded
- 16 health information, to a health researcher for use in a re-
- 17 search project engaged in by the health researcher, if an
- 18 institutional review board, using standards and procedures
- 19 that are generally consistent with the official written pol-
- 20 icy of the Secretary with respect to research involving
- 21 human subjects conducted, supported, or otherwise subject
- 22 to regulation by Federal departments and agencies, and
- 23 this Act, determines that the research project—
- 24 (1) requires use of the protected health infor-
- 25 mation for the effectiveness of the project and could

1	not be carried out with either coded or nonidentifi-
2	able health information; and
3	(2) has obtained an authorization for the disclo-
4	sure executed by an individual who is a subject of
5	the information that—
6	(A) is consistent with the requirements of
7	section 203; and
8	(B) in a case where the researcher foresees
9	using or disclosing the information for any pur-
10	pose subsequent to the conclusion of the
11	project, specifically states—
12	(i) such intent; and
13	(ii) that the individual has the right
14	to limit such subsequent uses or disclo-
15	sures consistent with this Act.
16	(b) Use of Coded or Nonidentifiable Health
17	Information.—A health information trustee may dis-
18	close coded health information that is not contained in a
19	protected health information subfile, or nonidentifiable
20	health information, to a health researcher for use in a re-
21	search project engaged in by the health researcher upon
22	approval of the proposed research by an institutional re-
23	view board, regardless of whether the researcher has ob-
24	tained an authorization for the disclosure consistent with
25	the requirements of section 203.

1	(c) Anonymization of Previously Stored Bio-
2	LOGICAL SAMPLES.—The Secretary may develop interim
3	guidelines for the use by a health researcher of biological
4	samples derived from a human body collected before the
5	effective date of this Act. Such guidelines shall address
6	the requirements pertinent to a health researcher who
7	wishes to use stored biological samples derived from a
8	human body in nonidentifiable or coded form. Such guide-
9	lines shall authorize a health researcher, for the purpose
10	of facilitating future health research—
11	(1) to convert protected health information into
12	nonidentifiable information or coded health informa-
13	tion, if such conversion is permitted in a written au-
14	thorization; or
15	(2) if no such authorization exists, to make
16	such conversion after publishing notice of the re-
17	searcher's intent and providing individuals the op-
18	portunity to prohibit the use of their biological sam-
19	ples for such purpose.
20	(d) Obligations of Recipient.—A person who re-
21	ceives protected health information pursuant to subsection
22	(a)—

(1) shall remove or destroy, at the earliest op-

portunity consistent with the purposes of the project,

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1	information that would enable an individual to be
2	identified, unless—
3	(A) an institutional review board has de-
4	termined that there is a health or research jus-
5	tification for retention of such identifiers; and
6	(B) there is an adequate plan to protect
7	the identifiers from disclosure that is inconsist-
8	ent with this section; and
9	(2) shall use the information solely for purposes
10	of the health research project for which disclosure
11	was authorized by an institutional review board
12	under subsection (a).
13	SEC. 211. JUDICIAL AND ADMINISTRATIVE PURPOSES.
14	A health care provider, health plan, health oversight
15	agency, employer, school, institution of higher education,
16	insurer, court, or a person who receives protected health
17	information pursuant to section 206 may disclose pro-
18	tected health information about an individual—
19	(1) pursuant to the requirements governing
20	subpoenas, warrants, and court orders under sec-
21	tions 212 and 213, where such information has been
22	determined to be discoverable by a court under any
23	applicable rules of civil or criminal procedure;

- 1 (2) to a court, and to others as ordered by the 2 court, if the information is developed in response to 3 a court-ordered physical or mental examination;
- 4 (3) where the subject of such information has 5 brought a claim for medical malpractice against a 6 health care provider and the information is nec-7 essary for the defense of the claim; and
- 8 (4) to legal counsel for the person making the 9 disclosure, where the disclosure is necessary to en-10 sure compliance with this Act or any other legal re-11 quirement.
- 12 SEC. 212. GENERAL REQUIREMENTS GOVERNING SUBPOE-
- 13 NAS.
- 14 (a) IN GENERAL.—A health care provider, health
- 15 plan, health oversight agency, employer, school, institution
- 16 of higher education, insurer, court, or a person who re-
- 17 ceives protected health information pursuant to section
- 18 206 may disclose protected health information to any per-
- 19 son, other than a law enforcement authority, under section
- 20 211(1), if the disclosure is pursuant to a subpoena issued
- 21 on behalf of a party to a lawsuit or other judicial or ad-
- 22 ministrative proceeding who has complied with subsection
- 23 (b) or (c), and subsection (d).
- 24 (b) Request for Access by Counsel To Review
- 25 PROTECTED HEALTH INFORMATION.—A person may have

- 1 access to protected health information under subsection
- 2 (a), by means solely of a review of the information by the
- 3 person's counsel, acting in the capacity of an officer of
- 4 the court, and on premises of, and under the control of,
- 5 the court, if—
- 6 (1) the person has included in a subpoena a
- 7 proffer of evidence specifying with reasonable speci-
- 8 ficity the information to which access is sought and
- 9 the precise grounds for seeking such access for re-
- 10 view;
- 11 (2) a copy of such subpoena for access to re-
- view, together with a notice of the individual's right
- to challenge the subpoena under subsection (d), has
- been served upon the individual on or before the
- date of return of the subpoena;
- 16 (3)(A) 15 days have passed since the date of
- service on the individual, and within that period the
- individual has not initiated a challenge in accordance
- with subsection (d)(1); or
- (B) such access is ordered by the court; and
- 21 (4) such counsel agrees not to copy such infor-
- 22 mation, remove such information from the court
- premises, or disclose the information to any person
- other than the person permitted access under this
- subsection.

1	(c) Request To Obtain Protected Health In-
2	FORMATION FOR INTRODUCTION IN COURT.—
3	(1) REQUIREMENTS FOR OBTAINING INFORMA-
4	TION.—A person may obtain protected health infor-
5	mation about an individual pursuant to a subpoena
6	for purposes of introducing such information as evi-
7	dence in a court, only if—
8	(A) counsel for the person has obtained ac-
9	cess to the information under subsection (b);
10	(B) a copy of the subpoena to obtain the
11	information for introduction in court, specifying
12	the precise information sought and the precise
13	grounds for seeking introduction of the infor-
14	mation as evidence in court, together with a no-
15	tice of the individual's right to challenge the
16	subpoena under subsection (d), has been served
17	upon the individual on or before the date of re-
18	turn of such subpoena; and
19	(C)(i) 15 days have passed since the date
20	of service on the individual, and within that
21	time period the individual has not indicated a
22	challenge in accordance with subsection $(d)(1)$
23	or
24	(ii) the information is ordered to be pro-
25	vided to the court

(2) USE AND DISCLOSURE.—A person who obtains protected health information under paragraph (1) may use and disclose such information only for the purpose of prosecuting or defending the lawsuit or other judicial or administrative proceeding described in subsection (a).

# (d) Challenge Procedures.—

(1) Motion to Quash subpoena.—After being served of a copy of a subpoena seeking access for review by counsel of, or access to, protected health information under subsection (b), or a subpoena seeking to obtain protected health information for introduction as evidence in court, under subsection (c), an individual who is a subject of such information may file in any court of competent jurisdiction a motion to quash the subpoena.

## (2) Standard for decision.—

- (A) IN GENERAL.—The court shall grant a motion under paragraph (1) unless the respondent demonstrates—
  - (i) by clear and convincing evidence that the information is necessary in relation to the lawsuit or other judicial or administrative proceeding with respect to

1	which the information is sought, includ-
2	ing—
3	(I) a demonstration that use or
4	disclosure of solely nonidentifiable
5	health information would be insuffi-
6	cient to accomplish the purpose for
7	which the information is sought; and
8	(II) if protected health informa-
9	tion that is not coded health informa-
10	tion is sought, a demonstration that
11	use or disclosure of coded health in-
12	formation would be insufficient to ac-
13	complish the purpose for which the in-
14	formation is sought; and
15	(ii) that the need of the respondent
16	for the information outweighs the privacy
17	interest of the individual.
18	(B) Criteria for Decision.—In deter-
19	mining whether the need of the respondent for
20	the information outweighs the privacy interest
21	of the individual, the court shall consider—
22	(i) the particular purpose for which
23	the information was collected;
24	(ii) the invasion of the individual's
25	privacy caused by the disclosure;

1	(iii) the degree to which disclosure of
2	the information would embarrass, injure,
3	or further invade, the privacy of the indi-
4	vidual;
5	(iv) the effect of the disclosure on the
6	individual's future health care;
7	(v) the importance of the information
8	to the lawsuit or proceeding; and
9	(vi) any other relevant factor.
10	(3) Attorney's fees.—In the case of a mo-
11	tion brought under paragraph (1) in which the indi-
12	vidual who brought the motion has prevailed in
13	whole or in part, the court may assess against the
14	respondent a reasonable attorney's fee and other liti-
15	gation costs and expenses (including expert fees)
16	reasonably incurred.
17	(e) SEALING OF INFORMATION.—Any portion of a
18	record of a court that contains protected health informa-
19	tion disclosed under this section shall be kept by the court
20	under seal and used or disclosed only pursuant to an order
21	of the court consistent with this section.
22	SEC. 213. ADDITIONAL REQUIREMENTS FOR LAW ENFORCE-
23	MENT ACCESS.
24	(a) Law Enforcement Subpoenas and War-
25	RANTS IN GENERAL.—A health care provider, health plan,

- 1 health oversight agency, employer, school, institution of
- 2 higher education, insurer, court, or a person who receives
- 3 protected health information pursuant to section 206 may
- 4 disclose protected health information to a law enforcement
- 5 authority under section 211(1), if—
- 6 (1)(A) the disclosure is made pursuant to a
- 7 subpoena for review under section 212(b), a sub-
- 8 poena for purposes of introducing evidence in a
- 9 court under section 212(c), or both, issued under the
- authority of a grand jury or a court; and
- 11 (B) the requirements of subsections (b) through
- 12 (e) of section 212, and subsections (b) and (c) of
- this section, are satisfied;
- 14 (2) the disclosure is made pursuant to a judicial
- 15 warrant for search and seizure and the requirements
- of subsection (d) are satisfied; or
- 17 (3)(A) the disclosure is made pursuant to a
- subpoena for purposes of introducing evidence in a
- court under section 212(c), issued under the author-
- 20 ity of a grand jury or a court, and obtained pursu-
- ant to subsection (d)(5) following the execution of a
- judicial warrant for search and seizure under sub-
- 23 section (d); and
- (B) the requirements of subsections (c) through
- (e) (other than subsection (c)(1)(A)) of section 212,

- and subsections (b) and (c) of this section, are satis-
- 2 fied.
- 3 (b) Clear and Convincing Requirement.—A law
- 4 enforcement authority may not obtain protected health in-
- 5 formation about an individual under subsection (a) unless
- 6 the authority demonstrates by clear and convincing evi-
- 7 dence that the information is necessary to a legitimate law
- 8 enforcement inquiry into a particular violation of criminal
- 9 law being conducted by the authority.
- 10 (c) Limitation on Use and Disclosure for
- 11 OTHER LAW ENFORCEMENT INQUIRIES.—Protected
- 12 health information about an individual that is disclosed
- 13 under this section may not be used in, or disclosed to any
- 14 person for use in, any administrative, civil, or criminal ac-
- 15 tion or investigation directed against the individual, unless
- 16 the action or investigation arises out of, or is directly re-
- 17 lated to, the law enforcement inquiry for which the infor-
- 18 mation was obtained.
- 19 (d) Requirements for Warrants for Search
- 20 AND SEIZURE.—
- 21 (1) LIMITED PURPOSE.—A health care pro-
- vider, health plan, health oversight agency, em-
- ployer, school, institution of higher education, in-
- surer, or a person who receives protected health in-
- formation pursuant to section 206 may disclose pro-

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- tected health information to a law enforcement authority pursuant to a warrant for search and seizure, issued under the authority of a court, for the exclusive purpose of permitting the authority to secure the information described in the warrant for delivery to the court.
  - LIMITATION ON EXECUTION WAR-RANTS.—In executing a warrant under paragraph (1), a law enforcement authority shall engage in the most minimal examination of protected health information that is necessary in order to determine whether the information is or is not within the scope of the warrant. The authority immediately shall place any such information that the authority determines is within the scope of the warrant under seal, and shall deliver such sealed information, without any further examination or other use or disclosure, to the court. The authority may not use or disclose for any purpose protected health information that the authority determines is not within the scope of the warrant, but that is obtained or discovered by the authority directly or indirectly through execution of the warrant.
  - (3) Notice of Warrant.—A law enforcement authority that obtains protected health information

about an individual pursuant to the execution of a warrant under paragraph (2) shall, not later than 30 days after the date of such execution, serve the individual with, or mail to the last known address of the individual, a notice that protected health information about the individual was obtained, together with a notice of the individual's right to challenge the warrant under paragraph (4).

- (4) CHALLENGE PROCEDURES FOR WAR-RANTS.—
  - (A) Motion to quash.—Within 15 days after the date of service of a notice of execution of a warrant of a law enforcement authority seeking protected health information about an individual under paragraph (3), the individual (or any other person who was in possession of the information and against whom the warrant was executed) may file in any court of competent jurisdiction a motion to quash the warrant.
  - (B) STANDARD FOR DECISION.—The court shall grant a motion under subparagraph (A) unless the law enforcement authority demonstrates by clear and convincing evidence that the protected health information is necessary to

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- a legitimate law enforcement inquiry being conducted by the law enforcement authority and the government authority's need for the information outweighs the privacy interest of the individual.
  - (C) Attorney's fees.—In the case of a motion brought under subparagraph (A) in which the individual has prevailed, in whole or in part, the court may assess against the law enforcement authority reasonable attorney's fees and other litigation costs (including expert fees) reasonably incurred.
- (5) ACTION IN COURT ON INFORMATION DELIV-ERED.—Upon termination of the period described in paragraph (4)(A) (in a case where a motion to quash is not filed under such paragraph), or upon the denial of a motion to quash under such paragraph, the law enforcement authority may obtain protected health information delivered to the court under this subsection solely through a disclosure under subsection (a)(3).
- (6) SEALING OF INFORMATION.—Any protected health information that is delivered to a court under this section shall be kept by the court under seal and

1 used or disclosed only pursuant to an order of the 2 court consistent with this section. TITLE III—SANCTIONS 3 **Subtitle A—Civil Sanctions** 4 SEC. 301. CIVIL PENALTY. 6 (a) VIOLATION.—Any person who the Secretary determines has materially failed to comply with this Act shall 8 be subject, in addition to any other penalties that may be prescribed by law, to— 10 (1) a civil penalty of not more than \$25,000 for 11 each such violation, but not to exceed \$150,000 in 12 the aggregate for multiple violations in any one year; 13 and 14 (2) a civil penalty of not more than \$500,000 15 and exclusion from participation in the program 16 under title XVIII of the Social Security Act, the pro-17 gram under title XIX of such Act, and any other 18 federally funded health care program, if the Sec-19 retary finds that such violations have occurred with 20 such frequency as to constitute a general business 21 practice. 22 (b) Procedures for Imposition of Penalties.— 23 Section 1128A of the Social Security Act, other than subsections (a) and (b) and the second sentence of subsection

(f) of that section, shall apply to the imposition of a civil,

monetary, or exclusionary penalty under this section in the same manner as such provisions apply with respect to the imposition of a penalty under section 1128A of such Act. 3 4 SEC. 302. CIVIL ACTION. 5 (a) IN GENERAL.—An individual who is aggrieved by conduct in violation of this Act may bring a civil action 6 7 to recover— 8 (1) such preliminary and equitable relief as the 9 court determines to be appropriate; (2) the greater of— 10 11 (A) actual damages; and 12 (B) liquidated damages of— 13 (i) \$25,000, in the case of a material 14 violation; or 15 (ii) \$50,000, in the case of a violation 16 that was willful or resulted in profit or 17 monetary gain; and 18 (3) punitive damages. 19 (b) ATTORNEY'S FEES.—In the case of a civil action brought under subsection (a) in which the individual has 20 21 substantially prevailed, the court may assess against the respondent a reasonable attorney's fee and other litigation costs and expenses (including expert fees) reasonably in-24 curred.

1	(c) Limitation.—No action may be commenced
2	under this section by an individual more than 3 years after
3	the date on which the violation was or should reasonably
4	have been discovered by the individual.
5	Subtitle B—Criminal Sanctions
6	SEC. 311. WRONGFUL DISCLOSURE OF PROTECTED
7	HEALTH INFORMATION.
8	(a) Offense.—Whoever knowingly—
9	(1) obtains protected health information relat-
10	ing to an individual in violation of this Act;
11	(2) discloses protected health information to an-
12	other person in violation of this Act;
13	(3) coerces or attempts to coerce a health infor-
14	mation trustee to disclose protected health informa-
15	tion in violation of this title; or
16	(4) without authorization pursuant to this Act,
17	identifies or attempts to identify an individual who
18	is the subject of protected health information that a
19	health information trustee has converted into coded
20	health information,
21	shall be punished as provided in subsection (b).
22	(b) Penalties.—A person referred to in subsection
23	(a) shall be fined under title 18,
24	United States Code, imprisoned not more than 1 year, or
25	both except that—

- 1 (1) if the offense is committed under false pre2 tenses, the person shall be fined under title 18,
  3 United States Code, imprisoned not more than 5
  4 years, or excluded from participation in the program
  5 under title XVIII of the Social Security Act, the pro6 gram under title XIX of such Act, or any other fed7 erally funded health care program, or any combina8 tion of such penalties; and
- 9 (2) if the offense is committed with intent to 10 sell, transfer, or use protected health information for 11 commercial advantage, personal gain, or malicious 12 harm, the person shall be fined under title 18, Unit-13 ed States Code, or imprisoned not more than 10 14 vears, or excluded from participation in the program 15 under title XVIII of the Social Security Act, the pro-16 gram under title XIX of such Act, or any other fed-17 erally funded health care program, or any combina-18 tion of such penalties.

# TITLE IV—MISCELLANEOUS

20 SEC. 401. REGULATIONS.

- 21 (a) Promulgation.—
- 22 (1) Consultation with advisory group.—
  23 In promulgating regulations under this Act, the Sec24 retary shall appoint and consult an advisory group
  25 of knowledgeable individuals.

1	(2) Membership.—The advisory group shall
2	consist of at least 7 but no more than 12 individ-
3	uals, including representatives of—
4	(A) health care providers;
5	(B) health care consumers;
6	(C) health plans;
7	(D) privacy advocates; and
8	(E) electronic security experts.
9	(3) Responsibilities.—The advisory group
10	shall review all proposed rules and regulations and
11	submit recommendations to the Secretary. The advi-
12	sory group shall also assist the Secretary in estab-
13	lishing the standards for compliance with rules and
14	regulations, in developing an annual report to the
15	Congress on the status of the requirements set forth
16	in this Act, their cost impact, and any recommenda-
17	tions for modifications to this Act in order to ensure
18	efficient and confidential electronic interchange of
19	protected health information.
20	(b) Consultation With Others.—In promulgat-
21	ing regulations under this Act, the Secretary may con-
22	sult—
23	(1) privacy, industry, health care professional,
24	and consumer groups;
25	(2) medical societies: and

1	(3) academic computer security and privacy ex-
2	perts.
3	SEC. 402. RELATIONSHIP TO OTHER LAWS.
4	(a) In General.—Nothing in this Act shall be con-
5	strued to preempt any provision of State law or any privi-
6	lege, whether derived from statute or common law, that—
7	(1) more completely protects the confidentiality
8	or privacy of an individual with respect to protected
9	health information about the individual than does
10	this Act; or
11	(2) provides a greater right of access to pro-
12	tected health information to a subject of the infor-
13	mation than does this Act.
14	(b) Criminal Penalties.—A State may establish
15	and enforce criminal penalties with respect to a failure to
16	comply with a provision of this Act.
17	(c) Privileges.—This Act does not preempt or mod-
18	ify State common or statutory law to the extent such law
19	concerns a privilege of a witness or person in a court of
20	the State. This Act does not supersede or modify Federal
21	common or statutory law to the extent such law concerns
22	a privilege of a witness or person in a court of the United
23	States and more completely protects the confidentiality or
24	privacy of an individual with respect to protected health

25 information about the individual than does this Act. The

- execution of an authorization pursuant to section 202 or 203 may not be construed as a waiver of any such privi-3 lege. 4 (d) Certain Duties Under State or Federal Law.—This Act does not preempt, supersede, or modify the operation of any of the following: 6 7 (1) Any law that provides for the reporting of vital statistics such as birth or death information. 8 9 (2) Any law requiring the reporting of abuse or 10 neglect information about any individual. 11 (3) Any State law relating to public or mental 12 health that prevents or otherwise restricts disclosure 13 of protected health information otherwise permitted 14 under this Act. 15 (4) Subpart II of part E of title XXVI of the 16 Public Health Service Act (relating to notifications 17 of emergency response employees of possible expo-18 sure to infectious diseases). 19 (5) Any Federal law or regulation governing 20 confidentiality of alcohol and drug patient records. 21 (6) The Americans With Disabilities Act of 22 1990. 23 (7) Any Federal or State statute that estab-
- lishes a privilege for records used in health professional peer review activities.

#### 1 SEC. 403. EFFECTIVE DATES.

- 2 (a) In General.—Except as provided in subsection
- 3 (b), this Act shall take effect on the date that is 18 months
- 4 after the date of the enactment of this Act.
- 5 (b) Provisions Effective Immediately.—A pro-
- 6 vision of this Act shall take effect on the date of the enact-
- 7 ment of this Act if the provision imposes on the Secretary
- 8 a duty to develop, establish, or promulgate regulations,
- 9 guidelines, or model forms.
- 10 (c) Deadline for Regulations.—The Secretary
- 11 shall promulgate regulations implementing this Act not
- 12 later than the date that is 12 months after the date of
- 13 the enactment of this Act.

#### 14 SEC. 404. APPLICABILITY.

- 15 (a) Protected Health Information.—Except as
- 16 provided in subsection (b), the provisions of this Act shall
- 17 apply to any protected health information that is received,
- 18 created, used, maintained, or disclosed by a health infor-
- 19 mation trustee on or after the date that is 18 months after
- 20 the date of the enactment of this Act, regardless of wheth-
- 21 er the information existed or was disclosed prior to such
- 22 date.
- 23 (b) Authorizations for Disclosures.—An au-
- 24 thorization for the disclosure of protected health informa-
- 25 tion about a protected individual that is executed by the
- 26 individual before the date that is 18 months after the date

- 1 of the enactment of this Act, and is recognized and valid
- 2 under State law on the day before such date, shall remain
- 3 valid and shall not be subject to the requirements of title
- 4 II until the date that is 30 months after the date of the
- 5 enactment of this Act, or the occurrence of the date or
- 6 event in the authorization upon which the authorization
- 7 expires, whichever occurs earlier.

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