104TH CONGRESS 1ST SESSION H.R.435

To establish a code of fair information practices for health information, to amend section 552a of title 5, United States Code, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 9, 1995

Mr. CONDIT introduced the following bill; which was referred to the Committee on Commerce and, in addition, to the Committees on Government Reform and Oversight and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

- To establish a code of fair information practices for health information, to amend section 552a of title 5, United States Code, 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 "Fair Health Information Practices Act of 1995".
 - 6 (b) TABLE OF CONTENTS.—The table of contents for
 - 7 this Act is as follows:
 - Sec. 1. Short title; table of contents.
 - Sec. 2. Findings and purposes.

Sec. 3. Definitions.

TITLE I—FAIR HEALTH INFORMATION PRACTICES

Subtitle A—Duties of Health Information Trustees

- Sec. 101. Inspection of protected health information.
- Sec. 102. Amendment of protected health information.
- Sec. 103. Notice of information practices.
- Sec. 104. Accounting for disclosures.
- Sec. 105. Security.

Subtitle B-Use and Disclosure of Protected Health Information

- Sec. 111. General limitations on use and disclosure.
- Sec. 112. Authorizations for disclosure of protected health information.
- Sec. 113. Treatment, payment, and oversight.
- Sec. 114. Next of kin and directory information.
- Sec. 115. Public health.
- Sec. 116. Health research.
- Sec. 117. Emergency circumstances.
- Sec. 118. Judicial and administrative purposes.
- Sec. 119. Law enforcement.
- Sec. 120. Subpoenas, warrants, and search warrants.
- Sec. 121. Health information service organizations.

Subtitle C—Access Procedures and Challenge Rights

- Sec. 131. Access procedures for law enforcement subpoenas, warrants, and search warrants.
- Sec. 132. Challenge procedures for law enforcement subpoenas.
- Sec. 133. Access and challenge procedures for other subpoenas.
- Sec. 134. Construction of subtitle; suspension of statute of limitations.
- Sec. 135. Responsibilities of Secretary.

Subtitle D—Miscellaneous Provisions

- Sec. 141. Payment card and electronic payment transactions.
- Sec. 142. Access to protected health information outside of the United States.
- Sec. 143. Standards for electronic documents and communications.
- Sec. 144. Duties and authorities of affiliated persons.
- Sec. 145. Agents and attorneys.
- Sec. 146. Minors.
- Sec. 147. Maintenance of certain protected health information.

Subtitle E—Enforcement

- Sec. 151. Civil actions.
- Sec. 152. Civil money penalties.
- Sec. 153. Alternative dispute resolution.
- Sec. 154. Amendments to criminal law.

TITLE II—AMENDMENTS TO TITLE 5, UNITED STATES CODE

Sec. 201. Amendments to title 5, United States Code.

TITLE III—REGULATIONS, RESEARCH, AND EDUCATION; EFFEC-TIVE DATES; APPLICABILITY; AND RELATIONSHIP TO OTHER LAWS

Sec. 301. Regulations; research and education.

Sec. 302. Effective dates.

Sec. 303. Applicability.

Sec. 304. Relationship to other laws.

1 SEC. 2. FINDINGS AND PURPOSES.

2 (a) FINDINGS.—The Congress finds as follows:

3 (1) The right to privacy is a personal and fun4 damental right protected by the Constitution of the
5 United States.

6 (2) The improper use or disclosure of personally 7 identifiable health information about an individual 8 may cause significant harm to the interests of the 9 individual in privacy and health care, and may un-10 fairly affect the ability of the individual to obtain 11 employment, education, insurance, credit, and other 12 necessities.

(3) Current legal protections for health information vary from State to State and are inadequate
to meet the need for fair information practices
standards.

17 (4) The movement of individuals and health in18 formation across State lines, access to and exchange
19 of health information from automated data banks
20 and networks, and the emergence of multistate
21 health care providers and payors create a compelling
22 need for uniform Federal law, rules, and procedures
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governing the use, maintenance, and disclosure of
 health information.

(5) Uniform rules governing the use, maintenance, and disclosure of health information are an
essential part of health care reform, are necessary to
support the computerization of health information,
and can reduce the cost of providing health services
by making the necessary transfer of health information more efficient.

10 (6) An individual needs access to health infor-11 mation about the individual as a matter of fairness, 12 to enable the individual to make informed decisions 13 about health care, and to correct inaccurate or in-14 complete information.

15 (b) PURPOSES.—The purposes of this Act are as16 follows:

17 (1) To define the rights of an individual with
18 respect to health information about the individual
19 that is created or maintained as part of the health
20 treatment and payment process.

(2) To define the rights and responsibilities of
a person who creates or maintains individually identifiable health information that originates or is used
in the health treatment or payment process.

(3) To establish effective mechanisms to enforce 1 2 the rights and responsibilities defined in this Act. 3 **SEC. 3. DEFINITIONS.** 4 (a) DEFINITIONS RELATING ТО PROTECTED 5 HEALTH INFORMATION.—For purposes of this Act: (1) DISCLOSE.—The term "disclose", when 6 7 used with respect to protected health information that is held by a health information trustee, means 8 9 to provide access to the information, but only if such access is provided by the trustee to a person other 10 11 than— (A) the trustee or an officer or employee of 12 13 the trustee: (B) an affiliated person of the trustee; or 14 15 (C) a protected individual who is a subject of the information. 16 17 DISCLOSURE.—The "'disclosure" (2)term 18 means the act or an instance of disclosing. 19 (3) PROTECTED HEALTH INFORMATION.—The term "protected health information" means any in-20 formation, whether oral or recorded in any form or 21 22 medium— 23 (A) that is created or received in a State by— 24 (i) a health care provider; 25

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1	(ii) a health benefit plan sponsor;
2	(iii) a health oversight agency;
3	(iv) a health information service orga-
4	nization; or
5	(v) a public health authority;
6	(B) that relates in any way to the past,
7	present, or future physical or mental health or
8	condition or functional status of a protected in-
9	dividual, the provision of health care to a pro-
10	tected individual, or payment for the provision
11	of health care to a protected individual; and
12	(C) that—
13	(i) identifies the individual; or
14	(ii) with respect to which there is a
15	reasonable basis to believe that the infor-
16	mation can be used to identify the individ-
17	ual.
18	(4) PROTECTED INDIVIDUAL.—The term "pro-
19	tected individual" means an individual who, with re-
20	spect to a date—
21	(A) is living on the date; or
22	(B) has died within the 2-year period end-
23	ing on the date.

(5) USE.—The term "use", when used with re-1 2 spect to protected health information that is held by a health information trustee, means— 3 4 (A) to use, or provide access to, the infor-5 mation in any manner that does not constitute 6 a disclosure: or 7 (B) any act or instance of using, or providing access, described in subparagraph (A). 8 9 (b) DEFINITIONS RELATING TO HEALTH INFORMA-TION TRUSTEES.—For purposes of this Act: 10 11 (1) CARRIER.—The term "carrier" means a li-12 censed insurance company, a hospital or medical 13 service corporation (including an existing Blue Cross 14 or Blue Shield organization, within the meaning of 15 section 833(c)(2) of the Internal Revenue Code of 16 1986), a health maintenance organization, or other 17 entity licensed or certified by a State to provide 18 health insurance or health benefits. 19 (2)BENEFIT PLAN.—The HEALTH term "health benefit plan" means— 20 (A) any contract of health insurance, in-21 22 cluding any hospital or medical service policy or certificate, hospital or medical service plan con-23 24 tract, or health maintenance organization group 25 contract, that is provided by a carrier; and

1 (B) an employee welfare benefit plan or 2 other arrangement insofar as the plan or ar-3 rangement provides health benefits and is fund-4 ed in a manner other than through the pur-5 chase of one or more policies or contracts de-6 scribed in subparagraph (A).

7 (3) HEALTH BENEFIT PLAN SPONSOR.—The 8 term "health benefit plan sponsor" means a person 9 who, with respect to a specific item of protected 10 health information, receives, creates, uses, main-11 tains, or discloses the information while acting in 12 whole or in part in the capacity of—

(A) a carrier or other person providing a
health benefit plan, including any public entity
that provides payments for health care items
and services under a health benefit plan that
are equivalent to payments provided by a private person under such a plan; or

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

(4) 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

1	the information while acting in whole or in part in
2	the capacity of—
3	(A) a person who is licensed, certified, reg-
4	istered, or otherwise authorized by law to pro-
5	vide an item or service that constitutes health
6	care in the ordinary course of business or prac-
7	tice of a profession;
8	(B) a Federal or State program that di-
9	rectly provides items or services that constitute
10	health care to beneficiaries; or
11	(C) an officer or employee of a person de-
12	scribed in subparagraph (A) or (B).
13	(5) Health information service organiza-
14	TION.—The term "health information service organi-
15	zation" means a person who, with respect to a spe-
16	cific item of protected health information, receives,
17	creates, uses, maintains, or discloses the information
18	while acting in whole or in part in the capacity of—
19	(A) a person, other than an affiliated per-
20	son, who performs specific functions for which
21	the Secretary has authorized (by means of a
22	designation or certification) the person to re-
23	ceive access to specific health care data in elec-
24	tronic or magnetic form; or

1	(B) an officer or employee of a person de-
2	scribed in subparagraph (A).
3	(6) Health information trustee.—The
4	term ''health information trustee'' means—
5	(A) a health care provider;
6	(B) a health information service organiza-
7	tion;
8	(C) a health oversight agency;
9	(D) a health benefit plan sponsor;
10	(E) a public health authority;
11	(F) a health researcher;
12	(G) a person who, with respect to a spe-
13	cific item of protected health information, is not
14	described in subparagraphs (A) through (F) but
15	receives the information—
16	(i) pursuant to—
17	(I) section 117 (relating to emer-
18	gency circumstances);
19	(II) section 118 (relating to judi-
20	cial and administrative purposes);
21	(III) section 119 (relating to law
22	enforcement); or
23	(IV) section 120 (relating to sub-
24	poenas, warrants, and search war-
25	rants); or

	11
1	(ii) while acting in whole or in part in
2	the capacity of an officer or employee of a
3	person described in clause (i).
4	(7) Health oversight agency.—The term
5	"health oversight agency" means a person who, with
6	respect to a specific item of protected health infor-
7	mation, receives, creates, uses, maintains, or dis-
8	closes the information while acting in whole or in
9	part in the capacity of—
10	(A) a person who performs or oversees the
11	performance of an assessment, evaluation, de-
12	termination, or investigation relating to the li-
13	censing, accreditation, or certification of health
14	care providers;
15	(B) a person who—
16	(i) performs or oversees the perform-
17	ance of an audit, assessment, evaluation,
18	determination, or investigation relating to
19	the effectiveness of, compliance with, or
20	applicability of, legal, fiscal, medical, or
21	scientific standards or aspects of perform-
22	ance related to the delivery of, or payment
23	for, health care; and
24	(ii) is a public agency, acting on be-
25	half of a public agency, acting pursuant to

1	a requirement of a public agency, or carry-
2	ing out activities under a State or Federal
3	statute regulating the assessment, evalua-
4	tion, determination, or investigation; or
5	(C) an officer or employee of a person de-
6	scribed in subparagraph (A) or (B).
7	(8) HEALTH RESEARCHER.—The term ''health
8	researcher" means a person who, with respect to a
9	specific item of protected health information, re-
10	ceives the information—
11	(A) pursuant to section 116 (relating to
12	health research); or
13	(B) while acting in whole or in part in the
14	capacity of an officer or employee of a person
15	described in subparagraph (A).
16	(9) Public health authority.—The term
17	"public health authority" means a person who, with
18	respect to a specific item of protected health infor-
19	mation, receives, creates, uses, maintains, or dis-
20	closes the information while acting in whole or in
21	part in the capacity of—
22	(A) an authority of the United States, a
23	State, or a political subdivision of a State that
24	is responsible for public health matters;

1	(B) a person acting under the direction of
2	such an authority; or
3	(C) an officer or employee of a person de-
4	scribed in subparagraph (A) or (B).
5	(c) OTHER DEFINITIONS.—For purposes of this Act:
6	(1) AFFILIATED PERSON.—The term "affiliated
7	person'' means a person who—
8	(A) is not a health information trustee;
9	(B) is a contractor, subcontractor, associ-
10	ate, or subsidiary of a person who is a health
11	information trustee; and
12	(C) pursuant to an agreement or other re-
13	lationship with such trustee, receives, creates,
14	uses, maintains, or discloses protected health
15	information.
16	(2) Approved health research project.—
17	The term "approved health research project" means
18	a biomedical, epidemiological, or health services re-
19	search or statistics project, or a research project on
20	behavioral and social factors affecting health, that
21	has been approved by a certified institutional review
22	board.
23	(3) Certified institutional review
24	BOARD.—The term ''certified institutional review
25	board" means a board—

1	(A) established by an entity to review re-
2	search involving protected health information
3	and the rights of protected individuals con-
4	ducted at or supported by the entity;
5	(B) established in accordance with regula-
6	tions of the Secretary under section 116(d)(1);
7	and
8	(C) certified by the Secretary under section
9	116(d)(2).
10	(4) HEALTH CARE.—The term "health care"—
11	(A) means—
12	(i) any preventive, diagnostic, thera-
13	peutic, rehabilitative, maintenance, or pal-
14	liative care, counseling, service, or proce-
15	dure—
16	(I) with respect to the physical or
17	mental condition, or functional status,
18	of an individual; or
19	(II) affecting the structure or
20	function of the human body or any
21	part of the human body, including
22	banking of blood, sperm, organs, or
23	any other tissue; or
24	(ii) any sale or dispensing of a drug,
25	device, equipment, or other item to an indi-

1	vidual, or for the use of an individual, pur-
2	suant to a prescription; but
3	(B) does not include any item or service
4	that is not furnished for the purpose of main-
5	taining or improving the health of an individual.
6	(5) LAW ENFORCEMENT INQUIRY.—The term
7	"law enforcement inquiry" means a lawful investiga-
8	tion or official proceeding inquiring into a violation
9	of, or failure to comply with, any criminal or civil
10	statute or any regulation, rule, or order issued pur-
11	suant to such a statute.
12	(6) PERSON.—The term "person" includes an
13	authority of the United States, a State, or a political
14	subdivision of a State.
15	(7) SECRETARY.—The term "Secretary" means
16	the Secretary of Health and Human Services.
17	(8) STATE.—The term "State" includes the
18	District of Columbia, Puerto Rico, the Virgin Is-
19	lands, Guam, American Samoa, and the Northern
20	Mariana Islands.

1TITLE I—FAIR HEALTH2INFORMATION PRACTICES3Subtitle A—Duties of Health4Information Trustees

5 SEC. 101. INSPECTION OF PROTECTED HEALTH INFORMA-

TION.

6

7 (a) IN GENERAL.—Except as provided in subsection
8 (b), a health information trustee described in subsection
9 (g)—

10 (1) shall permit a protected individual to in-11 spect any protected health information about the in-12 dividual that the trustee maintains, any accounting 13 with respect to such information required under sec-14 tion 104, and any copy of an authorization required 15 under section 112 that pertains to such information;

(2) shall provide the protected individual with a
copy of the information upon request by the individual and subject to any conditions imposed by the
trustee under subsection (d);

(3) shall permit a person who has been designated in writing by the protected individual to inspect the information on behalf of the individual or
to accompany the individual during the inspection;
and

(4) may offer to explain or interpret informa tion that is inspected or copied under this sub section.

4 (b) EXCEPTIONS.—A health information trustee is
5 not required by this section to permit inspection or copy6 ing of protected health information by a protected individ7 ual if any of the following conditions apply:

8 (1) Mental health treatment notes.— 9 The information consists of psychiatric, psychological, or mental health treatment notes about the 10 11 individual, the trustee determines in the exercise of 12 reasonable professional judgment that inspection or 13 copying of the notes would cause sufficient harm to 14 the protected individual so as to outweigh the desir-15 ability of permitting access, and the trustee does not 16 disclose the notes to any person not directly engaged 17 in treating the individual, except with the authoriza-18 tion of the individual or under compulsion of law.

19 (2) INFORMATION ABOUT OTHERS.—The infor-20 mation relates to an individual, other than the pro-21 tected individual or a health care provider, and the 22 trustee determines in the exercise of reasonable pro-23 fessional judgment that inspection or copying of the 24 information would cause sufficient harm to one or

both of the individuals so as to outweigh the desir-1 2 ability of permitting access. 3 (3) ENDANGERMENT TO LIFE OR SAFETY.—Inspection or copying of the information could reason-4 ably be expected to endanger the life or physical 5 6 safety of an individual. 7 (4) CONFIDENTIAL SOURCE.—The information identifies or could reasonably lead to the identifica-8 tion of an individual (other than a health care pro-9 vider) who provided information under a promise of 10 11 confidentiality to a health care provider concerning 12 a protected individual who is a subject of the infor-13 mation. (5) ADMINISTRATIVE PURPOSES.—The informa-14 15 tion— 16 (A) is used by the trustee solely for admin-17 istrative purposes and not in the provision of 18 health care to a protected individual who is a 19 subject of the information; and 20 (B) is not disclosed by the trustee to any 21 person. 22 (6) DUPLICATIVE INFORMATION.—The information duplicates information available for inspection 23 under subsection (a). 24

1	(7) INFORMATION COMPILED IN ANTICIPATION
2	OF LITIGATION.—The information is compiled prin-
3	cipally—
4	(A) in anticipation of a civil, criminal, or
5	administrative action or proceeding; or
6	(B) for use in such an action or proceed-
7	ing.
8	(c) INSPECTION AND COPYING OF SEGREGABLE POR-
9	TION.—A health information trustee shall permit inspec-
10	tion and copying under subsection (a) of any reasonably
11	segregable portion of a record after deletion of any portion
12	that is exempt under subsection (b).
13	(d) CONDITIONS.—A health information trustee
14	may—
15	(1) require a written request for the inspection
16	and copying of protected health information under
17	this section; and
18	(2) charge a reasonable cost-based fee for—
19	(A) permitting inspection of information
20	under this section; and
21	(B) providing a copy of protected health
22	information under this section.
23	(e) Statement of Reasons for Denial.—If a
24	health information trustee denies in whole or in part a
25	request for inspection or copying under this section, the

trustee shall provide the protected individual who made
 the request with a written statement of the reasons for
 the denial.

4 (f) DEADLINE.—A health information trustee shall 5 comply with or deny a request for inspection or copying 6 of protected health information under this section within 7 the 30-day period beginning on the date the trustee re-8 ceives the request.

9 (g) APPLICABILITY.—This section applies to a health 10 information trustee who is—

11 (1) a health benefit plan sponsor;

12 (2) a health care provider;

13 (3) a health information service organization;

14 (4) a health oversight agency; or

15 (5) a public health authority.

16 SEC. 102. AMENDMENT OF PROTECTED HEALTH INFORMA-

17 **TION.**

(a) IN GENERAL.—A health information trustee described in subsection (f) shall, within the 45-day period
beginning on the date the trustee receives from a protected
individual about whom the trustee maintains protected
health information a written request that the trustee correct or amend the information, complete the duties described in one of the following paragraphs:

1	(1) Correction or Amendment and Notifi-
2	CATION.—The trustee shall—
3	(A) make the correction or amendment re-
4	quested;
5	(B) inform the protected individual of the
6	amendment or correction that has been made;
7	(C) make reasonable efforts to inform any
8	person who is identified by the protected indi-
9	vidual, who is not an employee of the trustee,
10	and to whom the uncorrected or unamended
11	portion of the information was previously dis-
12	closed of the correction or amendment that has
13	been made; and
14	(D) at the request of the individual, make
15	reasonable efforts to inform any known source
16	of the uncorrected or unamended portion of the
17	information about the correction or amendment
18	that has been made.
19	(2) Reasons for refusal and review pro-
20	CEDURES.—The trustee shall inform the protected
21	individual of—
22	(A) the reasons for the refusal of the trust-
23	ee to make the correction or amendment;
24	(B) any procedures for further review of
25	the refusal; and

1 (C) the individual's right to file with the 2 trustee a concise statement setting forth the re-3 quested correction or amendment and the indi-4 vidual's reasons for disagreeing with the refusal 5 of the trustee.

6 (b) STANDARDS FOR CORRECTION OR AMEND-7 MENT.—A trustee shall correct or amend protected health 8 information in accordance with a request made under sub-9 section (a) if the trustee determines that the information 10 is not accurate, relevant, timely, or complete for the pur-11 poses for which the information may be used or disclosed 12 by the trustee.

13 (c) STATEMENT OF DISAGREEMENT.—After a pro-14 tected individual has filed a statement of disagreement 15 under subsection (a)(2)(C), the trustee, in any subsequent 16 disclosure of the disputed portion of the information, shall 17 include a copy of the individual's statement and may in-18 clude a concise statement of the trustee's reasons for not 19 making the requested correction or amendment.

(d) CONSTRUCTION.—This section may not be construed to require a health information trustee to conduct
a hearing or proceeding concerning a request for a correction or amendment to protected health information the
trustee maintains.

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health information when-

(e) CORRECTION.—For purposes of subsection (a), a

correction is deemed to have been made to protected

4 (1) information that is not timely, accurate, relevant, or complete is clearly marked as incorrect; or 5 6 (2) supplementary correct information is made 7 part of the information and adequately cross-ref-8 erenced. (f) APPLICABILITY.—This section applies to a health 9 information trustee who is— 10 (1) a health benefit plan sponsor; 11 (2) a health care provider; 12 (3) a health information service organization; 13 (4) a health oversight agency; or 14 15 (5) a public health authority. 16 **SEC. 103. NOTICE OF INFORMATION PRACTICES.** 17 (a) PREPARATION OF NOTICE.—A health information trustee described in subsection (d) shall prepare a written 18 notice of information practices describing the following: 19 20 (1) The rights under this Act of a protected individual who is the subject of protected health infor-21 22 mation, including the right to inspect and copy such information and the right to seek amendments to 23 such information, and the procedures for authorizing 24

	24
1	disclosures of protected health information and for
2	revoking such authorizations.
3	(2) The procedures established by the trustee
4	for the exercise of such rights.
5	(3) The uses and disclosures of protected health
6	information that are authorized under this Act.
7	(b) DISSEMINATION OF NOTICE.—A health informa-
8	tion trustee—
9	(1) shall, upon request, provide any person with
10	a copy of the trustee's notice of information prac-
11	tices (described in subsection (a)); and
12	(2) shall make reasonable efforts to inform per-
13	sons in a clear and conspicuous manner of the exist-
14	ence and availability of such notice.
15	(c) MODEL NOTICES.—Not later than July 1, 1996,
16	the Secretary, after notice and opportunity for public com-
17	ment, shall develop and disseminate model notices of infor-
18	mation practices for use by health information trustees
19	under this section.
20	(d) APPLICABILITY.—This section applies to a health
21	information trustee who is—
22	(1) a health benefit plan sponsor;
23	(2) a health care provider;
24	(3) a health information service organization; or
25	(4) a health oversight agency.

1 SEC. 104. ACCOUNTING FOR DISCLOSURES.

2 (a) IN GENERAL.—Except as provided in subsection
3 (b) and section 114, each health information trustee shall
4 create and maintain, with respect to any protected health
5 information the trustee discloses, a record of—

6 (1) the date and purpose of the disclosure;

7 (2) the name of the person to whom the disclo-8 sure was made;

9 (3) the address of the person to whom the dis-10 closure was made or the location to which the disclo-11 sure was made; and

12 (4) where practicable, a description of the infor-13 mation disclosed.

14 (b) REGULATIONS.—Not later than July 1, 1996, the 15 Secretary shall promulgate regulations that exempt a 16 health information trustee from maintaining a record 17 under subsection (a) with respect protected health infor-18 mation disclosed by the trustee for purposes of peer 19 review, licensing, certification, accreditation, and similar 20 activities.

21 SEC. 105. SECURITY.

(a) IN GENERAL.—Each health information trustee
who receives or creates protected health information that
is subject to this Act shall maintain reasonable and appropriate administrative, technical, and physical safeguards—

1	(1) to ensure the integrity and confidentiality of
2	the information;
3	(2) to protect against any reasonably antici-
4	pated—
5	(A) threats or hazards to the security or
6	integrity of the information; and
7	(B) unauthorized uses or disclosures of the
8	information; and
9	(3) otherwise ensure compliance with this Act
10	by the trustee and the officers and employees of the
11	trustee.
12	(b) GUIDELINES.—Not later than July 1, 1996, the
13	Secretary, after notice and opportunity for public com-
14	ment, shall develop and disseminate guidelines for the im-
15	plementation of this section. The guidelines shall take into
16	account—
17	(1) the technical capabilities of record systems
18	used to maintain protected health information;
19	(2) the costs of security measures;
20	(3) the need for training persons who have ac-
21	cess to protected health information; and
22	(4) the value of audit trails in computerized
23	record systems.

Subtitle B—Use and Disclosure of 1 **Protected Health Information** 2 3 SEC. 111. GENERAL LIMITATIONS ON USE AND DISCLO-4 SURE. 5 (a) USE.—Except as otherwise provided under this Act, a health information trustee may use protected health 6 information only for a purpose— 7 (1) that is compatible with and directly related 8 9 to the purpose for which the information— (A) was collected; or 10 11 (B) was received by the trustee; or (2) for which the trustee is authorized to dis-12 13 close the information under this Act. (b) DISCLOSURE.—A health information trustee may 14 disclose protected health information only as authorized 15 under this Act. 16 17 (c) SCOPE OF USES AND DISCLOSURES.— (1) IN GENERAL.—A use or disclosure of pro-18 tected health information by a health information 19 20 trustee shall be limited, when practicable, to the 21 minimum amount of information necessary to accomplish the purpose for which the information is 22 used or disclosed. 23 24 (2) GUIDELINES.—Not later than July 1, 1996,

the Secretary, after notice and opportunity for pub-

lic comment, shall issue guidelines to implement
 paragraph (1), which shall take into account the
 technical capabilities of the record systems used to
 maintain protected health information and the costs
 of limiting use and disclosure.

6 (d) IDENTIFICATION OF DISCLOSED INFORMATION 7 AS PROTECTED INFORMATION.—Except with respect to 8 protected health information that is disclosed under sec-9 tion 114 (relating to next of kin and directory informa-10 tion), a health information trustee may disclose protected health information only if the recipient has been notified 11 that the information is protected health information that 12 is subject to this Act. 13

14 (e) Agreement to Limit Use or Disclosure.— 15 A health information trustee who receives protected health information from any person pursuant to a written agree-16 ment to restrict use or disclosure of the information to 17 18 a greater extent than otherwise would be required under 19 this Act shall comply with the terms of the agreement, except where use or disclosure of the information in viola-20 tion of the agreement is required by law. A trustee who 21 22 fails to comply with the preceding sentence shall be subject to section 151 (relating to civil actions) with respect to 23 such failure. 24

(f) NO GENERAL REQUIREMENT TO DISCLOSE.—
 Nothing in this Act shall be construed to require a health
 information trustee to disclose protected health informa tion not otherwise required to be disclosed by law.

5 SEC. 112. AUTHORIZATIONS FOR DISCLOSURE OF PRO-6 TECTED HEALTH INFORMATION.

7 (a) WRITTEN AUTHORIZATIONS.—A health informa-8 tion trustee, other than a health information service orga-9 nization, may disclose protected health information pursu-10 ant to an authorization executed by the protected individ-11 ual who is the subject of the information, if each of the 12 following requirements is satisfied:

(1) WRITING.—The authorization is in writing,
signed by the individual, and dated on the date of
such signature.

16 (2) SEPARATE FORM.—The authorization is not
17 on a form used to authorize or facilitate the provi18 sion of, or payment for, health care.

(3) TRUSTEE DESCRIBED.—The trustee is specifically named or generically described in the authorization as authorized to disclose such information.

(4) RECIPIENT DESCRIBED.—The person to
whom the information is to be disclosed is specifically named or generically described in the author-

ization as a person to whom such information may
 be disclosed.

3 (5) STATEMENT OF INTENDED USES AND DIS4 CLOSURES RECEIVED.—The authorization contains
5 an acknowledgment that the individual has received
6 a statement described in subsection (b) from such
7 person.

8 (6) INFORMATION DESCRIBED.—The informa9 tion to be disclosed is described in the authorization.

10 (7) AUTHORIZATION TIMELY RECEIVED.—The
11 authorization is received by the trustee during a pe12 riod described in subsection (c)(1).

13 (8) DISCLOSURE TIMELY MADE.—The disclo14 sure occurs during a period described in subsection
15 (c)(2).

16 (b) STATEMENT OF INTENDED USES AND DISCLO-17 SURES.—

18 (1) IN GENERAL.—A person who wishes to re-19 ceive from a health information trustee protected 20 health information about a protected individual pursuant to an authorization executed by the individual 21 22 shall supply the individual, in writing and on a form 23 that is distinct from the authorization, with a statement of the uses for which the person intends the 24 25 information and the disclosures the person intends

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1	to make of the information. Such statement shall be
2	supplied before the authorization is executed.
3	(2) ENFORCEMENT.—If the person uses or dis-
4	closes the information in a manner that is inconsist-
5	ent with such statement, the person shall be subject
6	to section 151 (relating to civil actions) with respect
7	to such failure, except where such use or disclosure
8	is required by law.
9	(3) MODEL STATEMENTS.—Not later than July
10	1, 1996, the Secretary, after notice and opportunity
11	for public comment, shall develop and disseminate
12	model statements of intended uses and disclosures of
13	the type described in paragraph (1).
14	(c) TIME LIMITATIONS ON AUTHORIZATIONS.—
15	(1) RECEIPT BY TRUSTEE.—For purposes of
16	subsection (a)(7), an authorization is timely received
17	if it is received by the trustee during—
18	(A) the 1-year period beginning on the
19	date that the authorization is signed under sub-
20	section (a)(1), if the authorization permits the
21	disclosure of protected health information to—
22	(i) a health benefit plan sponsor;
23	(ii) a health care provider;
24	(iii) a health oversight agency;
25	(iv) a public health authority;

1	(v) a health researcher; or
2	(vi) a person who provides counseling
3	or social services to individuals; or
4	(B) the 30-day period beginning on the
5	date that the authorization is signed under sub-
6	section (a)(1), if the authorization permits the
7	disclosure of protected health information to a
8	person other than a person described in sub-
9	paragraph (A).
10	(2) Disclosure by trustee.—For purposes
11	of subsection $(a)(8)$, a disclosure is timely made if
12	it occurs before—
13	(A) the date or event (if any) specified in
14	the authorization upon which the authorization
15	expires; and
16	(B) the expiration of the 6-month period
17	beginning on the date the trustee receives the
18	authorization.
19	(d) Revocation or Amendment of Authoriza-
20	TION.—
21	(1) IN GENERAL.—A protected individual in
22	writing may revoke or amend an authorization de-
23	scribed in subsection (a), in whole or in part, at any
24	time, except insofar as—

1	(A) disclosure of protected health informa-
2	tion has been authorized to permit validation of
3	expenditures based on health condition by a
4	government authority; or
5	(B) action has been taken in reliance on
6	the authorization.
7	(2) NOTICE OF REVOCATION.—A health infor-
8	mation trustee who discloses protected health infor-
9	mation in reliance on an authorization that has been
10	revoked shall not be subject to any liability or pen-
11	alty under this Act if—
12	(A) the reliance was in good faith;
13	(B) the trustee had no notice of the rev-
14	ocation; and
15	(C) the disclosure was otherwise in accord-
16	ance with the requirements of this section.
17	(e) Additional Requirements of Trustee.—A
18	health information trustee may impose requirements for
19	an authorization that are in addition to the requirements
20	in this section.
21	(f) COPY.—A health information trustee who dis-
22	closes protected health information pursuant to an author-
23	ization under this section shall maintain a copy of the au-
24	thorization.

1 (g) CONSTRUCTION.—This section may not be con-2 strued—

3 (1) to require a health information trustee to
4 disclose protected health information; or

5 (2) to limit the right of a health information
6 trustee to charge a fee for the disclosure or repro7 duction of protected health information.

8 (h) SUBPOENAS, WARRANTS, AND SEARCH WAR-9 RANTS.—If a health information trustee discloses pro-10 tected health information pursuant to an authorization in 11 order to comply with an administrative subpoena or war-12 rant or a judicial subpoena or search warrant, the author-13 ization—

(1) shall specifically authorize the disclosure for
the purpose of permitting the trustee to comply with
the subpoena, warrant, or search warrant; and

17 (2) shall otherwise meet the requirements in18 this section.

19 SEC. 113. TREATMENT, PAYMENT, AND OVERSIGHT.

20 (a) DISCLOSURES BY PLANS, PROVIDERS, AND 21 OVERSIGHT AGENCIES.—A health information trustee de-22 scribed in subsection (d) may disclose protected health in-23 formation to a health benefit plan sponsor, health care 24 provider, or health oversight agency if the disclosure is—

1	(1) for the purpose of providing health care and
2	a protected individual who is a subject of the infor-
3	mation has not previously objected to the disclosure
4	in writing;
5	(2) for the purpose of providing for the pay-
6	ment for health care furnished to an individual; or
7	(3) for use by a health oversight agency for a
8	purpose that is described in subparagraph (A) or
9	(B)(i) of section $3(b)(7)$.
10	(b) Disclosures by Certain Other Trustees.—
11	A health information trustee may disclose protected health
12	information to a health care provider if—
13	(1) the disclosure is for the purpose described
14	in subsection (a)(1); and
15	(2) the trustee—
16	(A) is a public health authority;
17	(B) received protected health information
18	pursuant to section 117 (relating to emergency
19	circumstances); or
20	(C) is an officer or employee of a trustee
21	described in subsection (B).
22	(c) USE IN ACTION AGAINST INDIVIDUAL.—A person
23	who receives protected health information about a pro-
24	tected individual through a disclosure under this section
25	may not use or disclose the information in any administra-

tive, civil, or criminal action or investigation directed
 against the individual, except an action or investigation
 arising out of and related to receipt of health care or pay ment for health care.

5 (d) APPLICABILITY.—A health information trustee6 referred to in subsection (a) is any of the following:

7 (1) A health benefit plan sponsor.

8 (2) A health care provider.

9 (3) A health oversight agency.

10 (4) A health information service organization.

11 SEC. 114. NEXT OF KIN AND DIRECTORY INFORMATION.

(a) NEXT OF KIN.—A health information trustee who 12 is a health care provider, who received protected health 13 information pursuant to section 117 (relating to emer-14 15 gency circumstances), or who is an officer or employee of such a recipient may orally disclose protected health infor-16 mation about a protected individual to the next of kin of 17 the individual (as defined under State law), or to a person 18 with whom the individual has a close personal relationship, 19 20 if—

(1) the trustee has no reason to believe that the
individual would consider the information especially
sensitive;

24 (2) the individual has not previously objected to25 the disclosure;

1	(3) the disclosure is consistent with good medi-
2	cal or other professional practice; and
3	(4) the information disclosed is limited to infor-
4	mation about health care that is being provided to
5	the individual at or about the time of the disclosure.
6	(b) Directory Information.—
7	(1) IN GENERAL.—A health information trustee
8	who is a health care provider, who received protected
9	health information pursuant to section 117 (relating
10	to emergency circumstances), or who is an officer or
11	employee of a such a recipient may disclose to any
12	person the information described in paragraph (2)
13	if—
14	(A) a protected individual who is a subject
15	of the information has not objected in writing
16	to the disclosure;
17	(B) the disclosure is otherwise consistent
18	with good medical and other professional prac-
19	tice; and
20	(C) the information does not reveal specific
21	information about the physical or mental condi-
22	tion or functional status of a protected individ-
23	ual or about the health care provided to a pro-
24	tected individual.

(2) INFORMATION DESCRIBED.—The informa-1 tion referred to in paragraph (1) is the following: 2 (A) The name of an individual receiving 3 health care from a health care provider on a 4 premises controlled by the provider. 5 6 (B) The location of the individual on such 7 premises. (C) The general health status of the indi-8 9 vidual, described in terms of critical, poor, fair, stable, satisfactory, or terms denoting similar 10 11 conditions. (c) NO ACCOUNTING REQUIRED.—A health informa-12 tion trustee who discloses protected health information 13 under this section is not required to maintain an account-14 ing of the disclosure under section 104. 15 (d) RECIPIENTS.—A person to whom protected 16 health information is disclosed under this section shall not, 17 by reason of such disclosure, be subject to any require-18 ment under this Act. 19 20 SEC. 115. PUBLIC HEALTH. 21 (a) IN GENERAL.—A health information trustee who

(a) IN GENERAL.—A health information trustee who
is a health care provider or a public health authority may
disclose protected health information to—

24 (1) a public health authority for use in legally25 authorized—

1	(A) disease or injury reporting;
2	(B) public health surveillance; or
3	(C) public health investigation or interven-
4	tion; or
5	(2) an individual who is authorized by law to
6	receive the information in a public health interven-
7	tion.
8	(b) USE IN ACTION AGAINST INDIVIDUAL.—A public
9	health authority who receives protected health information
10	about a protected individual through a disclosure under
11	this section may not use or disclose the information in any
12	administrative civil or criminal action or investigation di-

10 about a protected individual through a disclosure under 11 this section may not use or disclose the information in any 12 administrative, civil, or criminal action or investigation di-13 rected against the individual, except where the use or dis-14 closure is authorized by law for protection of the public 15 health.

16 (c) INDIVIDUAL RECIPIENTS.—An individual to 17 whom protected health information is disclosed under sub-18 section (a)(2) shall not, by reason of such disclosure, be 19 subject to any requirement under this Act.

20 SEC. 116. HEALTH RESEARCH.

(a) IN GENERAL.—A health information trustee described in subsection (d) may disclose protected health information to a person if—

24 (1) the person is conducting an approved health25 research project;

1	(2) the information is to be used in the project;
2	and
3	(3) the project has been determined by a cer-
4	tified institutional review board to be—
5	(A) of sufficient importance so as to out-
6	weigh the intrusion into the privacy of the pro-
7	tected individual who is the subject of the infor-
8	mation that would result from the disclosure;
9	and
10	(B) impracticable to conduct without the
11	information.
12	(b) Disclosures by Health Information Serv-
13	ICE ORGANIZATIONS.—A health information service orga-
14	nization may disclose protected health information under
15	subsection (a) only if the certified institutional review
16	board referred to in subsection (a)(3) has been certified
17	as being qualified to make determinations under such sub-
18	section with respect to disclosures by such organizations.
19	(c) Limitations on Use and Disclosure; Obliga-
20	TIONS OF RECIPIENT.—A health researcher who receives
21	protected health information about a protected individual
22	pursuant to subsection (a)—
23	(1) may use the information solely for purposes
24	of an approved health research project;

(2) may not use or disclose the information in
 any administrative, civil, or criminal action or inves tigation directed against the individual; and

4 (3) shall remove or destroy, at the earliest opportunity consistent with the purposes of the ap-5 6 proved health research project in connection with 7 which the disclosure was made, information that 8 would enable an individual to be identified, unless a certified institutional review board has determined 9 that there is a health or research justification for re-10 tention of such identifiers and there is an adequate 11 plan to protect the identifiers from use and disclo-12 13 sure that is inconsistent with this Act.

(d) APPLICABILITY.—A health information trustee
referred to in subsection (a) is any health information
trustee other than a person who, with respect to the specific protected health information to be disclosed under
such subsection, received the information—

19 (1) pursuant to—

20 (A) section 118 (relating to judicial and21 administrative purposes);

(B) paragraph (1), (2), (3), or (4) of section 119(a) (relating to law enforcement); or
(C) section 120 (relating to subpoenas,

25 warrants, and search warrants); or

(2) while acting in whole or in part in the ca pacity of an officer or employee of a person de scribed in paragraph (1).

4 (e) REQUIREMENTS FOR INSTITUTIONAL REVIEW5 BOARDS.—

(1) REGULATIONS.—Not later than July 1, 6 7 1996, the Secretary, after opportunity for notice and comment, shall promulgate regulations establishing 8 9 requirements for certified institutional review boards under this Act. The regulations shall be based on 10 11 regulations promulgated under section 491(a) of the 12 Public Health Service Act and shall ensure that cer-13 tified institutional review boards are qualified to as-14 sess and protect the confidentiality of research sub-15 jects. The regulations shall include specific requirements for certified institutional review boards that 16 17 make determinations under subsection (a)(3) with 18 respect to disclosures by health information service 19 organizations.

20 (2) CERTIFICATION.—The Secretary shall cer21 tify that an institutional review board satisfies the
22 requirements of the regulations promulgated under
23 paragraph (1).

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1 SEC. 117. EMERGENCY CIRCUMSTANCES.

2 (a) IN GENERAL.—A health information trustee may 3 disclose protected health information if the trustee be-4 lieves, on reasonable grounds, that the disclosure is nec-5 essary to prevent or lessen a serious and imminent threat 6 to the health or safety of an individual.

7 (b) USE IN ACTION AGAINST INDIVIDUAL.—A person 8 who receives protected health information about a pro-9 tected individual through a disclosure under this section 10 may not use or disclose the information in any administrative, civil, or criminal action or investigation directed 11 against the individual, except an action or investigation 12 arising out of and related to receipt of health care or pay-13 ment for health care. 14

15 SEC. 118. JUDICIAL AND ADMINISTRATIVE PURPOSES.

(a) IN GENERAL.—A health information trustee described in subsection (d) may disclose protected health information—

19 (1) pursuant to the Federal Rules of Civil Pro-20 cedure, the Federal Rules of Criminal Procedure, or 21 comparable rules of other courts or administrative 22 agencies in connection with litigation or proceedings 23 to which a protected individual who is a subject of 24 the information is a party and in which the individ-25 ual has placed the individual's physical or mental condition or functional status in issue: 26

1	(2) if directed by a court in connection with a
2	court-ordered examination of an individual; or
3	(3) to assist in the identification of a dead
4	individual.
5	(b) WRITTEN STATEMENT.—A person seeking pro-
6	tected health information about a protected individual held
7	by health information trustee under—
8	(1) subsection (a)(1)—
9	(A) shall notify the protected individual or
10	the attorney of the protected individual of the
11	request for the information;
12	(B) shall provide the trustee with a signed
13	document attesting—
14	(i) that the protected individual is a
15	party to the litigation or proceedings for
16	which the information is sought;
17	(ii) that the individual has placed the
18	individual's physical or mental condition or
19	functional status in issue; and
20	(iii) the date on which the protected
21	individual or the attorney of the protected
22	individual was notified under subparagraph
23	(A); and
24	(C) shall not accept any requested pro-
25	tected health information from the trustee until

	40
1	the termination of the 10-day period beginning
2	on the date notice was given under subpara-
3	graph (A); or
4	(2) subsection $(a)(3)$ shall provide the trustee
5	with a written statement that the information is
6	sought to assist in the identification of a dead
7	individual.
8	(c) USE AND DISCLOSURE.—A person to whom pro-
9	tected health information is disclosed under this section
10	may use and disclose the information only to accomplish
11	the purpose for which the disclosure was made.
12	(d) APPLICABILITY.—A health information trustee
13	referred to in subsection (a) is any of the following:
14	(1) A health benefit plan sponsor.
15	(2) A health care provider.
16	(3) A health oversight agency.
17	(4) A person who, with respect to the specific
18	protected health information to be disclosed under
19	such subsection, received the information—
20	(A) pursuant to—
21	(i) section 117 (relating to emergency
22	circumstances); or
23	(ii) section 120 (relating to subpoe-
24	nas, warrants, and search warrants); or

(B) while acting in whole or in part in the
 capacity of an officer or employee of a person
 described in subparagraph (A).

4 SEC. 119. LAW ENFORCEMENT.

5 (a) IN GENERAL.—A health information trustee, 6 other than a health information service organization, may 7 disclose protected health information to a law enforcement 8 agency, other than a health oversight agency—

9 (1) if the information is disclosed for use in an 10 investigation or prosecution of a health information 11 trustee;

(2) in connection with criminal activity committed against the trustee or an affiliated person of the
trustee or on premises controlled by the trustee; or

(3) if the information is needed to determine
whether a crime has been committed and the nature
of any crime that may have been committed (other
than a crime that may have been committed by the
protected individual who is the subject of the information).

(b) ADDITIONAL AUTHORITY OF CERTAIN TRUSTEES.—A health information trustee who is not a health
information service organization, a public health authority, or a health researcher may disclose protected health

information to a law enforcement agency (other than a
 health oversight agency)—

3 (1) to assist in the identification or location of
4 a victim, fugitive, or witness in a law enforcement
5 inquiry;

6 (2) pursuant to a law requiring the reporting of 7 specific health care information to law enforcement 8 authorities; or

9 (3) if the information is specific health informa-10 tion described in paragraph (2) and the trustee is 11 operated by a Federal agency;

(c) CERTIFICATION.—Where a law enforcement agency requests a health information trustee to disclose protected health information under subsection (a) or (b)(1),
the agency shall provide the trustee with a written certification that—

17 (1) is signed by a supervisory official of a rank18 designated by the head of the agency;

19 (2) specifies the information requested; and

20 (3) states that the information is needed for a21 lawful purpose under this section.

(d) RESTRICTIONS ON DISCLOSURE AND USE.—A
person who receives protected health information about a
protected individual through a disclosure under this section may not use or disclose the information—

1 (1) in any administrative, civil, or criminal ac-2 tion or investigation directed against the individual, 3 except an action or investigation arising out of and 4 directly related to the action or investigation for 5 which the information was obtained; and

6 (2) otherwise unless the use or disclosure is 7 necessary to fulfill the purpose for which the infor-8 mation was obtained and is not prohibited by any 9 other provision of law.

10 sec. 120. subpoenas, warrants, and search war-11rants.

12 (a) IN GENERAL.—A health information trustee de-13 scribed in subsection (g) may disclose protected health in-14 formation if the disclosure is pursuant to any of the fol-15 lowing:

(1) A subpoena issued under the authority of a
grand jury and the trustee is provided a written certification by the grand jury that the grand jury has
complied with the applicable access provisions of section 5151.

(2) An administrative subpoena or warrant or
a judicial subpoena or search warrant and the trustee is provided a written certification by the person
seeking the information that the person has com-

plied with the applicable access provisions of section
 131 or 133(a).

3 (3) An administrative subpoena or warrant or 4 a judicial subpoena or search warrant and the dis-5 closure otherwise meets the conditions of one of sec-6 tions 113 through 119.

7 (b) AUTHORITY OF ALL TRUSTEES.—Any health in8 formation trustee may disclose protected health informa9 tion if the disclosure is pursuant to subsection (a)(3).

10 (c) RESTRICTIONS ON USE AND DISCLOSURE.—Pro-11 tected health information about a protected individual that 12 is disclosed by a health information trustee pursuant to—

(1) subsection (a)(2) may not be otherwise used
or disclosed by the recipient unless the use or disclosure is necessary to fulfill the purpose for which the
information was obtained; and

17 (2) subsection (a)(3) may not be used or dis-18 closed by the recipient unless the recipient complies 19 with the conditions and restrictions on use and dis-20 closure with which the recipient would have been required to comply if the disclosure by the trustee had 21 22 been made under the section referred to in subsection (a)(3) the conditions of which were met by 23 the disclosure. 24

(d) RESTRICTIONS ON GRAND JURIES.—Protected
 health information that is disclosed by a health informa tion trustee under subsection (a)(1)—

4 (1) shall be returnable on a date when the 5 grand jury is in session and actually presented to 6 the grand jury;

(2) shall be used only for the purpose of considering whether to issue an indictment or report by
that grand jury, or for the purpose of prosecuting a
crime for which that indictment or report is issued,
or for a purpose authorized by rule 6(e) of the Federal Rules of Criminal Procedure or a comparable
State rule;

(3) shall be destroyed or returned to the trustee
if not used for one of the purposes specified in paragraph (2); and

17 (4) shall not be maintained, or a description of 18 the contents of such information shall not be main-19 tained, by any government authority other than in 20 the sealed records of the grand jury, unless such information has been used in the prosecution of a 21 22 crime for which the grand jury issued an indictment or presentment or for a purpose authorized by rule 23 24 6(e) of the Federal Rules of Criminal Procedure or 25 a comparable State rule.

1 (e) Use in Action Against Individual.—A person who receives protected health information about a pro-2 tected individual through a disclosure under this section 3 may not use or disclose the information in any administra-4 tive, civil, or criminal action or investigation directed 5 against the individual, except an action or investigation 6 7 arising out of and directly related to the inquiry for which 8 the information was obtained;

9 (f) CONSTRUCTION.—Nothing in this section shall be 10 construed as authority for a health information trustee to 11 refuse to comply with a valid administrative subpoena or 12 warrant or a valid judicial subpoena or search warrant 13 that meets the requirements of this Act.

(g) APPLICABILITY.—A health information trustee
referred to in subsection (a) is any trustee other than the
following:

17 (1) A health information service organization.

18 (2) A public health authority.

19 (3) A health researcher.

20 SEC. 121. HEALTH INFORMATION SERVICE ORGANIZA-21TIONS.

A health information trustee may disclose protected health information to a health information service organization for the purpose of permitting the organization to perform a function for which the Secretary has authorized (by means of a designation or certification) the organiza tion to receive access to specific health care data in elec tronic or magnetic form.

4 Subtitle C—Access Procedures and 5 Challenge Rights

6 SEC. 131. ACCESS PROCEDURES FOR LAW ENFORCEMENT 7 SUBPOENAS, WARRANTS, AND SEARCH WAR-

RANTS.

8

9 (a) PROBABLE CAUSE REQUIREMENT.—A government authority may not obtain protected health informa-10 tion about a protected individual from a health informa-11 tion trustee under paragraph (1) or (2) of section 120(a)12 for use in a law enforcement inquiry unless there is prob-13 able cause to believe that the information is relevant to 14 a legitimate law enforcement inquiry being conducted by 15 the government authority. 16

17 (b) WARRANTS AND SEARCH WARRANTS.—A government authority that obtains protected health information 18 about a protected individual from a health information 19 trustee under circumstances described in subsection (a) 20 21 and pursuant to a warrant or search warrant shall, not 22 later than 30 days after the date the warrant was served 23 on the trustee, serve the individual with, or mail to the 24 last known address of the individual, a copy of the war-25 rant.

(c) SUBPOENAS.—Except as provided in subsection 1 (d), a government authority may not obtain protected 2 3 health information about a protected individual from a 4 health information trustee under circumstances described in subsection (a) and pursuant to a subpoena unless a 5 copy of the subpoena has been served by hand delivery 6 7 upon the individual, or mailed to the last known address 8 of the individual, on or before the date on which the sub-9 poena was served on the trustee, together with a notice (published by the Secretary under section 135(1)) of the 10 individual's right to challenge the subpoena in accordance 11 with section 132, and— 12

(1) 30 days have passed from the date of service, or 30 days have passed from the date of mailing,
and within such time period the individual has not
initiated a challenge in accordance with section 132;
or

18 (2) disclosure is ordered by a court under sec-19 tion 132.

20 (d) Application for Delay.—

(1) IN GENERAL.—A government authority may
apply to an appropriate court to delay (for an initial
period of not longer than 90 days) serving a copy of
a subpoena and a notice otherwise required under
subsection (c) with respect to a law enforcement in-

quiry. The government authority may apply to the
 court for extensions of the delay.

3 (2) REASONS FOR DELAY.—An application for
4 a delay, or extension of a delay, under this sub5 section shall state, with reasonable specificity, the
6 reasons why the delay or extension is being sought.

7 (3) EX PARTE ORDER.—The court shall enter 8 an ex parte order delaying, or extending the delay 9 of, the notice and an order prohibiting the trustee 10 from revealing the request for, or the disclosure of, 11 the protected health information being sought if the 12 court finds that—

(A) the inquiry being conducted is within
the lawful jurisdiction of the government authority seeking the protected health information;

(B) there is probable cause to believe that
the protected health information being sought is
relevant to a legitimate law enforcement inquiry
being conducted by the government authority;

(C) the government authority's need for
the information outweighs the privacy interest
of the protected individual who is the subject of
the information; and

1	(D) there are reasonable grounds to believe
2	that receipt of a notice by the individual will re-
3	sult in—
4	(i) endangering the life or physical
5	safety of any individual;
6	(ii) flight from prosecution;
7	(iii) destruction of or tampering with
8	evidence or the information being sought;
9	or
10	(iv) intimidation of potential wit-
11	nesses.
12	(4) Service of application on individ-
13	UAL.—Upon the expiration of a period of delay of
14	notice under this subsection, the government author-
15	ity shall serve upon the individual, with the service
16	of the subpoena and the notice, a copy of any appli-
17	cations filed and approved under this subsection.
18	SEC. 132. CHALLENGE PROCEDURES FOR LAW ENFORCE-
19	MENT SUBPOENAS.
20	(a) MOTION TO QUASH SUBPOENA.—Within 30 days
21	of the date of service, or 30 days of the date of mailing,
22	of a subpoena of a government authority seeking protected
23	health information about a protected individual from a
24	health information trustee under paragraph (1) or (2) of
25	section 120(a) (except a subpoena to which section 133

1	applies), the individual may file (without filing fee) a mo-
2	tion to quash the subpoena—
3	(1) in the case of a State judicial subpoena, in
4	the court which issued the subpoena;
5	(2) in the case of a subpoena issued under the
6	authority of a State that is not a State judicial sub-
7	poena, in a court of competent jurisdiction;
8	(3) in the case of a subpoena issued under the
9	authority of a Federal court, in any court of the
10	United States of competent jurisdiction; or
11	(4) in the case of any other subpoena issued
12	under the authority of the United States, in—
13	(A) the United States district court for the
14	district in which the individual resides or in
15	which the subpoena was issued; or
16	(B) another United States district court of
17	competent jurisdiction.
18	(b) COPY.—A copy of the motion shall be served by
19	the individual upon the government authority by delivery
20	of registered or certified mail.
21	(c) Affidavits and Sworn Documents.—The gov-
22	ernment authority may file with the court such affidavits
23	and other sworn documents as sustain the validity of the
24	subpoena. The individual may file with the court, within
25	5 days of the date of the authority's filing, affidavits and

sworn documents in response to the authority's filing. The
 court, upon the request of the individual, the government
 authority, or both, may proceed in camera.

(d) PROCEEDINGS AND DECISION ON MOTION.—The
court may conduct such proceedings as it deems appropriate to rule on the motion. All such proceedings shall
be completed, and the motion ruled on, within 10 calendar
days of the date of the government authority's filing.

9 (e) EXTENSION OF TIME LIMITS FOR GOOD 10 CAUSE.—The court, for good cause shown, may at any 11 time in its discretion enlarge the time limits established 12 by subsections (c) and (d).

13 (f) STANDARD FOR DECISION.—A court may deny a motion under subsection (a) if it finds that there is prob-14 15 able cause to believe that the protected health information being sought is relevant to a legitimate law enforcement 16 inquiry being conducted by the government authority, un-17 less the court finds that the individual's privacy interest 18 outweighs the government authority's need for the infor-19 mation. The individual shall have the burden of dem-20 onstrating that the individual's privacy interest outweighs 21 22 the need established by the government authority for the 23 information.

24 (g) SPECIFIC CONSIDERATIONS WITH RESPECT TO25 PRIVACY INTEREST.—In determining under subsection (f)

whether an individual's privacy interest outweighs the gov ernment authority's need for the information, the court
 shall consider—

4 (1) the particular purpose for which the infor-5 mation was collected by the trustee;

6 (2) the degree to which disclosure of the infor7 mation will embarrass, injure, or invade the privacy
8 of the individual;

9 (3) the effect of the disclosure on the individ-10 ual's future health care;

(4) the importance of the inquiry being conducted by the government authority, and the importance of the information to that inquiry; and

14 (5) any other factor deemed relevant by the15 court.

16 (h) ATTORNEY'S FEES.—In the case of any motion 17 brought under subsection (a) in which the individual has 18 substantially prevailed, the court, in its discretion, may as-19 sess against a government authority a reasonable attor-20 ney's fee and other litigation costs (including expert fees) 21 reasonably incurred.

(i) NO INTERLOCUTORY APPEAL.—A court ruling denying a motion to quash under this section shall not be
deemed a final order and no interlocutory appeal may be
taken therefrom by the individual. An appeal of such a

ruling may be taken by the individual within such period
 of time as is provided by law as part of any appeal from
 a final order in any legal proceeding initiated against the
 individual arising out of or based upon the protected
 health information disclosed.

6 SEC. 133. ACCESS AND CHALLENGE PROCEDURES FOR 7 OTHER SUBPOENAS.

8 (a) IN GENERAL.—A person (other than a govern-9 ment authority seeking protected health information under 10 circumstances described in section 131(a)) may not obtain 11 protected health information about a protected individual 12 from a health information trustee pursuant to a subpoena 13 under section 120(a)(2) unless—

(1) a copy of the subpoena has been served 14 15 upon the individual or mailed to the last known address of the individual on or before the date on 16 17 which the subpoena was served on the trustee, to-18 gether with a notice (published by the Secretary 19 under section 135(2)) of the individual's right to 20 challenge the subpoena, in accordance with subsection (b); and 21

22 (2) either—

(A) 30 days have passed from the date of
service or 30 days have passed from the date of
the mailing and within such time period the in-

1	dividual has not initiated a challenge in accord-
2	ance with subsection (b); or
3	(B) disclosure is ordered by a court under
4	such subsection.
5	(b) MOTION TO QUASH.—Within 30 days of the date

of service or 30 days of the date of mailing of a subpoena 6 7 seeking protected health information about a protected in-8 dividual from a health information trustee under sub-9 section (a), the individual may file (without filing fee) in any court of competent jurisdiction, a motion to quash the 10 subpoena, with a copy served on the person seeking the 11 information. The individual may oppose, or seek to limit, 12 the subpoena on any grounds that would otherwise be 13 available if the individual were in possession of the infor-14 15 mation.

16 (c) STANDARD FOR DECISION.—The court shall 17 grant an individual's motion under subsection (b) if the 18 person seeking the information has not sustained the bur-19 den of demonstrating that—

20 (1) there are reasonable grounds to believe that
21 the information will be relevant to a lawsuit or other
22 judicial or administrative proceeding; and

(2) the need of the person for the informationoutweighs the privacy interest of the individual.

(d) SPECIFIC CONSIDERATIONS WITH RESPECT TO PRIVACY INTEREST.—In determining under subsection (c) whether the need of the person for the information outweighs the privacy interest of the individual, the court

6 (1) the particular purpose for which the infor7 mation was collected by the trustee;

8 (2) the degree to which disclosure of the infor9 mation will embarrass, injure, or invade the privacy
10 of the individual;

11 (3) the effect of the disclosure on the individ-12 ual's future health care;

13 (4) the importance of the information to the14 lawsuit or proceeding; and

15 (5) any other factor deemed relevant by the16 court.

17 (e) ATTORNEY'S FEES.—In the case of any motion 18 brought under subsection (b) by an individual against a 19 person in which the individual has substantially prevailed, 20 the court, in its discretion, may assess against the person 21 a reasonable attorney's fee and other litigation costs (in-22 cluding expert fees) reasonably incurred.

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shall consider—

1SEC. 134. CONSTRUCTION OF SUBTITLE; SUSPENSION OF2STATUTE OF LIMITATIONS.

3 (a) IN GENERAL.—Nothing in this subtitle shall af-4 fect the right of a health information trustee to challenge 5 a request for protected health information. Nothing in this 6 subtitle shall entitle a protected individual to assert the 7 rights of a health information trustee.

8 (b) EFFECT OF MOTION ON STATUTE OF LIMITA-9 TIONS.—If an individual who is the subject of protected health information files a motion under this subtitle which 10 has the effect of delaying the access of a government au-11 thority to such information, the period beginning on the 12 date such motion was filed and ending on the date on 13 which the motion is decided shall be excluded in computing 14 any period of limitations within which the government au-15 thority may commence any civil or criminal action in con-16 nection with which the access is sought. 17

18 SEC. 135. RESPONSIBILITIES OF SECRETARY.

19 Not later than July 1, 1996, the Secretary, after no-20 tice and opportunity for public comment, shall develop and 21 disseminate brief, clear, and easily understood model 22 notices—

(1) for use under subsection (c) of section 131,
detailing the rights of a protected individual who
wishes to challenge, under section 132, the disclo-

sure of protected health information about the indi-1 2 vidual under such subsection; and (2) for use under subsection (a) of section 133, 3 4 detailing the rights of a protected individual who wishes to challenge, under subsection (b) of such 5 6 section, the disclosure of protected health informa-7 tion about the individual under such section. Subtitle D—Miscellaneous 8

Subtitle D—Miscellaneous Provisions

10sec. 141. PAYMENT CARD AND ELECTRONIC PAYMENT11TRANSACTIONS.

12 (a) PAYMENT FOR HEALTH CARE THROUGH CARD OR ELECTRONIC MEANS.—If a protected individual pays 13 a health information trustee for health care by presenting 14 15 a debit, credit, or other payment card or account number, or by any other electronic payment means, the trustee may 16 disclose to a person described in subsection (b) only such 17 protected health information about the individual as is 18 necessary for the processing of the payment transaction 19 or the billing or collection of amounts charged to, debited 20 from, or otherwise paid by, the individual using the card, 21 22 number, or other electronic payment means.

(b) TRANSACTION PROCESSING.—A person who is a
debit, credit, or other payment card issuer, is otherwise
directly involved in the processing of payment transactions

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involving such cards or other electronic payment trans actions, or is otherwise directly involved in the billing or
 collection of amounts paid through such means, may only
 use or disclose protected health information about a pro tected individual that has been disclosed in accordance
 with subsection (a) when necessary for—

7 (1) the authorization, settlement, billing or col8 lection of amounts charged to, debited from, or oth9 erwise paid by, the individual using a debit, credit,
10 or other payment card or account number, or by
11 other electronic payment means;

12 (2) the transfer of receivables, accounts, or in-13 terest therein;

14 (3) the audit of the credit, debit, or other pay-15 ment card account information;

16 (4) compliance with Federal, State, or local law;17 or

(5) a properly authorized civil, criminal, or regulatory investigation by Federal, State, or local authorities.

21 SEC. 142. ACCESS TO PROTECTED HEALTH INFORMATION
22 OUTSIDE OF THE UNITED STATES.

(a) IN GENERAL.—Notwithstanding the provisions of
subtitle B, and except as provided in subsection (b), a
health information trustee may not permit any person who

1 is not in a State to have access to protected health infor-2 mation about a protected individual unless one or more3 of the following conditions exist:

4 (1) SPECIFIC AUTHORIZATION.—The individual
5 has specifically consented to the provision of such
6 access outside of the United States in an authoriza7 tion that meets the requirements of section 112.

(2) EQUIVALENT PROTECTION.—The provision 8 of such access is authorized under this Act and the 9 Secretary has determined that there are fair infor-10 11 mation practices for protected health information in the jurisdiction where the access will be provided 12 that provide protections for individuals and pro-13 14 tected health information that are equivalent to the 15 protections provided for by this Act.

16 (3) ACCESS REQUIRED BY LAW.—The provision
17 of such access is required under—

18 (A) a Federal statute; or

(B) a treaty or other international agree-ment applicable to the United States.

(b) EXCEPTIONS.—Subsection (a) does not apply
where the provision of access to protected health information—

24 (1) is to a foreign public health authority;

(2) is authorized under section 114 (relating to
 next of kin and directory information), 116 (relating
 to health research), or 117 (relating to emergency
 circumstances); or

5 (3) is necessary for the purpose of providing for
6 payment for health care that has been provided to
7 an individual.

8 SEC. 143. STANDARDS FOR ELECTRONIC DOCUMENTS AND 9 COMMUNICATIONS.

10 (a) STANDARDS.—Not later than July 1, 1996, the Secretary, after notice and opportunity for public com-11 ment and in consultation with appropriate private stand-12 ard-setting organizations and other interested parties, 13 shall establish standards with respect to the creation, 14 transmission, receipt, and maintenance, in electronic and 15 magnetic form, of each type of written document specifi-16 cally required or authorized under this Act. Where a sig-17 nature is required under any other provision of this Act, 18 such standards shall provide for an electronic or magnetic 19 substitute that serves the functional equivalent of a signa-20 21 ture.

(b) TREATMENT OF COMPLYING DOCUMENTS AND
COMMUNICATIONS.—An electronic or magnetic document
or communication that satisfies the standards established
under subsection (a) with respect to such document or

communication shall be treated as satisfying the require ments of this Act that apply to an equivalent written docu ment.

4 SEC. 144. DUTIES AND AUTHORITIES OF AFFILIATED PER-5 SONS.

6 (a) REQUIREMENTS ON TRUSTEES.—

7 (1) PROVISION OF INFORMATION.—A health in-8 formation trustee may provide protected health in-9 formation to a person who, with respect to the trust-10 ee, is an affiliated person and may permit the affili-11 ated person to use such information, only for the 12 purpose of conducting, supporting, or facilitating an 13 activity that the trustee is authorized to undertake.

14 (2) NOTICE TO AFFILIATED PERSON.—A health 15 information trustee shall notify a person who, with 16 respect to the trustee, is an affiliated person of any 17 duties under this Act that the affiliated person is re-18 quired to fulfill and of any authorities under this 19 Act that the affiliated person is authorized to exer-20 cise.

21 (b) DUTIES OF AFFILIATED PERSONS.—

(1) IN GENERAL.—An affiliated person shall
fulfill any duty under this Act that—

24 (A) the health information trustee with25 whom the person has an agreement or relation-

1 ship described in section 3(c)(1)(C) is required 2 to fulfill; and (B) the person has undertaken to fulfill 3 4 pursuant to such agreement or relationship. 5 (2) CONSTRUCTION OF OTHER SUBTITLES.— 6 With respect to a duty described in paragraph (1) 7 that an affiliated person is required to fulfill, the person shall be considered a health information 8 9 trustee for purposes of this Act. The person shall be subject to subtitle E (relating to enforcement) with 10 11 respect to any such duty that the person fails to fulfill. 12 13 (3) EFFECT ON TRUSTEE.—An agreement or 14 relationship with an affiliated person does not relieve 15 a health information trustee of any duty or liability under this Act. 16 17 (b) AUTHORITIES OF AFFILIATED PERSONS.— 18 (1) IN GENERAL.—An affiliated person may

only exercise an authority under this Act that the health information trustee with whom the person is affiliated may exercise and that the person has been given by the trustee pursuant to an agreement or relationship described in section 3(c)(1)(C). With respect to any such authority, the person shall be considered a health information trustee for purposes of this Act. The person shall be subject to subtitle E
 (relating to enforcement) with respect to any act
 that exceeds such authority.

4 (2) EFFECT ON TRUSTEE.—An agreement or
5 relationship with an affiliated person does not affect
6 the authority of a health information trustee under
7 this Act.

8 SEC. 145. AGENTS AND ATTORNEYS.

9 (a) IN GENERAL.—Except as provided in subsections 10 (b) and (c), a person who is authorized by law (on grounds other than an individual's minority), or by an instrument 11 12 recognized under law, to act as an agent, attorney, proxy, or other legal representative for a protected individual or 13 the estate of a protected individual, or otherwise to exer-14 cise the rights of the individual or estate, may, to the ex-15 tent authorized, exercise and discharge the rights of the 16 individual or estate under this Act. 17

(b) HEALTH CARE POWER OF ATTORNEY.—A person who is authorized by law (on grounds other than an individual's minority), or by an instrument recognized under law, to make decisions about the provision of health care to an individual who is incapacitated may exercise and discharge the rights of the individual under this Act to the extent necessary to effectuate the terms or purposes of the grant of authority.

(c) NO COURT DECLARATION.—If a health care pro-1 vider determines that an individual, who has not been de-2 clared to be legally incompetent, suffers from a medical 3 condition that prevents the individual from acting know-4 ingly or effectively on the individual's own behalf, the right 5 of the individual to authorize disclosure under section 112 6 may be exercised and discharged in the best interest of 7 the individual by— 8

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

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

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

(4) the health care provider, but only if a person described in paragraph (1), (2), or (3) cannot be
contacted after a reasonable effort.

21 SEC. 146. MINORS.

(a) INDIVIDUALS WHO ARE 18 OR LEGALLY CAPABLE.—In the case of an individual—

(1) who is 18 years of age or older, all rights 1 2 of the individual shall be exercised by the individual, except as provided in section 145; or 3 4 (2) who, acting alone, has the legal capacity to apply for and obtain health care and has sought 5 such care, the individual shall exercise all rights of 6 an individual under this Act with respect to pro-7 tected health information relating to such care. 8 9 (b) INDIVIDUALS UNDER 18.—Except as provided in subsection (a)(2), in the case of an individual who is— 10 11 (1) under 14 years of age, all the individual's 12 rights under this Act shall be exercised through the 13 parent or legal guardian of the individual; or 14 (2) 14, 15, 16, or 17 years of age, the right of 15 inspection (under section 101), the right of amendment (under section 102), and the right to authorize 16 17 disclosure of protected health information (under 18 section 112) of the individual may be exercised ei-19 ther by the individual or by the parent or legal 20 guardian of the individual. 21 SEC. 147. MAINTENANCE OF CERTAIN PROTECTED HEALTH 22 **INFORMATION.**

(a) IN GENERAL.—A State shall establish a process
under which the protected health information described in
subsection (b) that is maintained by a person described

1	in subsection (c) is delivered to, and maintained by, the
2	State or an individual or entity designated by the State.
3	(b) INFORMATION DESCRIBED.—The protected
4	health information referred to in subsection (a) is pro-
5	tected health information that—
6	(1) is recorded in any form or medium;
7	(2) is created by—
8	(A) a health care provider; or
9	(B) a health benefit plan sponsor that pro-
10	vides benefits in the form of items and services
11	to enrollees and not in the form of reimburse-
12	ment for items and services; and
13	(3) relates in any way to the past, present, or
14	future physical or mental health or condition or
15	functional status of a protected individual or the
16	provision of health care to a protected individual.
17	(c) PERSONS DESCRIBED.—A person referred to in
18	subsection (a) is any of the following:
19	(1) A health care facility previously located in
20	the State that has closed.
21	(2) A professional practice previously operated
22	by a health care provider in the State that has
23	closed.
24	(3) A health benefit plan sponsor that—

	10
1	(A) previously provided benefits in the
2	form of items and services to enrollees in the
3	State; and
4	(B) has ceased to do business.
5	Subtitle E—Enforcement
6	SEC. 151. CIVIL ACTIONS.
7	(a) IN GENERAL.—Any individual whose right under
8	this Act has been knowingly or negligently violated—
9	(1) by a health information trustee, or any
10	other person, who is not described in paragraph (2),
11	(3), (4) , or (5) may maintain a civil action for actual
12	damages and for equitable relief against the health
13	information trustee or other person;
14	(2) by an officer or employee of the United
15	States while the officer or employee was acting with-
16	in the scope of the office or employment may main-
17	tain a civil action for actual damages and for equi-
18	table relief against the United States;
19	(3) by an officer or employee of any government
20	authority of a State that has waived its sovereign
21	immunity to a claim for damages resulting from a
22	violation of this Act while the officer or employee
23	was acting within the scope of the office or employ-

24 ment may maintain a civil action for actual damages

and for equitable relief against the State govern ment;

3 (4) by an officer or employee of a government
4 of a State that is not described in paragraph (3)
5 may maintain a civil action for actual damages and
6 for equitable relief against the officer or employee;
7 or

(5) by an officer or employee of a government 8 9 authority while the officer or employee was not acting within the scope of the office or employment 10 may maintain a civil action for actual damages and 11 12 for equitable relief against the officer or employee. (b) KNOWING VIOLATIONS.—Any individual entitled 13 to recover actual damages under this section because of 14 15 a knowing violation of a provision of this Act (other than subsection (c) or (d) of section 111) shall be entitled to 16 recover the amount of the actual damages demonstrated 17 or \$5000, whichever is greater. 18

(c) ACTUAL DAMAGES.—For purposes of this section,
the term "actual damages" includes damages paid to compensate an individual for nonpecuniary losses such as
physical and mental injury as well as damages paid to
compensate for pecuniary losses.

24 (d) PUNITIVE DAMAGES; ATTORNEY'S FEES.—In 25 any action brought under this section in which the com-

plainant has prevailed because of a knowing violation of 1 a provision of this Act (other than subsection (c) or (d) 2 of section 111), the court may, in addition to any relief 3 4 awarded under subsections (a) and (b), award such punitive damages as may be warranted. In such an action, the 5 court, in its discretion, may allow the prevailing party a 6 7 reasonable attorney's fee (including expert fees) as part 8 of the costs, and the United States shall be liable for costs 9 the same as a private person.

10 (e) LIMITATION.—A civil action under this section 11 may not be commenced more than 2 years after the date 12 on which the aggrieved individual discovered the violation 13 or the date on which the aggrieved individual had a rea-14 sonable opportunity to discover the violation, whichever oc-15 curs first.

16 (f) INSPECTION AND AMENDMENT.—If a health in-17 formation trustee has established a formal internal proce-18 dure that allows an individual who has been denied inspec-19 tion or amendment of protected health information to ap-20 peal the denial, the individual may not maintain a civil 21 action in connection with the denial until the earlier of—

(1) the date the appeal procedure has been ex-hausted; or

24 (2) the date that is 4 months after the date on25 which the appeal procedure was initiated.

1 (g) NO LIABILITY FOR PERMISSIBLE DISCLO-2 SURES.—A health information trustee who makes a disclo-3 sure of protected health information about a protected in-4 dividual that is permitted by this Act and not otherwise 5 prohibited by State or Federal statute shall not be liable 6 to the individual for the disclosure under common law.

7 (h) NO LIABILITY FOR INSTITUTIONAL REVIEW 8 BOARD DETERMINATIONS.—If the members of a certified institutional review board have in good faith determined 9 10 that an approved health research project is of sufficient importance so as to outweigh the intrusion into the privacy 11 of an individual pursuant to section 116(a)(1), the mem-12 bers, the board, and the parent institution of the board 13 shall not be liable to the individual as a result of such 14 15 determination.

16 (i) GOOD FAITH RELIANCE ON CERTIFICATION.—A 17 health information trustee who relies in good faith on a 18 certification by a government authority or other person 19 and discloses protected health information about an indi-20 vidual in accordance with this Act shall not be liable to 21 the individual for such disclosure.

22 SEC. 152. CIVIL MONEY PENALTIES.

(a) VIOLATION.—Any health information trustee who
the Secretary determines has demonstrated a pattern or
practice of failure to comply with the provisions of this

Act shall be subject, in addition to any other penalties that 1 may be prescribed by law, to a civil money penalty of not 2 more than \$10,000 for each such failure. In determining 3 4 the amount of any penalty to be assessed under the procedures established under subsection (b), the Secretary shall 5 take into account the previous record of compliance of the 6 7 person being assessed with the applicable requirements of this Act and the gravity of the violation. 8

9 (b) PROCEDURES FOR IMPOSITION OF PENALTIES.— 10 The provisions of section 1128A of the Social Security Act 11 (other than subsections (a) and (b)) shall apply to the im-12 position of a civil monetary penalty under this section in 13 the same manner as such provisions apply with respect 14 to the imposition of a penalty under section 1128A of such 15 Act.

16 SEC. 153. ALTERNATIVE DISPUTE RESOLUTION.

(a) IN GENERAL.—Not later than July 1, 1996, the
Secretary shall, by regulation, develop alternative dispute
resolution methods for use by individuals, health information trustees, and other persons in resolving claims under
section 151.

22 (b) EFFECT ON INITIATION OF CIVIL ACTIONS.—

(1) IN GENERAL.—Subject to paragraph (2),
the regulations established under subsection (a) may
provide that an individual alleging that a right of

the individual under this Act has been violated shall
 pursue at least one alternative dispute resolution
 method developed under such subsection as a condi tion precedent to commencing a civil action under
 section 151.

6 (2) LIMITATION.—Such regulations may not re-7 quire an individual to refrain from commencing a 8 civil action to pursue one or more alternative dispute 9 resolution method for a period that is greater than 10 6 months.

11 (3)SUSPENSION OF STATUTE OF LIMITA-12 TIONS.—The regulations established by the Secretary under subsection (a) may provide that a pe-13 14 riod in which an individual described in paragraph 15 (1) pursues (as defined by the Secretary) an alter-16 native dispute resolution method under this section 17 shall be excluded in computing the period of limita-18 tions under section 151(e).

19 (c) METHODS.—The methods under subsection (a)20 shall include at least the following:

21 (1) ARBITRATION.—The use of arbitration.

22 (2) MEDIATION.—The use of mediation.

23 (3) EARLY OFFERS OF SETTLEMENT.—The use
24 of a process under which parties make early offers
25 of settlement.

1	(d) Standards for Establishing Methods.—In
2	developing alternative dispute resolution methods under
3	subsection (a), the Secretary shall ensure that the meth-
4	ods promote the resolution of claims in a manner that—
5	(1) is affordable for the parties involved;
6	(2) provides for timely and fair resolution of
7	claims; and
8	(3) provides for reasonably convenient access to
9	dispute resolution for individuals.
10	SEC. 154. AMENDMENTS TO CRIMINAL LAW.
11	(a) IN GENERAL.—Title 18, United States Code, is
12	amended by inserting after chapter 89 the following:

13 **"CHAPTER 90—PROTECTED HEALTH**

14

INFORMATION

- "Sec.
- "1831. Definitions.
- "1832. Obtaining protected health information under false pretenses.
- "1833. Monetary gain from obtaining protected health information under false pretenses.
- "1834. Knowing and unlawful obtaining of protected health information.
- "1835. Monetary gain from knowing and unlawful obtaining of protected health information.
- "1836. Knowing and unlawful use or disclosure of protected health information.
- "1837. Monetary gain from knowing and unlawful sale, transfer, or use of protected health information.

15 **"§1831. Definitions**

- 16 "As used in this chapter—
- 17 "(1) the term 'health information trustee' has
- 18 the meaning given such term in section 3(b)(6) of
- 19 the Fair Health Information Practices Act of 1995;

1	(2) the term 'protected health information' has
2	the meaning given such term in section $3(a)(3)$ of
3	such Act; and
4	"(3) the term 'protected individual' has the
5	meaning given such term in section 3(a)(4) of such
6	Act.
7	"§1832. Obtaining protected health information
8	under false pretenses
9	"Whoever under false pretenses—
10	"(1) requests or obtains protected health infor-
11	mation from a health information trustee; or
12	"(2) obtains from a protected individual an au-
13	thorization for the disclosure of protected health in-
14	formation about the individual maintained by a
15	health information trustee;
16	shall be fined under this title or imprisoned not more than
17	5 years, or both.
18	"§1833. Monetary gain from obtaining protected
19	health information under false pretenses
20	"Whoever under false pretenses—
21	"(1) requests or obtains protected health infor-
22	mation from a health information trustee with the
23	intent to sell, transfer, or use such information for
24	profit or monetary gain; or

"(2) obtains from a protected individual an authorization for the disclosure of protected health information about the individual maintained by a
health information trustee with the intent to sell,
transfer, or use such authorization for profit or
monetary gain;

7 and knowingly sells, transfers, or uses such information
8 or authorization for profit or monetary gain shall be fined
9 under this title or imprisoned not more than 10 years, or
10 both.

11 "§1834. Knowing and unlawful obtaining of pro12 tected health information

13 "Whoever knowingly obtains protected health information from a health information trustee in violation of 14 the Fair Health Information Practices Act of 1995, know-15 ing that such obtaining is unlawful, shall be fined under 16 this title or imprisoned not more than 5 years, or both. 17 18 "§1835. Monetary gain from knowing and unlawful 19 obtaining of protected health information "Whoever knowingly— 20 "(1) obtains protected health information from 21

a health information trustee in violation of the Fair
Health Information Practices Act of 1995, knowing
that such obtaining is unlawful and with the intent

1	to sell, transfer, or use such information for profit
2	or monetary gain; and
3	''(2) knowingly sells, transfers, or uses such in-
4	formation for profit or monetary gain;
5	shall be fined under this title or imprisoned not more than
6	10 years, or both.

7 "§1836. Knowing and unlawful use or disclosure of 8 protected health information

9 "Whoever knowingly uses or discloses protected 10 health information in violation of the Fair Health Infor-11 mation Practices Act of 1995, knowing that such use or 12 disclosure is unlawful, shall be fined under this title or 13 imprisoned not more than 5 years, or both.

14 "§1837. Monetary gain from knowing and unlawful
15 sale, transfer, or use of protected health
16 information

17 "Whoever knowingly sells, transfers, or uses pro-18 tected health information in violation of the Fair Health 19 Information Practices Act of 1995, knowing that such 20 sale, transfer, or use is unlawful, shall be fined under this 21 title or imprisoned not more than 10 years, or both.".

(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 89 the following:

"90. Protected health information 1831".

TITLE II—AMENDMENTS TO TITLE 5, UNITED STATES CODE

3 SEC. 201. AMENDMENTS TO TITLE 5, UNITED STATES CODE.

4 (a) NEW SUBSECTION.—Section 552a of title 5,
5 United States Code, is amended by adding at the end the
6 following:

7 "(w) MEDICAL EXEMPTIONS.—The head of an agency that is a health information trustee (as defined in sec-8 tion 3(b)(6) of the Fair Health Information Practices Act 9 of 1995) shall promulgate rules, in accordance with the 10 requirements (including general notice) of subsections 11 (b)(1), (b)(2), (b)(3), (c), and (e) of section 553 of this 12 title, to exempt a system of records within the agency, to 13 the extent that the system of records contains protected 14 health information (as defined in section 3(a)(3) of such 15 Act), from all provisions of this section except subsections 16 17 (e)(1), (e)(2), subparagraphs (A) through (C) and (E) through (I) of subsection (e)(4), and subsections (e)(5), 18 19 (e)(6), (e)(9), (e)(12), (l), (n), (o), (p), (q), (r), and (u).20 (b) REPEAL.—Section 552a(f)(3) of title 5, United 21 States Code, is amended by striking "pertaining to him," and all that follows through the semicolon and inserting 22 "pertaining to the individual;". 23

TITLE III—REGULATIONS, RE SEARCH, AND EDUCATION; EFFECTIVE DATES; APPLICA BILITY; AND RELATIONSHIP TO OTHER LAWS

6 SEC. 301. REGULATIONS; RESEARCH AND EDUCATION.

7 (a) REGULATIONS.—Not later than July 1, 1996, the
8 Secretary shall prescribe regulations to carry out this Act.
9 (b) RESEARCH AND TECHNICAL SUPPORT.—The

10 Secretary may sponsor—

(1) research relating to the privacy and securityof protected health information;

13 (2) the development of consent forms governing14 disclosure of such information; and

15 (3) the development of technology to implement16 standards regarding such information.

17 (c) EDUCATION.—The Secretary shall establish edu-18 cation and awareness programs—

19 (1) to foster adequate security practices by20 health information trustees;

(2) to train personnel of health information
trustees respecting the duties of such personnel with
respect to protected health information; and

(3) to inform individuals and employers who
 purchase health care respecting their rights with re spect to such information.

4 SEC. 302. EFFECTIVE DATES.

5 (a) IN GENERAL.—Except as provided in subsection
6 (b), this Act, and the amendments made by this Act, shall
7 take effect on January 1, 1997.

8 (b) PROVISIONS EFFECTIVE IMMEDIATELY.—A pro9 vision of this Act shall take effect on the date of the enact10 ment of this Act if the provision—

(1) imposes a duty on the Secretary to develop,
establish, or promulgate regulations, guidelines, notices, statements, or education and awareness programs; or

15 (2) authorizes the Secretary to sponsor researchor the development of forms or technology.

17 SEC. 303. APPLICABILITY.

(a) PROTECTED HEALTH INFORMATION.—Except as
provided in subsections (b) and (c), the provisions of this
Act shall apply to any protected health information that
is received, created, used, maintained, or disclosed by a
health information trustee in a State on or after January
1, 1997, regardless of whether the information existed or
was disclosed prior to such date.

25 (b) EXCEPTION.—

1	(1) IN GENERAL.—The provisions of this Act
2	shall not apply to a trustee described in paragraph
3	(2), except with respect to protected health informa-
4	tion that is received by the trustee on or after Janu-
5	ary 1, 1997.
6	(2) APPLICABILITY.—A trustee referred to in
7	paragraph (1) is—
8	(A) a health researcher; or
9	(B) a person who, with respect to specific
10	protected health information, received the infor-
11	mation—
12	(i) pursuant to—
13	(I) section 117 (relating to emer-
14	gency circumstances);
15	(II) section 118 (relating to judi-
16	cial and administrative purposes);
17	(III) section 119 (relating to law
18	enforcement); or
19	(IV) section 120 (relating to sub-
20	poenas, warrants, and search war-
21	rants); or
22	(ii) while acting in whole or in part in
23	the capacity of an officer or employee of a
24	person described in clause (i).

(c) AUTHORIZATIONS FOR DISCLOSURES .- An au-1 thorization for the disclosure of protected health informa-2 tion about a protected individual that is executed by the 3 4 individual before January 1, 1997, and is recognized and valid under State law on December 31, 1996, shall remain 5 valid and shall not be subject to the requirements of sec-6 7 tion 112 until January 1, 1998, or the occurrence of the date or event (if any) specified in the authorization upon 8 9 which the authorization expires, whichever occurs earlier.

10 SEC. 304. RELATIONSHIP TO OTHER LAWS.

(a) STATE LAW.—Except as otherwise provided in
subsections (b), (c), (d), and (f), a State may not establish, continue in effect, or enforce any State law to the
extent that the law is inconsistent with, or imposes additional requirements with respect to, any of the following:
(1) A duty of a health information trustee
under this Act.

18 (2) An authority of a health information trustee
19 under this Act to disclose protected health informa20 tion.

(3) A provision of subtitle C (relating to access
procedures and challenge rights), subtitle D (miscellaneous provisions), or subtitle E (relating to enforcement).

(b) LAWS RELATING TO PUBLIC HEALTH AND MEN TAL HEALTH.—This Act does not preempt, supersede, or
 modify the operation of any State law regarding public
 health or mental health to the extent that the law prohibits
 or regulates a disclosure of protected health information
 that is permitted under this Act.

7 (c) CRIMINAL PENALTIES.—A State may establish
8 and enforce criminal penalties with respect to a failure to
9 comply with a provision of this Act.

10 (d) PRIVILEGES.—A privilege that a person has 11 under law in a court of a State or the United States or 12 under the rules of any agency of a State or the United 13 States may not be diminished, waived, or otherwise af-14 fected by—

(1) the execution by a protected individual of an
authorization for disclosure of protected health information under this Act, if the authorization is executed for the purpose of receiving health care or providing for the payment for health care; or

20 (2) any provision of this Act that authorizes the
21 disclosure of protected health information for the
22 purpose of receiving health care or providing for the
23 payment for health care.

24 (e) DEPARTMENT OF VETERANS AFFAIRS.—The lim-25 itations on use and disclosure of protected health informa-

1 tion under this Act shall not be construed to prevent any
2 exchange of such information within and among compo3 nents of the Department of Veterans Affairs that deter4 mine eligibility for or entitlement to, or that provide, bene5 fits under laws administered by the Secretary of Veterans
6 Affairs.

7 (f) CERTAIN DUTIES UNDER STATE OR FEDERAL
8 LAW.—This Act shall not be construed to preempt, super9 sede, or modify the operation of any of the following:

10 (1) Any law that provides for the reporting of11 vital statistics such as birth or death information.

12 (2) Any law requiring the reporting of abuse or13 neglect information about any individual.

(3) Subpart II of part E of title XXVI of the
Public Health Service Act (relating to notifications
of emergency response employees of possible exposure to infectious diseases).

18 (4) The Americans with Disabilities Act of19 1990.

20 (5) Any Federal or State statute that estab21 lishes a privilege for records used in health profes22 sional peer review activities.

23 (f) SECRETARIAL AUTHORITY.—

24 (1) SECRETARY OF HEALTH AND HUMAN SERV25 ICES.—A provision of this Act does not preempt, su-

persede, or modify the operation of section 543 of 1 2 the Public Health Service Act, except to the extent that the Secretary of Health and Human Services 3 4 determines through regulations promulgated by such Secretary that the provision provides greater protec-5 6 tion for protected health information, and the rights of protected individuals, than is provided under such 7 8 section 543.

9 (2) SECRETARY OF VETERANS AFFAIRS.—A 10 provision of this Act does not preempt, supersede, or 11 modify the operation of section 7332 of title 38, 12 United States Code, except to the extent that the Secretary of Veterans Affairs determines through 13 14 regulations promulgated by such Secretary that the 15 provision provides greater protection for protected 16 health information, and the rights of protected indi-17 viduals, than is provided under such section 7332.

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