# H.R.3900

To establish Federal penalties for prohibited uses and disclosures of individually identifiable health information, to establish a right in an individual to inspect and copy their own health information, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

May 19, 1998

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

### A BILL

To establish Federal penalties for prohibited uses and disclosures of individually identifiable health information, to establish a right in an individual to inspect and copy their own health information, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.
- 4 (a) Short Title.—This Act may be cited as the
- 5 "Consumer Health and Research Technology (CHART)
- 6 Protection Act".

- 1 (b) Table of Contents for
- 2 this Act is as follows:
  - Sec. 1. Short title; table of contents.

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

- Sec. 101. General prohibitions and exceptions.
- Sec. 102. Special rules for anonymized information.
- Sec. 103. General requirements for authorization of disclosure of information.
- Sec. 104. Disclosure in civil proceedings.
- Sec. 105. Disclosure for criminal law enforcement purposes.
- Sec. 106. Disclosures for archival research.

#### TITLE II—INDIVIDUALS' RIGHTS

- Sec. 201. Inspection and copying of health information.
- Sec. 202. Amendment of individually identifiable health information.
- Sec. 203. Notice of confidentiality practices.

#### TITLE III—ENFORCEMENT

- Sec. 301. Criminal penalties.
- Sec. 302. Civil action.
- Sec. 303. Program exclusions.

#### TITLE IV—GENERAL PROVISIONS

- Sec. 401. Standards for electronic disclosures.
- Sec. 402. Authorized representatives.
- Sec. 403. Relationship to other laws.
- Sec. 404. Reports analyzing impact of Act.
- Sec. 405. Effective date.
- Sec. 406. Definitions.

### 3 TITLE I—RESTRICTIONS ON USE

### 4 AND DISCLOSURE

- 5 SEC. 101. GENERAL PROHIBITIONS AND EXCEPTIONS.
- 6 Except as otherwise provided in this Act, and subject
- 7 to the following exceptions, the following prohibited ac-
- 8 tions and inactions on the part of a person shall be consid-
- 9 ered a violation of this Act:
- 10 (1) Disclosure in absence of, or incon-
- 11 SISTENT WITH, AUTHORIZATION.—

1	(A) In general.—Subject to the excep-
2	tions described in subparagraph (B)—
3	(i) a negligent or intentional disclo-
4	sure of individually identifiable health in-
5	formation without an authorization with
6	respect to the information that satisfies
7	the requirements of section 103, is prohib-
8	ited, unless the disclosure is governed by
9	section 104 or 105; and
10	(ii) a negligent or intentional disclo-
11	sure of individually identifiable health in-
12	formation, by a person granted authority
13	under an authorization with respect to the
14	information that satisfies the requirements
15	of section 103, that is inconsistent with the
16	provisions of the authorization, is prohib-
17	ited.
18	(B) Exceptions.—A disclosure otherwise
19	prohibited under subparagraph (A) is not pro-
20	hibited when—
21	(i) made by an individual whose
22	health or health care is the subject of the
23	information (or an authorized representa-
24	tive of such an individual, pursuant to sec-
25	tion 402);

1	(ii) made for the purpose of providing,
2	or facilitating the provision of, health care
3	to an individual described in clause (i);
4	(iii) made for the purpose of facilitat-
5	ing payment activities related to health
6	care provided to an individual described in
7	clause (i);
8	(iv) made pursuant to a specific af-
9	firmative authorization, or a requirement,
10	under State or Federal law, for use in le-
11	gally authorized—
12	(I) reporting of abuse, domestic
13	violence, or neglect information about
14	any individual;
15	(II) disease or injury reporting
16	about any individual;
17	(III) public health surveillance,
18	such as birth and death reporting;
19	(IV) public health investigation
20	or intervention;
21	(V) management audits, financial
22	audits, or program monitoring and
23	evaluation; or
24	(VI) licensure, certification, ac-
25	creditation, utilization review, quality

1	assurance activities, benchmarking, or
2	outcomes management and assess-
3	ment;
4	(v) made pursuant to an authorization
5	granted in a contract providing health care
6	benefits for an individual described in
7	clause (i), for the purpose of licensure, cer-
8	tification, accreditation, utilization review,
9	quality assurance activities, benchmarking,
10	or outcomes management and assessment;
11	(vi) made to a health researcher—
12	(I) in accordance with a research
13	protocol approved by an institutional
14	review board; or
15	(II) in accordance with section
16	106(a); or
17	(vii) made to a party to, or potential
18	party to, a merger or acquisition of a com-
19	mercial enterprise, in anticipation of, or
20	upon, the merger or acquisition.
21	(2) Failure to provide for reasonable
22	PROTECTIONS AGAINST PROHIBITED DISCLO-
23	SURES.—
24	(A) In general.—Subject to the excep-
25	tion described in subparagraph (B), a negligent

1	or intentional failure to provide for reasonable
2	protections against disclosures of individually
3	identifiable health information that are prohib-
4	ited under this Act is prohibited, including—
5	(i) a failure to establish and enforce
6	reasonable and appropriate administrative,
7	technical, and physical safeguards—
8	(I) to ensure the confidentiality
9	of individually identifiable health in-
10	formation; and
11	(II) to protect against—
12	(aa) any reasonably antici-
13	pated threats or hazards to the
14	security or integrity of such in-
15	formation; and
16	(bb) unauthorized uses or
17	disclosures of the information;
18	(ii) a failure to establish procedures
19	for determining a response to a subpoena,
20	warrant, court order, or other request from
21	a government authority for disclosure of
22	such information; and
23	(iii) a failure to provide for secure de-
24	struction of such information, where de-
25	struction of the information is desired.

1	(B) Exception.—A failure described in
2	subparagraph (A) is not prohibited when it is
3	by an individual whose health or health care is
4	the subject of the information (or an authorized
5	representative of such an individual, pursuant
6	to section 402).
7	(3) Failure to implement written poli-
8	CIES FOR COMPLIANCE.—
9	(A) In general.—Subject to the excep-
10	tion described in subparagraph (B), with re-
11	spect to a person whose employees, agents, or
12	contractors come in contact with individually
13	identifiable health information in the course of
14	their employment, agency, or contract execu-
15	tion, a negligent or intentional failure to estab-
16	lish and implement written policies concerning
17	compliance with this Act is prohibited, includ-
18	ing—
19	(i) a failure to establish procedures
20	for monitoring access to individually identi-
21	fiable health information;
22	(ii) a failure to establish rules limiting
23	access to such information to persons
24	whose duties require such access; and

- 1 (iii) a failure to provide for the en-2 forcement of such policies.
  - (B) EXCEPTION.—A failure described in subparagraph (A) is not prohibited when it is by an individual whose health or health care is the subject of the information (or an authorized representative of such an individual, pursuant to section 402).
    - (4) Failure to enter into written agreement with an agent, comenter into a written agreement with an agent, contractor, or other person to whom individually identifiable health information is disclosed for a business purpose (such as persons who encode or encrypt information, data management contractors, and utilization review and accreditation organizations), prior to such disclosure, specifying the limitations on their use and retention of such information and informing them of their responsibilities under this Act, is prohibited.
    - (5) COMPLIANCE WITH RESEARCH REQUIRE-MENTS.—A negligent or intentional action is prohibited where it consists of—

1	(A) a disclosure for health research pur-
2	poses of individually identifiable health informa-
3	tion that—
4	(i) has not been approved by an insti-
5	tutional review board; or
6	(ii) does not satisfy the requirements
7	of section 106; or
8	(B) a use or disclosure of individually iden-
9	tifiable health information in violation of—
10	(i) a research protocol approved by an
11	institutional review board or any other re-
12	quirement or condition concerning such use
13	or disclosure established by such a review
14	board; or
15	(ii) any requirement or condition con-
16	cerning such use or disclosure established
17	by a person making, or approving, a disclo-
18	sure under section 106.
19	(6) Anonymized information.—A use of
20	anonymized information, or an encryption key or
21	coding system used to anonymize information, in
22	violation of section 102, is prohibited.
23	(7) CIVIL PROCEEDING.—A negligent or inten-
24	tional disclosure of individually identifiable health in-
25	formation pursuant to a subpoena or discovery re-

1	quest related to a civil proceeding, in violation of
2	section 104, is prohibited.
3	(8) Criminal proceeding.—A negligent or in-
4	tentional disclosure of individually identifiable health
5	information for a criminal law enforcement purpose,
6	in violation of section 105, or a negligent or inten-
7	tional use of information obtained pursuant to such
8	section in violation of the section, is prohibited.
9	(9) Sale or commercial publication.—
10	(A) In general.—Subject to the excep-
11	tions described in subparagraph (B), an inten-
12	tional disclosure of individually identifiable
13	health information that constitutes a sale or
14	commercial publication of the information, is
15	prohibited.
16	(B) Exceptions.—A disclosure otherwise
17	prohibited under subparagraph (A) is not pro-
18	hibited when—
19	(i) the disclosure is made by an indi-
20	vidual whose health or health care is the
21	subject of the information (or an author-
22	ized representative of such an individual,
23	pursuant to section 402); or
24	(ii) the disclosure is made to a person
25	having a written authorization permitting

the disclosure that satisfies the require-
ments of section 103.
(10) Fraud or misrepresentation.—Use of
fraud, duress, deceit, or misrepresentation to obtain
access to individually identifiable health information
is prohibited.
SEC. 102. SPECIAL RULES FOR ANONYMIZED INFORMA-
TION.
(a) Definition.—For purposes of this Act, the term
"anonymized information" means individually identifiable
health information from which personal identifiers and
means of directly contacting any subject of the informa-
tion (including name, address, and social security num-
ber), have been removed, encrypted, or replaced with a
code, in a manner such that the identity of any such sub-
ject is not apparent from the facts contained in the infor-
mation, but may, in the case of encrypted or coded infor-
mation, be determined by a person with access to the
encryption key or coding system. Such term does not in-
clude any such encryption key or coding system.
(b) Use.—
(1) In general.—Subject to paragraph (2), a
person may use anonymized information, or an
encryption key or coding system described in sub-

1	section (c)(2), for any lawful purpose, if the person,
2	in such use, does not—
3	(A) attempt to identify any individual with
4	respect to whom information has been removed,
5	encrypted, or replaced with a code; or
6	(B) intentionally use the anonymized infor-
7	mation, the key, or the coding system in any
8	way that results in the identification of any
9	such individual.
10	(2) Exceptions.—A use otherwise prohibited
11	under paragraph (1) is not prohibited when any of
12	the following circumstances apply:
13	(A) The use is by an individual whose
14	health or health care is the subject of the infor-
15	mation (or an authorized representative of such
16	an individual, pursuant to section 402).
17	(B) The use is by a person having an au-
18	thorization permitting the use that satisfies the
19	requirements of section 103.
20	(C) The use is for the purpose of provid-
21	ing, or facilitating the provision of, health care
22	to an individual described in subparagraph (A).
23	(D) The use is for the purpose of facilitat-
24	ing payment activities related to health care

1	provided to an individual described in subpara-
2	graph (A).
3	(E) The use is pursuant to a specific af-
4	firmative authorization, or a requirement, under
5	State or Federal law, for legally authorized—
6	(i) disease or injury reporting;
7	(ii) public health surveillance, such as
8	birth and death reporting, and reporting
9	incidents of abuse, domestic violence, or
10	neglect;
11	(iii) public health investigation or
12	intervention;
13	(iv) management audits, financial au-
14	dits, or program monitoring and evalua-
15	tion; or
16	(v) licensure, certification, accredita-
17	tion, utilization review, quality assurance
18	activities, benchmarking, or outcomes man-
19	agement and assessment.
20	(F) The use is pursuant to an authoriza-
21	tion granted in a contract providing health care
22	benefits for an individual described in subpara-
23	graph (A), for the purpose of licensure, certifi-
24	cation, accreditation, utilization review, quality

1	assurance activities, benchmarking, or outcomes
2	management and assessment.
3	(G) The use is by a health researcher and
4	is—
5	(i) in accordance with a research pro-
6	tocol approved by an institutional review
7	board and any other requirement or condi-
8	tion concerning such use established by
9	such a review board; or
10	(ii) in accordance with any require-
11	ment or condition concerning such use es-
12	tablished by a person making, or approv-
13	ing, a disclosure under section 106.
14	(H) The use is by a party to, or potential
15	party to, a merger or acquisition of a commer-
16	cial enterprise, in anticipation of, or upon, the
17	merger or acquisition.
18	(c) Disclosure.—
19	(1) Anonymized information.—For purposes
20	of this Act, disclosure of anonymized information
21	shall not be considered disclosure of individually
22	identifiable health information, unless it is disclosed
23	with an encryption key or coding system described in
24	paragraph (2) in manner such that the combined in-

- 1 formation satisfies the requirements of section 2 406(8).
- (2) Encryption key or code.—For purposes 3 of this Act, disclosure of an encryption key or coding 5 system that is used to determine the identity of any 6 individual with respect to whom information has 7 been removed, encrypted, or replaced with a code, in 8 order to create anonymized information, shall not be 9 considered disclosure of individually identifiable 10 health information, unless it is disclosed with 11 anonymized information in manner such that the 12 combined information satisfies the requirements of 13 section 406(8).
- (d) Decoded Information.—Formerly anonymized information that has been manipulated to reveal a part of the information that had been removed, encrypted, or replaced with a code in order to render it anonymized information is individually identifiable health information and is subject, beginning on the date of such manipulation, to all of the requirements of this part relating to individually identifiable information.

1	SEC. 103. GENERAL REQUIREMENTS FOR AUTHORIZATION
2	OF DISCLOSURE OF INFORMATION.
3	(a) In General.—For purposes of section 101, an
4	authorization satisfies the requirements of this section if
5	it—
6	(1) is in writing;
7	(2) is executed by an individual whose health or
8	health care is the subject of the information (or an
9	authorized representative of such an individual, pur-
10	suant to section 402); and
11	(3) satisfies the requirements of subsection (b).
12	(b) REQUIREMENTS.—An authorization satisfies the
13	requirements in this subsection if—
14	(1) it includes the following:
15	(A) a general statement of the purposes
16	for which the individually identifiable health in-
17	formation disclosed pursuant to the authoriza-
18	tion may be used;
19	(B) a general description of the persons
20	who are authorized to use such information;
21	(C) a valid signature of an individual
22	whose health or health care is the subject of the
23	information (or an authorized representative of
24	such individual);
25	(D) the date of the signature;

1	(E) an expiration date upon which the au-
2	thorization is no longer valid; and
3	(F) reasonable procedures permitting such
4	individual or representative to revoke the au-
5	thorization; and
6	(2) in a case in which the purposes under para-
7	graph (1)(A) include health research, the provisions
8	of the authorization that relate to such research—
9	(A) include each of the elements described
10	in paragraph (1);
11	(B) are set out separately from the re-
12	maining provisions and are independent from
13	them; and
14	(C) are subject to separate revocation pro-
15	cedures, the use of which does not per se effect
16	a revocation of the remaining provisions.
17	(c) Effect of Good Faith Reliance on Author-
18	IZATION.—A person shall not be liable, or subject to pun-
19	ishment under State or Federal law, for a disclosure of
20	individually identifiable health information, where the dis-
21	closure—
22	(1) was made in good faith reliance on an au-
23	thorization executed by the individual that satisfies
24	the requirements of this section; and

1	(2) was consistent with the provisions of the au-
2	thorization.
3	SEC. 104. DISCLOSURE IN CIVIL PROCEEDINGS.
4	(a) In General.—A person may not disclose individ-
5	ually identifiable health information for use in a civil law
6	enforcement investigation, a civil administrative action, or
7	a civil action brought in Federal or State court, in the
8	absence of—
9	(1) an otherwise valid discovery request, an ad-
10	ministrative subpoena or summons, or a judicial sub-
11	poena; and
12	(2) an order issued by the presiding judge or
13	official upon a determination that the need for the
14	information of the person requesting the disclosure
15	substantially outweighs the privacy interest of each
16	individual whose health or health care is the subject
17	of the information.
18	(b) Construction.—This section shall not be con-
19	strued to supersede any ground that may otherwise apply
20	under Federal or State law for an objection to the disclo-
21	sure of individually identifiable health information in any

22 civil action.

1	SEC. 105. DISCLOSURE FOR CRIMINAL LAW ENFORCEMENT
2	PURPOSES.
3	(a) In General.—A person may not disclose individ-
4	ually identifiable health information for a criminal law en-
5	forcement purpose—
6	(1) in the absence of—
7	(A) a subpoena issued under the authority
8	of a grand jury;
9	(B) an administrative subpoena or sum-
0	mons or a judicial subpoena or warrant; or
1	(C) a request otherwise authorized by law
2	from a law enforcement agency; and
3	(2) in the case of a disclosure under subpara-
4	graph (B) or (C) of paragraph (1), in the absence
5	of a court order issued upon a determination that
6	the need for the information of the person request-
7	ing the disclosure substantially outweighs the pri-
8	vacy interest of each individual whose health or
9	health care is the subject of the information.
20	(b) Destruction or Return of Information.—
21	When the proceeding for which individually identifiable
22	health information was disclosed is concluded, including
23	any derivative matters arising from such proceeding, the
24	person to whom the disclosure was made shall either de-
25	stroy the individually identifiable health information, or
26	return it to the person from whom it was obtained.

1 (c) Redactions.—To the extent practicable, and 2 consistent with the requirements of due process, a criminal 3 law enforcement agency shall redact personally identifying information from individually identifiable health informa-5 tion prior to the public disclosure of such information in a judicial or administrative proceeding. 6 7 (d) Use of Information.—Individually identifiable 8 health information obtained by a criminal law enforcement agency pursuant to this section may only be used for pur-10 poses of a legitimate criminal law enforcement activity. SEC. 106. DISCLOSURES FOR ARCHIVAL RESEARCH. (a) In General.—A person described in subsection 12 (b) may disclose individually identifiable health information, that was previously created or collected by the person 14 15 and maintained by the person in an archive or other repository, to a health researcher pursuant to this subsection, 17 if— 18 (1) the disclosure is made for the purpose of 19 permitting the health researcher to carry out health 20 research that involves analysis of the information; 21 (2) the disclosure has been reviewed and ap-22 proved, by a board, committee, or other group for-23

mally designated by the person to review requests

for such information, in accordance with written

standards for confidentiality that specify permissible

24

- and impermissible uses of such information for
  health research;
- 3 (3) the person enters into a written agreement 4 with the health researcher that is consistent with 5 this Act and specifies the permissible and impermis-6 sible future uses and disclosures of the information;
- (4) the person provides notice to the health researcher that any future use or disclosure of the information that is prohibited under this Act or the
  agreement described in paragraph (3) may provide a
  basis for a civil action against the researcher or may
  result in other adverse consequences for the researcher; and
- 14 (5) the person maintains a permanent record 15 documenting the scope and substance of the disclo-16 sure.
- 17 (b) Persons Described.—A person described in 18 this subsection is any of the following:
- 19 (1) A health care provider.
- 20 (2) A health plan.
- 21 (3) A public health authority.
- 22 (4) An employer.
- 23 (5) A health or life insurer.
- 24 (6) A school or university.

## TITLE II—INDIVIDUALS' RIGHTS

2	SEC. 201. INSPECTION AND COPYING OF HEALTH INFORMA-
3	TION.
4	(a) In General.—Subject to subsections (b) and (c),
5	a person who is a health care provider, health plan, em-
6	ployer, health or life insurer, school, or university shall
7	permit an individual who is the subject of individually
8	identifiable health information, or the individual's des-
9	ignee, to inspect and copy individually identifiable health
10	information concerning the individual, including records
11	created under section 202, that the person maintains. The
12	person may set forth appropriate procedures to be followed
13	for such inspection and copying and may require an indi-
14	vidual to pay reasonable fees associated with such inspec-
15	tion and copying and may require an individual to provide
16	written authorization of a provider designated by such in-
17	dividual through which the requested information will be
18	made available.
19	(b) Effect of Other Law.—
20	(1) Disclosure prohibited by other
21	LAW.—A person described in subsection (a) may not
22	permit the inspection or copying of individually iden-
23	tifiable health information under such subsection, if
24	such inspection or copying is prohibited by any pro-

vision of law other than this Act.

- 1 (2) Disclosure limited by other law.—A
  2 person described in subsection (a) shall limit the in3 spection or copying of individually identifiable health
  4 information under such subsection to the extent re5 quired by, and consistent with, any limitation on
  6 such inspection or copying in any provision of law
  7 other than this Act that is applicable to the person.
- 8 (c) Additional Exceptions.—A person described 9 in subsection (a) is not required to permit the inspection 10 or copying of individually identifiable health information 11 if any of the following exceptions apply:
  - (1) Endangerment to life or safety.—

    The person determines that the disclosure of the information could reasonably be expected to endanger the life or physical safety of any individual.
    - (2) Confidential source.—The information identifies, or could reasonably lead to the identification of, a person who provided information under a promise of confidentiality to a health care provider or life insurer concerning the individual who is the subject of the information.
    - (3) Information compiled in anticipation of Litigation.—The information is compiled principally—

1	(A) in the anticipation of a civil, criminal,
2	or administrative action or proceeding; or
3	(B) for use in such action or proceeding.
4	(4) Research Purposes.—The information
5	was collected for or during a clinical trial monitored
6	by an institutional review board in which the individ-
7	ual was a participant.
8	(d) Denial of a Request for Inspection or
9	Copying.—If a person described in subsection (a) denies
10	an individual's request for inspection or copying pursuant
11	to subsection (b) or (c), the person shall inform the indi-
12	vidual of—
13	(1) the reasons for the denial of the request for
14	inspection or copying;
15	(2) any procedures for further review of the de-
16	nial; and
17	(3) the individual's right to file with the person
18	a concise statement setting forth the request for in-
19	spection or copying.
20	(e) Statement Regarding Request.—If an indi-
21	vidual has filed a statement under subsection (d)(3), the
22	person, in any subsequent disclosure of the portion of the
23	information requested under subsection (a), shall in-
24	clude—

1	(1) a notation that such individual has filed a
2	request for inspection and that such request was de-
3	nied; and
4	(2) a concise statement of the reasons for deny-
5	ing the request for inspection or copying.
6	(f) Deadline.—A person described in subsection (a)
7	shall comply with or deny, in accordance with subsection
8	(d), a request for inspection or copying of individually
9	identifiable health information under this section not later
10	than 45 days after the date on which the person receives
11	the request.
12	(g) Rules Governing Agents.—An agent of a per-
13	son described in subsection (a) shall not be required to
14	provide for the inspection and copying of individually iden-
15	tifiable health information, except where—
16	(1) the individually identifiable health informa-
17	tion is retained by the agent; and
18	(2) the agent has been asked by the person to
19	fulfill the requirements of this section.
20	(h) Rule of Construction.—This section shall not
21	be construed to require a person described in subsection
22	(a) to conduct a formal, informal, or other hearing or pro-
23	ceeding concerning a request for inspection or copying of
24	individually identifiable health information.

1	SEC. 202. AMENDMENT OF INDIVIDUALLY IDENTIFIABLE
2	HEALTH INFORMATION.
3	(a) In General.—Not later than 45 days after the
4	date on which a person who is a health care provider
5	health plan, employer, health or life insurer, school, or uni-
6	versity receives from an individual who is a subject of indi-
7	vidually identifiable health information a request in writ-
8	ing to amend the information, the person—
9	(1) shall make the amendment requested;
10	(2) shall inform the individual of the amend-
11	ment that has been made; and
12	(3) shall make reasonable efforts to inform any
13	person who is identified by the individual, who is not
14	an officer, employer, or agent of the entity, and to
15	whom the unamended portion of the information was
16	disclosed during the preceding year, of any nontech-
17	nical amendment that has been made.
18	(b) Refusal To Amend.—If a person described in
19	subsection (a) refuses to make an amendment requested
20	by an individual under such subsection, the person shall
21	inform the individual of—
22	(1) the reasons for the refusal to make the
23	amendment;
24	(2) any procedures for further review of the re-
25	fugal, and

1	(3) the individual's right to file with the person
2	a concise statement setting forth the requested
3	amendment and the individual's reasons for dis-
4	agreeing with the refusal.
5	(c) Statement of Disagreement.—If an individ-
6	ual has filed a statement of disagreement with a person
7	under subsection (b)(3), the person, in any subsequent dis-
8	closure of the disputed portion of the information—
9	(1) shall include a notation that such individual
10	has filed a statement of disagreement; and
11	(2) may include a concise statement of the rea-
12	sons for not making the requested amendment.
13	(d) Rules Governing Agents.—The agent of a
14	person described in subsection (a) shall not be required
15	to make amendments to individually identifiable health in-
16	formation, except where—
17	(1) the information is retained by the agent
18	and
19	(2) the agent has been asked by such person to
20	fulfill the requirements of this section.
21	(e) Repeated Requests for Amendments.—If a
22	person described in subsection (a) receives a duplicative
23	request for an amendment of information as provided for
24	in such subsection and a statement of disagreement with

respect to the request has been filed pursuant to sub-

- 1 section (c), the person shall inform the individual of such
- 2 filing and shall not be required to carry out the procedures
- 3 required under this section.
- 4 (f) Rule of Construction.—This section shall not
- 5 be construed—
- 6 (1) to require a person described in subsection
- 7 (a) to conduct a formal, informal, or other hearing
- 8 or proceeding concerning a request for an amend-
- 9 ment to individually identifiable health information;
- 10 (2) to require a person described in subsection
- 11 (a) to make an amendment with which the person
- disagrees; or
- 13 (3) to require the alteration of any arrange-
- ment, written agreement, or obligation with respect
- to the delivery of, or payment for, health care.

#### 16 SEC. 203. NOTICE OF CONFIDENTIALITY PRACTICES.

- 17 (a) Preparation of Written Notice.—A health
- 18 care provider, health plan, health oversight agency, public
- 19 health authority, employer, health or life insurer, health
- 20 researcher, school, or university shall post or provide, in
- 21 writing and in a clear and conspicuous manner, notice of
- 22 the person's confidentiality practices, that shall include—
- 23 (1) a description of an individual's rights with
- respect to individually identifiable health informa-
- 25 tion;

1	(2) the uses and disclosures of individually
2	identifiable health information authorized under this
3	Act;
4	(3) the procedures established by the person for
5	authorizing disclosures of individually identifiable
6	health information and for revoking such authoriza-
7	tions;
8	(4) the procedures established by the person for
9	the exercise of the individual's rights; and
10	(5) the procedures established by the person for
11	providing copies of the notice.
12	(b) Model Notice.—The Secretary, after notice
13	and opportunity for public comment, shall develop and dis-
14	seminate model notices of confidentiality practices, for use
15	under this section. Use of the model notice developed by
16	the Secretary shall serve as a complete defense in any civil
17	action to an allegation that a violation of this section has
18	occurred.
19	TITLE III—ENFORCEMENT
20	SEC. 301. CRIMINAL PENALTIES.
21	(a) Offense.—A person who knowingly and in viola-
22	tion of this Act obtains individually identifiable health in-
23	formation, uses such information, or discloses such infor-
24	mation to another person, knowing that such obtaining,

- 1 use, or disclosure is unlawful, shall be punished as pro-
- 2 vided in subsection (b).
- 3 (b) Penalties.—A person described in subsection
- 4 (a) shall—
- 5 (1) be fined not more than \$50,000, imprisoned
- 6 not more than 1 year, or both;
- 7 (2) if the offense is committed under false pre-
- 8 tenses, be fined not more than \$100,000, imprisoned
- 9 not more than 5 years, or both; and
- 10 (3) if the offense is committed with intent to
- sell, transfer, or use individually identifiable health
- information for commercial advantage, personal
- gain, or malicious harm, be fined not more than
- \$250,000, imprisoned not more than 10 years, or
- both.
- 16 SEC. 302. CIVIL ACTION.
- 17 (a) IN GENERAL.—Any individual whose rights under
- 18 this Act have been knowingly or negligently violated may
- 19 bring a civil action to recover such preliminary and equi-
- 20 table relief as the court determines to be appropriate.
- 21 (b) Attorney's Fees.—In the case of a civil action
- 22 brought under subsection (a) in which the plaintiff has
- 23 substantially prevailed, the court may assess against the
- 24 respondent a reasonable attorney's fee and other litigation

- 1 costs and expenses (including expert fees) reasonably in-
- 2 curred.
- 3 (c) Limitation.—No action may be commenced
- 4 under this subsection by an individual more than 2 years
- 5 after the date on which the violation was, or should rea-
- 6 sonably have been, discovered by the individual.
- 7 (d) No Liability for Permissible Disclo-
- 8 SURES.—A person who makes a disclosure of individually
- 9 identifiable health information about an individual that is
- 10 permitted under this Act shall not be liable to the individ-
- 11 ual for such disclosure under common law.
- 12 SEC. 303. PROGRAM EXCLUSIONS.
- 13 (a) Exclusion From Participation in Federal
- 14 AND STATE HEALTH CARE PROGRAMS.—Section 1128(b)
- 15 of the Social Security Act (42 U.S.C. 1320a-7(b)) is
- 16 amended by adding at the end the following:
- 17 "(16) Failure lawfully to treat individ-
- 18 UALLY IDENTIFIABLE HEALTH INFORMATION.—Any
- individual or entity that the Secretary determines
- 20 has failed substantially to comply with a provision of
- the Consumer Health and Research Technology
- 22 (CHART) Protection Act.".
- 23 (b) Exclusion of Providers From Participa-
- 24 TION IN FEDERAL EMPLOYEES HEALTH BENEFITS PRO-

- 1 GRAM.—Section 8902a(b) of title 5, United States Code,
- 2 is amended by adding at the end the following:
- 3 "(6) Any provider that the Secretary of Health
- 4 and Human Services has determined has failed sub-
- 5 stantially to comply with a provision of the Con-
- 6 sumer Health and Research Technology (CHART)
- 7 Protection Act.".

### 8 TITLE IV—GENERAL

### 9 **PROVISIONS**

- 10 SEC. 401. STANDARDS FOR ELECTRONIC DISCLOSURES.
- 11 The National Committee on Vital and Health Statis-
- 12 tics, in consultation with the National Science Foundation,
- 13 shall promulgate standards for disclosing, authorizing the
- 14 use and disclosure of, and authenticating, individually
- 15 identifiable health information in electronic form, in a
- 16 manner consistent with this Act.
- 17 SEC. 402. AUTHORIZED REPRESENTATIVES.
- 18 (a) In General.—Except as provided in subsections
- 19 (b) and (c), a person who is authorized by law, or by an
- 20 instrument recognized under law, to act as an agent, at-
- 21 torney, proxy, or other legal representative for an individ-
- 22 ual, otherwise to exercise the rights of the individual, may,
- 23 to the extent so authorized, exercise and discharge the
- 24 rights of the individual under this Act.

1	(b) HEALTH CARE POWER OF ATTORNEY.—A person
2	who is not described in subsection (a), but is authorized
3	by law or by an instrument recognized under law to make
4	decisions about the provision of health care to an individ-
5	ual who is incapacitated, may exercise and discharge the
6	rights of the individual under this Act, to the extent nec-
7	essary to effectuate the terms or purposes of the grant
8	of authority.
9	(c) No Court Declaration.—If a health care pro-
10	vider determines that an individual, who has not been de-
11	clared to be legally incompetent, suffers from a medical
12	condition that prevents the individual from acting know-
13	ingly or effectively on the individual's own behalf, the right
14	of the individual to authorize disclosure under this Act
15	may be exercised and discharged in the best interest of
16	the individual by—
17	(1) a person described in subsection (b) with re-
18	spect to the individual;
19	(2) a person described in subsection (a) with re-
20	spect to the individual, but only if a person de-
21	scribed in paragraph (1) cannot be contacted after
22	a reasonable effort;
23	(3) the next of kin of the individual, but only
24	if a person described in paragraph (1) or (2) cannot
25	be contacted after a reasonable effort; or

1	(4) the health care provider, but only if a per-
2	son described in paragraph (1), (2), or (3) cannot be
3	contacted after a reasonable effort.
4	(d) Application to Deceased Individuals.—The
5	provisions of this Act shall continue to apply to individ-
6	ually identifiable health information concerning a deceased
7	individual for a period of 2 years following the death of
8	that individual.
9	(e) Exercise of Rights on Behalf of a De-
10	CEASED INDIVIDUAL.—A person who is authorized by law
11	or by an instrument recognized under law, to act as an
12	executor of the estate of a deceased individual, or other-
13	wise to exercise the rights of the deceased individual, may,
14	to the extent so authorized, exercise and discharge the
15	rights of such deceased individual under this Act for a pe-
16	riod of 2 years following the death of that individual. If
17	no such designee has been authorized, the rights of the
18	deceased individual may be exercised as provided for in
19	subsection (e).
20	SEC. 403. RELATIONSHIP TO OTHER LAWS.
21	(a) In General.—
22	(1) State law.—Except as provided in sub-
23	sections (b) through (f), the provisions of this Act
24	shall preempt any State law that directly relates to

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matters covered by this Act.

1	(2) Federal Law.—This Act shall not be con-
2	strued as repealing, explicitly or implicitly, other
3	Federal laws or regulations relating to individually
4	identifiable health information or relating to an indi-
5	vidual's access to health care services.
6	(b) Privileges.—This Act does not preempt or mod-
7	ify State common or statutory law to the extent such law
8	concerns a privilege of a witness or person in a court of
9	the State. This Act does not supersede or modify Federal
10	common or statutory law to the extent such law concerns
11	a privilege of a witness or person in a court of the United
12	States. The execution of an authorization pursuant to sec-
13	tion 103 may not be construed as a waiver of any such
14	privilege.
15	(c) CERTAIN DUTIES UNDER LAW.—Nothing in this
16	Act shall be construed to preempt, supersede, or modify
17	the operation of any State law that—
18	(1) provides for the reporting of vital statistics
19	such as birth or death information;
20	(2) requires the reporting of abuse, domestic vi-
21	olence, or neglect information about any individual
22	(3) regulates information concerning an individ-
23	ual's mental health or communicable disease status
24	or

1	(4) governs a minor's rights to access individ-
2	ually identifiable health information or health care
3	services.
4	(d) RELATIONSHIP TO CLINICAL RESEARCH AND RE-
5	PORTS.—This Act shall not apply to individually identifi-
6	able health information that is created, received, main-
7	tained, used, disclosed, or transmitted by any person in
8	connection with—
9	(1) any activity conducted pursuant to an inves-
10	tigational new drug exemption, or for which approval
11	of an institutional review board is required by the
12	Food and Drug Administration; or
13	(2) any record required to be maintained or re-
14	port required to be filed by the Food and Drug Ad-
15	ministration.
16	(e) Federal Privacy Act.—
17	(1) Medical exemptions.—Sections 552a of
18	title 5, United States Code, is amended by adding
19	at the end the following:
20	"(w) Medical Exemptions.—The head of an agen-
21	cy that is subject to the Consumer Health and Research
22	Technology (CHART) Protection Act shall promulgate
23	rules, in accordance with the requirements (including gen-
24	eral notice) of subsections (b)(1), (b)(2), (b)(3), (c), and

(e) of section 553 of this title, to exempt a system of

- 1 records within the agency, to the extent that the system
- 2 of records contains individually identifiable health infor-
- 3 mation (as defined in section 406 of such Act), from all
- 4 provisions of this section except subsections (b)(6), (d),
- 5 (e)(1), (e)(2), subparagraphs (A) and (C) and (E) through
- 6 (I) of subsection (e)(4), and subsections (e)(5), (e)(6),
- 7 (e)(9), (e)(12), (l), (n), (o), (p), (r), and (u).".
- 8 (2) TECHNICAL AMENDMENT.—Section
- 9 552a(f)(3) of title 5, United States Code, is amend-
- ed by striking "pertaining to him," and all that fol-
- lows through the semicolon and inserting "pertain-
- ing to the individual;".
- 13 (f) Application to Certain Federal Agen-
- 14 CIES.—
- 15 (1) Department of Defense.—
- 16 (A) Exceptions.—The Secretary of De-
- fense may, by regulation, establish exceptions to
- the requirements of this Act to the extent such
- 19 Secretary determines that disclosure of individ-
- 20 ually identifiable health information relating to
- 21 members of the Armed Forces from systems of
- records operated by the Department of Defense
- is necessary under circumstances different from
- those permitted under this Act for the proper

1 conduct of national defense functions by mem-2 bers of the Armed Forces.

> (B) APPLICATION TO CIVILIAN EMPLOY-EES.—The Secretary of Defense may, by regulation, establish for civilian employees of the Department of Defense and employees of Department of Defense contractors, limitations on the right of such persons to revoke or amend authorizations for disclosures under section 103 when such authorizations were provided by such employees as a condition of employment and the disclosure is determined necessary by the Secretary of Defense to the proper conduct of national defense functions by such employees.

## (2) Department of transportation.—

- (A) EXCEPTIONS.—The Secretary of Transportation may, with respect to members of the Coast Guard, exercise the same powers as the Secretary of Defense may exercise under paragraph (1)(A).
- (B) APPLICATION TO CIVILIAN EMPLOY-EES.—The Secretary of Transportation may, with respect to civilian employees of the Coast Guard and Coast Guard contractors, exercise

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- the same powers as the Secretary of Defense may exercise under paragraph (1)(B).
- 3 (3) Department of Veterans Affairs.— The limitations on use and disclosure of individually 5 identifiable health information under this Act shall 6 not be construed to prevent any exchange of such in-7 formation within and among components of the De-8 partment of Veterans Affairs that determine eligi-9 bility for or entitlement to, or that provide, benefits 10 under laws administered by the Secretary of Veteran 11 Affairs.

## 12 SEC. 404. REPORTS ANALYZING IMPACT OF ACT.

13 (a) Efforts To Combat Fraud and Abuse.—Beginning not later than 12 months after the effective date 14 in section 405(a), the Inspector General of the Department of Health and Human Services shall submit to the Committee on Ways and Means and the Committee on 18 Government Reform and Oversight of the House of Representatives and the Committee on Commerce, Science, 19 20 and Transportation and the Committee on Finance of the 21 Senate an annual report containing the results of an annual study. The study shall analyze whether this Act has had an adverse effect on efforts to combat fraud and abuse undertaken under title XVIII, XIX, or XXI of the Social

Security Act.

- 1 (b) Health Research.—Beginning not later than
- 2 12 months after the effective date in section 405(a), the
- 3 Secretary, in consultation with the National Research
- 4 Council of the National Academy of Sciences and the In-
- 5 stitute of Medicine, shall submit to the Congress an an-
- 6 nual report containing the results of an annual study. The
- 7 study shall analyze the effect of this Act on the quality
- 8 and efficacy of health research.
- 9 (c) Administrative Simplification.—Not later
- 10 than 12 months after the effective date in section 405(a),
- 11 the Comptroller General of the United States shall submit
- 12 to the Congress a report containing the results of a study.
- 13 The study shall analyze the effect of this Act on the imple-
- 14 mentation of subtitle F of title II of the Health Insurance
- 15 Portability and Accountability Act of 1996 and part C of
- 16 title XI of the Social Security Act.
- 17 SEC. 405. EFFECTIVE DATE.
- 18 (a) In General.—Except as provided in subsection
- 19 (b), this Act shall take effect on the date that is 18 months
- 20 after the date of the enactment of this Act.
- 21 (b) Provisions Effective Immediately.—A pro-
- 22 vision of this Act shall take effect on the date of the enact-
- 23 ment of this Act if the provision authorizes or requires
- 24 the Secretary of Defense, the Secretary of Transportation,
- 25 or the Secretary of Health and Human Services to de-

1	velop, establish, or promulgate regulations or model no-
2	tices.
3	(c) Deadline for Regulations.—The Secretary
4	shall promulgate regulations implementing this Act not
5	later than the date that is 12 months after the date of
6	the enactment of this Act.
7	SEC. 406. DEFINITIONS.
8	As used in this Act:
9	(1) Employer.—The term "employer" has the
10	meaning given such term under section 3(5) of the
11	Employee Retirement Income Security Act of 1974
12	(29 U.S.C. 1002(5)), except that such term shall in-
13	clude only employers of two or more employees.
14	(2) Health care.—The term "health care"
15	means—
16	(A) preventive, diagnostic, therapeutic, re-
17	habilitative, maintenance, or palliative care, in-
18	cluding appropriate assistance with disease or
19	symptom management and maintenance, coun-
20	seling, service, or procedure—
21	(i) with respect to the physical or
22	mental condition of an individual; or
23	(ii) affecting the structure or function
24	of the human body or any part of the
25	human body, including the banking of

1	blood, sperm, organs, or any other tissue;
2	and
3	(B) any sale or dispensing of a drug, de-
4	vice, equipment, or other health care related
5	item to an individual, or for the use of an indi-
6	vidual, pursuant to a prescription.
7	(3) Health care provider.—The term
8	"health care provider" means a person, who with re-
9	spect to a specific item of individually identifiable
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—
13	(A) a person who is licensed, certified, reg-
14	istered, or otherwise authorized by Federal or
15	State law to provide an item or service that
16	constitutes health care in the ordinary course of
17	business, or practice of a profession;
18	(B) a Federal, State, employer-sponsored
19	or other privately sponsored program that di-
20	rectly provides items or services that constitute
21	health care to beneficiaries; or
22	(C) an officer or employee of a person de-
23	scribed in subparagraph (A) or (B).
24	(4) Health or life insurer.—The term
25	"health or life insurer" means a health insurance

- issuer as defined in section 9805(b)(2) of the Internal Revenue Code of 1986 or a life insurance company as defined in section 816 of such Code.
  - (5) Health oversight agency.—The term "health oversight agency" means a person who, with respect to a specific item of individually identifiable health information, receives, creates, uses, maintains, or discloses the information while acting in whole or in part in the capacity of—
    - (A) a person who performs or oversees the performance of an assessment, evaluation, determination, or investigation, relating to the licensing, accreditation, or credentialing of health care providers; or

## (B) a person who—

- (i) performs or oversees the performance of an audit, assessment, evaluation, determination, or investigation relating to the effectiveness of, compliance with, or applicability of, legal, fiscal, medical, or scientific standards or aspects of performance related to the delivery of, or payment activities related to, health care; and
- (ii) is a public agency, acting on behalf of a public agency, acting pursuant to

- a requirement of a public agency, or carrying out activities under a Federal or State
  law governing the assessment, evaluation,
  determination, investigation, or prosecution
  described in subparagraph (A).
  - (6) Health Plan.—The term "health plan" means any health insurance plan, including any hospital or medical service plan, dental or other health service plan, health maintenance organization plan, plan offered by a provider-sponsored organization (as defined in section 1855(d) of the Social Security Act (42 U.S.C. 1395w–25(d))), or other program providing or arranging for the provision of health benefits, whether or not funded through the purchase of insurance.
  - (7) HEALTH RESEARCHER.—The term "health researcher" means a person, or an officer, employee, or agent of a person, who receives individually identifiable health information as part of a research project that involves data with respect to human subjects.
  - (8) Individually identifiable health information.—The term "individually identifiable health information" means any information, including demographic information, collected from an indi-

1	vidual, whether oral or recorded in any form or me-
2	dium, that—
3	(A) is created or received by a health care
4	provider, health plan, health oversight agency,
5	public health authority, employer, health or life
6	insurer, school or university; and
7	(B)(i) relates to the past, present, or fu-
8	ture physical or mental health or condition of
9	an individual (including individual cells and
10	their components), the provision of health care
11	to an individual, or the past, present, or future
12	payment activities related to the provision of
13	health care to an individual; and
14	(ii)(I) identifies an individual;
15	(II) contains personal identifiers that pro-
16	vide a direct means of identifying the individ-
17	ual; or
18	(III) has been provided in an encrypted
19	format that does not directly identify an indi-
20	vidual, but that provides a method for
21	decrypting the information.
22	(9) Institutional review board.—The term
23	"institutional review board" means an entity estab-
24	lished to review proposed health research with re-
25	spect to potential risks to human subjects pursuant

1	to Federal regulations adopted under section
2	1802(b) of the Public Health Service Act (42 U.S.C
3	300v-1(b)).
4	(10) Payment activities.—The term "pay-
5	ment activities"—
6	(A) means activities undertaken—
7	(i) by, or on behalf of, a health plan
8	to determine its responsibility for coverage
9	under the plan; or
10	(ii) by a health care provider to obtain
11	payment for items or services provided to
12	an individual, provided under a health plan
13	or provided based on a determination by
14	the health plan of responsibility for cov-
15	erage under the plan; and
16	(B) includes the following activities, when
17	performed in a manner consistent with subpara-
18	graph (A):
19	(i) Billing, claims management, medi-
20	cal data processing, practice management
21	or other administrative services and actual
22	payment.
23	(ii) Determinations of coverage or ad-
24	judication of health benefit claims and sub-
25	rogation claims.

1	(iii) Review of health care services
2	with respect to medical necessity, coverage
3	under a health plan, appropriateness of
4	care, or justification of charges.
5	(11) Person.—The term "person" means a
6	natural person, a government, governmental subdivi-
7	sion, agency or authority, a company, corporation,
8	estate, firm, trust, partnership, association, joint
9	venture, society, joint stock company, or any other
10	legal entity.
11	(12) Public Health Authority.—The term
12	"public health authority" means an authority or in-
13	strumentality of the United States, a tribal govern-
14	ment, a State, or a political subdivision of a State
15	that is—
16	(A) primarily responsible for public health
17	matters; and
18	(B) primarily engaged in activities such as
19	injury reporting, public health surveillance, and
20	public health investigation or intervention.
21	(13) QUALITY ASSURANCE ACTIVITIES.—The
22	term "quality assurance activities" means a formal
23	methodology and set of activities designed to assess
24	the quality of health care services provided to an in-

dividual. The term includes formal review of care,

- problem identification, corrective actions taken to remedy any deficiencies, and evaluation of actions taken. The term also includes activities undertaken by a quality control and peer review organization (as defined in section 1152 of the Social Security Act (42 U.S.C. 1320c-1)).
  - "school or university" means an institution or place accredited or licensed for purposes of providing instruction or education, including an elementary school, secondary school, or institution of higher learning, a college, or an assemblage of colleges united under one corporate organization or government.
    - (15) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.
    - (16) STATE.—The term "State" includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.
  - (17) Writing.—The term "writing" means writing in either a paper-based or computer-based form, including electronic signatures.