

110TH CONGRESS
2^D SESSION

H. R. 5442

To provide individuals with access to health information of which they are a subject, to ensure personal privacy, security, and confidentiality with respect to health related information in promoting the development of a nationwide interoperable health information infrastructure, to impose criminal and civil penalties for unauthorized use of personal health information, to provide for the strong enforcement of these rights, to protect States' rights, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 14, 2008

Mr. MARKEY (for himself, Mr. EMANUEL, and Mrs. CAPPS) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, and Financial Services, 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 provide individuals with access to health information of which they are a subject, to ensure personal privacy, security, and confidentiality with respect to health related information in promoting the development of a nationwide interoperable health information infrastructure, to impose criminal and civil penalties for unauthorized use of personal health information, to provide for the strong enforcement of these rights, to protect States' rights, 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.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
 5 “Technologies for Restoring Users’ Security and Trust in
 6 Health Information Act of 2008” or as the “TRUST in
 7 Health Information Act of 2008”.

8 (b) **TABLE OF CONTENTS.**—The table of contents of
 9 this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Findings; purposes.

TITLE I—HEALTH INFORMATION PRIVACY AND SECURITY

Sec. 100. Summary of privacy rights and security obligations.

Subtitle A—Access to and Accuracy of Personal Health Information

- Sec. 101. Inspection and copying of personal health information.
- Sec. 102. Modifications to personal health information.

Subtitle B—Security of Personal Health Information

- Sec. 111. Notice of privacy practices.
- Sec. 112. Establishment of safeguards.
- Sec. 113. Notification in the case of breach.
- Sec. 114. Transparency.
- Sec. 115. Risk management.
- Sec. 116. Accounting for disclosures and use.

Subtitle C—Use and Disclosure of Personal Health Information

CHAPTER 1—GENERAL RESTRICTIONS

- Sec. 121. General rules regarding use and disclosure.
- Sec. 122. Informed consent for disclosure of personal health information for treatment and payment.
- Sec. 123. Informed consent and authorization for disclosure of personal health information other than for treatment or payment.

CHAPTER 2—EXCEPTIONS

- Sec. 131. Disclosure for law enforcement, national security, and intelligence purposes.
- Sec. 132. Disclosure for public health purposes.
- Sec. 133. Reporting of abuse and neglect to protection and advocacy agencies.
- Sec. 134. Disclosure to next of kin and directory information.

CHAPTER 3—SPECIAL CIRCUMSTANCES

- Sec. 141. Emergency circumstances.
- Sec. 142. Health research.
- Sec. 143. Health oversight functions.
- Sec. 144. Individual representatives.

Subtitle D—Enforcement

- Sec. 151. In general.
- Sec. 152. Enforcement by State attorneys general.

Subtitle E—Miscellaneous

- Sec. 161. Office of Health Information Privacy.
- Sec. 162. Protection for whistleblowers.
- Sec. 163. Demonstration grant for individuals with limited English language proficiency or limited health literacy.
- Sec. 164. Relationship to other laws.
- Sec. 165. Effective date.

Subtitle F—General Definitions

- Sec. 171. General definitions.

TITLE II—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

Subtitle A—Improving the Interoperability of Health Information Technology

- Sec. 201. Office of the National Coordinator of Health Information Technology.
- Sec. 202. Partnership for Health Care Improvement.
- Sec. 203. American Health Information Community policies.
- Sec. 204. Research access to health care data and reporting on performance.

Subtitle B—Facilitating the Widespread Adoption of Interoperable Health Information Technology

- Sec. 211. Facilitating the widespread adoption of interoperable health information technology.
- Sec. 212. Demonstration program to integrate information technology into clinical education.
- Sec. 213. Qualified health information technology system defined.

Subtitle C—Improving the Quality of Health Care

- Sec. 221. Fostering development and use of health care quality measures.
- Sec. 222. Adoption and use of quality measures; reporting.

Subtitle D—Miscellaneous Provisions

- Sec. 231. Health Information Technology Resource Center.
- Sec. 232. Facilitating the provision of telehealth services across State lines.

Subtitle E—Definitions

- Sec. 241. Definitions.

TITLE III—ADDITIONAL PROVISIONS

Sec. 301. Federal purchasing and data collection by CMS and other Federal agencies.

Sec. 302. Ensuring health care providers participating in the medicare program may maintain health information in electronic form.

1 **SEC. 2. FINDINGS; PURPOSES.**

2 (a) FINDINGS.—Congress finds the following:

3 (1) Americans are deeply concerned about the
4 privacy and security of their personal information,
5 including their health records.

6 (2) In October 2007, a Harris Interactive Poll
7 commissioned by the Institute of Medicine found
8 that 58 percent of respondents indicated they do not
9 believe Federal and State laws and organizational
10 practices offer sufficient protection of personal
11 health information.

12 (3) In February 2007, the Markle Foundation
13 reported that 80 percent of individuals surveyed
14 were very concerned about identity theft or fraud
15 and 77 percent were very concerned that their med-
16 ical information would be used for marketing pur-
17 poses.

18 (4) Concerns about the privacy and security of
19 personal health information are fueled by the esca-
20 lating number of breaches of personal information
21 that have occurred in recent years and numerous re-
22 ports of the inadequacy of the security of electronic
23 networks.

1 (5) According to the Privacy Rights Clearing-
2 house, more than 216,000,000 data records belong-
3 ing to U.S. residents have been exposed to potential
4 misuse as a result of security breaches since Janu-
5 ary 2005.

6 (6) A nationwide interoperable health informa-
7 tion infrastructure can strengthen privacy, security,
8 and confidentiality safeguards, protecting patients'
9 personal health information while also improving
10 health care quality, safety, and affordability.

11 (7) In order for individuals, health care pro-
12 viders, and health care payers to achieve the benefits
13 associated with such infrastructure, strong data pri-
14 vacy, security, and confidentiality standards must be
15 developed, adopted, and incorporated into the health
16 information technology infrastructure.

17 (8) While Executive Order 13335 regarding
18 interoperable health information technology issued
19 on April 27, 2004, called for widespread adoption of
20 interoperable electronic health records within 10
21 years, established the position of National Coordi-
22 nator of Health Information Technology, and stipu-
23 lated that the plan for the nationwide implementa-
24 tion of interoperable health information technology
25 should address privacy and security issues, adequate

1 progress has not been made to ensure that a strong
2 data privacy, security, and confidentiality approach
3 will guide the development of this nationwide infra-
4 structure beginning in its initial stages and con-
5 tinuing throughout its formulation.

6 (9) According to a February 1, 2007, report of
7 the Government Accountability Office (GAO), the
8 Department of Health and Human Services and its
9 Office of the National Coordinator of Health Infor-
10 mation Technology have not yet defined an overall
11 approach for integrating privacy-related initiatives
12 the Department has undertaken in the area of
13 health information technology or addressing key pri-
14 vacy principles, nor has the Department defined
15 milestones for integrating the results of these activi-
16 ties while it has moved forward with development of
17 standards for a national electronic health informa-
18 tion system.

19 (10) All Americans have a right to privacy, se-
20 curity, and confidentiality with respect to the elec-
21 tronic disclosure of their personal health informa-
22 tion, and the nationwide implementation of inter-
23 operable health information technology should abide
24 by, and be consistent with, this right.

1 (11) Without adequate privacy, security, and
2 confidentiality standards, individuals will be more
3 likely to avoid or delay medical treatment or with-
4 hold pertinent information from their health pro-
5 viders, potentially resulting in lost productivity, in-
6 creased morbidity rates, and increased costs to the
7 health care system.

8 (12) As stipulated by the Secretary of Health
9 and Human Services in the Final Rule for Stand-
10 ards for Privacy of Individually Identifiable Health
11 Information (45 C.F.R. parts 160 and 164), the
12 standards contained in the Final Rule are intended
13 to establish a floor of privacy protection and are not
14 designed to serve as “best practices” for the use or
15 disclosure of personal health information.

16 (13) To guide the development, implementation,
17 and operation of an interoperable nationwide health
18 information technology infrastructure, Congress
19 should establish specific minimum standards for the
20 use and disclosure of individuals’ personal health in-
21 formation and direct the Department of Health and
22 Human Services to promulgate regulations relating
23 to personal health information that are consistent
24 with individuals’ right to privacy, security, and con-
25 fidentiality with respect to the electronic use or dis-

1 closure of their personal health information, the
2 public interest, and the purposes of this Act.

3 (b) PURPOSE.—The purposes of this Act are as fol-
4 lows:

5 (1) To recognize that individuals have a right
6 to privacy, confidentiality, and security with respect
7 to health information, including genetic information,
8 and that those fundamental rights are rooted in the
9 Nation’s history and medical ethics and must be
10 protected.

11 (2) To ensure that individuals are able to exer-
12 cise their right to health information privacy by re-
13 quiring their consent for the use and disclosure of
14 their identifiable health information unless otherwise
15 required by law.

16 (3) To encourage the development of a nation-
17 wide interoperable health information technology in-
18 frastructure that protects individuals’ privacy, con-
19 fidentiality, and security with respect to their health
20 information while also improving health care quality,
21 promoting data accuracy, reducing medical errors,
22 and increasing the efficiency of care.

23 (4) To create incentives to turn personal health
24 information into de-identified health information (as
25 defined in section 171(5)), where appropriate.

1 (5) To designate an Office of Health Informa-
2 tion Privacy within the Department of Health and
3 Human Services to protect individuals' right of pri-
4 vacy.

5 (6) To provide individuals with—

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

8 (B) the opportunity to challenge the accu-
9 racy and completeness of such information by
10 being able to file modifications to or request the
11 deletion of such information; and

12 (C) the right to limit the use and dislo-
13 sure of personal health information.

14 (7) To establish strong and effective mecha-
15 nisms to protect against the unauthorized and inap-
16 propriate use of personal health information and en-
17 sure that these mechanisms safeguard this informa-
18 tion wherever it may reside.

19 (8) To provide notice to individuals of breaches
20 of their personal health information.

21 (9) To invoke the sweep of congressional pow-
22 ers, including the power to enforce the 14th Amend-
23 ment to the Constitution, to regulate commerce, and
24 to abrogate the immunity of the States under the
25 11th Amendment to the Constitution, in order to ad-

1 dress violations of the rights of individuals to pri-
2 vacy, to provide individuals with access to their
3 health information, and to prevent the unauthorized
4 use of personal health information that is genetic in-
5 formation.

6 (10) To establish strong and effective remedies
7 for violations of this Act.

8 (11) To protect the rights of States.

9 **TITLE I—HEALTH INFORMATION**
10 **PRIVACY AND SECURITY**

11 **SEC. 100. SUMMARY OF PRIVACY RIGHTS AND SECURITY**
12 **OBLIGATIONS.**

13 (a) PRIVACY RIGHTS.—In order to provide individ-
14 uals who are the subject of personal health information
15 with privacy, security, and control in the use and dislo-
16 sure of such information, such individuals are provided the
17 following rights under this title:

18 (1) The right to not have their personal health
19 information disclosed without their informed consent
20 unless otherwise required by law, pursuant to sub-
21 title C.

22 (2) The right to inspect and copy their personal
23 health information, pursuant to section 101.

1 (3) The right to correct, supplement, or remove
2 their personal information held by a person, pursu-
3 ant to section 102.

4 (4) The right to prohibit access by certain cat-
5 egories of persons to particularly sensitive personal
6 health information about individuals, such as infor-
7 mation relating to mental health, domestic violence,
8 sexually transmitted diseases, and infection with the
9 human immunodeficiency virus (HIV), pursuant to
10 section 122.

11 (5) The right to receive notification of actual or
12 suspected security breaches of their personal health
13 information, pursuant to section 113.

14 (6) The right to receive an accounting of all
15 electronic disclosures of their personal health infor-
16 mation upon request, pursuant to section 116.

17 (b) SECURITY OBLIGATIONS.—A person that dis-
18 closes, uses, or receives an individual’s personal health in-
19 formation has obligations under this title, including the
20 following:

21 (1) The obligation to expressly recognize the
22 right to privacy and security of such individual with
23 respect to the use and disclosure of such information
24 under subtitle B.

1 (2) The obligation to permit individuals who are
2 the subject of such personal health information to
3 inspect and copy the personal health information
4 concerning the individual pursuant to section 101.

5 (3) The obligation to provide written notifica-
6 tion to an individual of the person's privacy prac-
7 tices pursuant to section 111.

8 (4) The obligation to promptly notify individ-
9 uals of an actual or suspected security breach of
10 their personal health information pursuant to section
11 113.

12 (5) The obligation to establish and maintain ap-
13 propriate administrative, organizational, technical
14 and physical safeguards to ensure the privacy, con-
15 fidentiality, security, accuracy, and integrity of per-
16 sonal health information that is accessed, main-
17 tained, modified, recorded, stored, destroyed, or oth-
18 erwise used or disclosed by such person pursuant to
19 section 112.

20 (6) The obligation to make publicly available on
21 the Internet a list, including contact information, of
22 each data partner with which the person has entered
23 into a contract or relationship to provide services in-
24 volving personal health information pursuant to sec-
25 tion 114.

1 (7) The obligation to obtain an individual’s in-
2 formed consent or authorization before using or dis-
3 closing an individual’s personal health information
4 pursuant to chapter 1 of subtitle C.

5 (8) The obligation to establish and update risk
6 management processes to protect against
7 vulnerabilities to the privacy and security of individ-
8 ual’s personal health information pursuant to sec-
9 tions 112 and 114.

10 (9) The obligation to establish and maintain a
11 record of each disclosure of an individual’s personal
12 health information pursuant to section 116.

13 (10) The obligation to provide individuals with
14 concise, comprehensive, and explicit information if
15 seeking to use or disclose their personal health infor-
16 mation for marketing purposes and receive a sepa-
17 rate authorization from an individual before using or
18 disclosing the information for that purpose pursuant
19 to section 123.

20 **Subtitle A—Access to and Accuracy**
21 **of Personal Health Information**

22 **SEC. 101. INSPECTION AND COPYING OF PERSONAL**
23 **HEALTH INFORMATION.**

24 (a) **RIGHT OF INDIVIDUAL.—**

1 (1) IN GENERAL.—A health information person
2 (as defined in section 171(13)) shall permit an indi-
3 vidual who is the subject of personal health informa-
4 tion (as defined in section 171(23)) that the person
5 holds, uses, or discloses, or the individual’s designee,
6 to inspect and copy the personal health information
7 concerning the individual.

8 (2) PROCEDURES AND FEES.—A health infor-
9 mation person may establish appropriate procedures
10 to be followed for inspection and copying under
11 paragraph (1) and may require an individual to pay
12 reasonable fees associated with such inspection and
13 copying in an amount that is not in excess of the ac-
14 tual costs of providing such copying. Such fees may
15 not be assessed where such an assessment would
16 have the effect of inhibiting an individual from gain-
17 ing access to the information described in paragraph
18 (1).

19 (b) DEADLINE.—A health information person shall
20 comply with a request for inspection or copying of personal
21 health information under this section not later than—

22 (1) 15 business days after the date on which
23 the person receives the request, if such request re-
24 quires the inspection, copying, or sending of printed
25 materials; or

1 (2) 5 business days after the date on which the
2 person receives the request, or sooner if the Sec-
3 retary determines appropriate, if such request re-
4 quires only the inspection, copying, or sending of
5 electronic or other digital materials.

6 (c) RULES GOVERNING AGENTS.—A person that is
7 the agent, officer, or employee of a health information per-
8 son shall provide for the inspection and copying of per-
9 sonal health information if—

10 (1) the personal health information is retained
11 by the person; and

12 (2) the person has been asked by the health in-
13 formation person to fulfill the requirements of this
14 section.

15 (d) SPECIAL RULE RELATING TO ONGOING CLINICAL
16 TRIALS.—With respect to personal health information
17 that is created as part of an individual’s voluntary partici-
18 pation in an ongoing clinical trial, access to the informa-
19 tion shall be provided within 15 business days after the
20 date on which the health information person receives the
21 request or consistent with the individual’s agreement to
22 participate in the clinical trial, whichever is sooner.

1 **SEC. 102. MODIFICATIONS TO PERSONAL HEALTH INFOR-**
2 **MATION.**

3 (a) IN GENERAL.—Not later than 15 business days,
4 or earlier if the Secretary determines appropriate, after
5 the date on which a health information person receives
6 from an individual a request in writing to supplement, cor-
7 rect, amend, segregate, or remove personal health infor-
8 mation that the person holds, uses, or discloses concerning
9 the individual, such person—

10 (1) shall, subject to subsections (b) and (c),
11 modify the information, by adding the requested
12 supplement, correction, or amendment to the infor-
13 mation, or by removing any information that has
14 been requested to be destroyed;

15 (2) shall inform the individual that the modi-
16 fication has been made; and

17 (3) shall make reasonable efforts to inform any
18 person to which the portion of the unmodified infor-
19 mation was previously disclosed, of any substantive
20 modification that has been made.

21 (b) REFUSAL TO MODIFY.—If a health information
22 person declines to make the modification requested under
23 subsection (a) within 15 business days after receipt of
24 such request, such person shall inform the individual in
25 writing of—

1 (1) the reasons for declining to make the modi-
2 fication;

3 (2) any procedures for further review of the de-
4 clining of such modification; and

5 (3) the individual's right to file with the person
6 a concise statement setting forth the requested
7 modification and the individual's reasons for dis-
8 agreeing with the declining person and the individ-
9 ual's right to include a copy of this refusal in the
10 health record set (as defined in section 171(17))
11 concerning the individual.

12 (c) STATEMENT OF DISAGREEMENT.—If an indi-
13 vidual has filed with a health information person a state-
14 ment of disagreement under subsection (b)(3), the person,
15 in any subsequent disclosure of the disputed portion of
16 the information—

17 (1) shall include, at the individual's request, a
18 copy of the individual's statement in the individual's
19 health record set; and

20 (2) may include a concise statement of the rea-
21 sons for not making the requested modification.

22 (d) RULES GOVERNING AGENTS.—A person that is
23 the agent of a health information person shall only be re-
24 quired to make a modification to personal health informa-
25 tion where—

1 (1) the personal health information is retained,
2 distributed, used, or maintained by the agent; and

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

5 **Subtitle B—Security of Personal**
6 **Health Information**

7 **SEC. 111. NOTICE OF PRIVACY PRACTICES.**

8 (a) PREPARATION OF WRITTEN NOTICE.—A health
9 information person shall prepare a written notice of the
10 privacy practices of such person, including information
11 with respect to the following:

12 (1) The express right of an individual to pri-
13 vacy, security, and confidentiality with respect to the
14 disclosure of such individual’s personal health infor-
15 mation.

16 (2) The procedures for an individual to exercise
17 that right by authorizing disclosures of personal
18 health information, and to object to, modify, and re-
19 voke such authorizations.

20 (3) The right of an individual to inspect, copy,
21 and modify that individual’s personal health infor-
22 mation.

23 (4) The right of an individual not to have em-
24 ployment or the receipt of services or choice of
25 health plan conditioned upon the execution by the

1 individual of an authorization for disclosure, except
2 as permitted by section 122(e).

3 (5) A description of—

4 (A) the categories or types of employees,
5 by general category or by general job descrip-
6 tion, who have access to or use of personal
7 health information regarding the individual;

8 (B) the right of the individual to limit ac-
9 cess to or use of his or her personal health in-
10 formation by employees, agents, and contractors
11 of the person; and

12 (C) the procedures for effecting such limi-
13 tations.

14 (6) A simple, concise description of any infor-
15 mation systems used to store or transmit personal
16 health information, including a description of any
17 linkages made with other networks, systems, or
18 databases outside the person's direct control.

19 (7) The circumstances under which the infor-
20 mation will be, lawfully and actually, used or dis-
21 closed without an authorization executed by the indi-
22 vidual.

23 (8) A statement that, if an individual elects to
24 pay for health care from the individual's own funds,
25 that individual may elect for personal health infor-

1 mation, including any identifying information, not to
2 be disclosed to anyone other than designated health
3 care providers, unless such disclosure is required by
4 mandatory reporting requirements or other similar
5 information collection duties required by law.

6 (9) The right of the individual to have contin-
7 ued maintenance, distribution, or storage of that in-
8 dividual's personal health information not condi-
9 tioned upon whether that individual amends or re-
10 vokes an authorization for disclosure, or requests a
11 modification of personal health information.

12 (10) The right of and procedures for an indi-
13 vidual to request that personal health information be
14 transferred to a third party person without unrea-
15 sonable delay.

16 (11) The right to prompt notification of an ac-
17 tual or suspected security breach of personal health
18 information, and how such breaches will be remedied
19 by the person.

20 (12) The right of an individual to inspect and
21 obtain a copy of records of authorized and unauthor-
22 ized disclosures as well as attempted and actual ac-
23 cess and use by an authorized or unauthorized per-
24 son.

1 (13) The right of an individual to exercise non-
2 disclosure and nonuse rights with respect to their
3 personal health information, including the right to
4 opt out of any local, regional, or nationwide health
5 information network or system that is used by the
6 person.

7 (b) PROVISION AND POSTING OF WRITTEN NO-
8 TICE.—

9 (1) PROVISION.—A health information person
10 shall provide in writing a copy of the notice of pri-
11 vacy practices required under subsection (a)—

12 (A) at the first contact between the indi-
13 vidual and the person; and

14 (B) upon the request of an individual.

15 (2) POSTING.—A health information person
16 shall post, in a clear and conspicuous manner, a
17 brief summary of the privacy practices of the person.

18 (c) MODEL NOTICE.—The Secretary, in consultation
19 with the Director of the Office of Health Information Pri-
20 vacy, after notice and opportunity for public comment,
21 shall develop and disseminate model notices of privacy
22 practices, and model summary notices for posting for use
23 under this section. Use of such model notice shall be
24 deemed to satisfy the requirements of this section.

1 **SEC. 112. ESTABLISHMENT OF SAFEGUARDS.**

2 (a) IN GENERAL.—A health information person
3 shall—

4 (1) establish and maintain appropriate adminis-
5 trative, organizational, technical, and physical safe-
6 guards and procedures to ensure the privacy, con-
7 fidentiality, security, accuracy, and integrity of per-
8 sonal health information that is accessed, main-
9 tained, retained, modified, recorded, stored, de-
10 stroyed, or otherwise held, used, or disclosed by such
11 person; and

12 (2) employ an individual whose responsibilities
13 include the management of the person's information
14 security.

15 (b) FACTORS TO BE CONSIDERED.—The policies and
16 safeguards established under subsection (a) shall ensure
17 that—

18 (1) personal health information is used or dis-
19 closed only with informed consent (as defined in sec-
20 tion 171(19));

21 (2) the categories of personnel who will, with
22 the informed consent of the individual, have access
23 to personal health information are identified;

24 (3) the feasibility of limiting access to personal
25 health information is considered;

1 (4) the privacy, security, and confidentiality of
2 personal health information is maintained;

3 (5) personal health information is protected
4 against any reasonably anticipated vulnerabilities to
5 the privacy, security, or integrity of such informa-
6 tion; and

7 (6) personal health information is protected
8 against unauthorized access, use, or misuse of such
9 information.

10 (c) MODEL GUIDELINES.—The Secretary, in con-
11 sultation with the Director of the Office of Health Infor-
12 mation Privacy appointed under section 161, after notice
13 and opportunity for public comment, in accordance with
14 the requirements of chapter 5 of title 5, United States
15 Code, shall develop and disseminate model guidelines for
16 the establishment of safeguards and procedures for use
17 under this section, such as, where appropriate, individual
18 authentication of uses of computer systems, access con-
19 trols, audit trails, encryption or any additional security
20 methodology or technology other than encryption which
21 renders data in electronic form unreadable or indecipher-
22 able, physical security, protection of remote access points
23 and protection of external electronic communications, peri-
24 odic security assessments, incident reports, and sanctions.
25 The Secretary, in consultation with the Director, shall up-

1 date and disseminate the guidelines, as appropriate, to
2 take advantage of new technologies, so as to ensure that
3 the guidelines emphasize the need for stringent privacy,
4 security, and confidentiality safeguards and procedures.

5 (d) REVIEW AND UPDATING OF SAFEGUARDS.—Per-
6 sons subject to this title shall monitor, evaluate, and ad-
7 just, as appropriate, all safeguards and procedures, con-
8 comitant with relevant changes in technology, the sensi-
9 tivity of personally identifiable information, internal or ex-
10 ternal threats to personally identifiable information, and
11 any changes in the contracts or business of the person.
12 For the purpose of reviewing and updating safeguards, the
13 Secretary may provide technical assistance to health infor-
14 mation persons, as appropriate.

15 **SEC. 113. NOTIFICATION IN THE CASE OF BREACH.**

16 (a) IN GENERAL.—A health information person that
17 accesses, maintains, retains, modifies, records, stores, de-
18 stroys, or otherwise holds, uses, or discloses personal
19 health information shall, following the discovery of a secu-
20 rity breach (as defined in section 171(28)) of such infor-
21 mation, notify each individual whose personal health infor-
22 mation has been, or is reasonably believed to have been,
23 accessed, or acquired during such breach.

24 (b) OBLIGATION OF OWNER OR LICENSEE.—

1 (1) NOTICE TO OWNER OR LICENSEE.—Any
2 person engaged in interstate commerce, that uses,
3 accesses, transmits, stores, disposes of, or collects
4 personal health information that the person does not
5 own or license shall notify the owner or licensee of
6 the information following the discovery of a security
7 breach involving such information.

8 (2) NOTICE BY OWNER, LICENSEE, OR OTHER
9 DESIGNATED THIRD PARTY.—Nothing in this sub-
10 title shall be construed to prevent or abrogate an
11 agreement between a person required to give notice
12 under this section and a designated third party, in-
13 cluding an owner or licensee of the personal health
14 information subject to the security breach, to pro-
15 vide the notifications required under subsection (a).

16 (3) PERSON RELIEVED FROM GIVING NOTICE.—
17 A person obligated to give notice under subsection
18 (a) shall be relieved of such obligation if an owner
19 or licensee of the personal health information subject
20 to the security breach, or other designated third
21 party, provides such notification.

22 (c) TIMELINESS OF NOTIFICATION.—

23 (1) IN GENERAL.—All notifications required
24 under this section shall be made within 15 business
25 days, or earlier if the Secretary determines appro-

1 appropriate, following the discovery by the person of a se-
2 curity breach.

3 (2) BURDEN OF PROOF.—The person required
4 to provide notification under this section shall have
5 the burden of demonstrating that all notifications
6 were made as required under this subtitle, including
7 evidence demonstrating the necessity of any delay.

8 (d) METHODS OF NOTICE.—A person described in
9 subsection (a) shall provide to an individual the following
10 forms of notice in the case of a security breach:

11 (1) INDIVIDUAL NOTICE.—Notice required
12 under this section shall be provided in such form as
13 the individual selects, including—

14 (A) written notification to the last known
15 home mailing address of the individual in the
16 records of the person;

17 (B) telephone notice to the individual per-
18 sonally; or

19 (C) e-mail notice, if the individual has con-
20 sented to receive such notice and the notice is
21 consistent with the provisions permitting elec-
22 tronic transmission of notices under section 101
23 of the Electronic Signatures in Global and Na-
24 tional Commerce Act (15 U.S.C. 7001).

1 (2) MEDIA NOTICE.—Notice shall be provided
2 to prominent media outlets serving a State or juris-
3 diction, if the personal health information of more
4 than 500 residents of such State or jurisdiction is,
5 or is reasonably believed to have been, acquired by
6 an unauthorized person.

7 (3) NOTICE TO SECRETARY.—Notice shall be
8 provided to the Secretary for health information per-
9 sons that have lost, stolen, disclosed, or used in an
10 unauthorized manner or for an unauthorized pur-
11 pose the personal health information of a significant
12 number of individuals.

13 (e) CONTENT OF NOTIFICATION.—Regardless of the
14 method by which notice is provided to individuals under
15 this section, notice of a security breach shall include, to
16 the extent possible—

17 (1) a description of the personal health infor-
18 mation that has been, or is reasonably believed to
19 have been, accessed, disclosed, or otherwise used by
20 an unauthorized person;

21 (2) a toll-free number that the individual may
22 use to contact the person described in subsection (a)
23 to learn what types of personal health information
24 the person maintained about that individual; and

1 (3) toll-free contact telephone numbers and ad-
2 dresses for major credit reporting agencies.

3 (f) DELAY OF NOTIFICATION AUTHORIZED FOR LAW
4 ENFORCEMENT PURPOSES.—

5 (1) IN GENERAL.—If a Federal law enforce-
6 ment agency determines that the notification re-
7 quired under this section would impede a criminal
8 investigation or cause damage to national security,
9 such notification shall be delayed upon written no-
10 tice from the Federal law enforcement agency to the
11 person that experienced the breach.

12 (2) EXTENDED DELAY OF NOTIFICATION.—If
13 the notification required under subsection (a) is de-
14 layed pursuant to paragraph (1), a person shall give
15 notice not later than 30 days after such law enforce-
16 ment delay was invoked unless a Federal law en-
17 forcement agency provides written notification that
18 further delay is necessary.

19 **SEC. 114. TRANSPARENCY.**

20 (a) PUBLIC LIST OF DATA PARTNERS.—

21 (1) IN GENERAL.—A health information person
22 shall establish a list of data partners (as defined in
23 paragraph (2)) with which such person has entered
24 into a contract or relationship for the purposes of
25 providing services involving any personal health in-

1 formation held, used, or disclosed by the person.
2 Such list and the contact information for each part-
3 ner shall be made publicly accessible on the Internet.

4 (2) DATA PARTNER DEFINED.—In paragraph
5 (1), the term “data partner” means a data bank,
6 data warehouse, information clearinghouse, record
7 locator system, or other business entity, which for
8 monetary fees, dues, or on a cooperative nonprofit
9 basis, engages in the practice of accessing, col-
10 lecting, maintaining, modifying, storing, recording,
11 transmitting, destroying, or otherwise using or dis-
12 closing the personal health information of individ-
13 uals. Any person maintaining personal health infor-
14 mation for the purposes of making such information
15 available to the individual or the health care pro-
16 vider, including persons furnishing free or paid per-
17 sonal health records, electronic health records, elec-
18 tronic medical records, and related products and
19 services, shall be deemed to be a data partner sub-
20 ject to the requirements of this title.

21 (b) SUBCONTRACTING AND OUTSOURCING OVER-
22 SEAS.—In the event a health information person contracts
23 with service providers not subject to this title, including
24 service providers operating in a foreign country, such per-
25 son shall—

1 (1) take reasonable steps to select and retain
2 third party service providers capable of maintaining
3 appropriate safeguards for the security, privacy, and
4 integrity of personal health information;

5 (2) require by contract that such service pro-
6 viders implement and maintain appropriate meas-
7 ures designed to meet the requirements applicable to
8 health information persons under this title;

9 (3) be held liable for any violation of this title
10 by an overseas service provider or other provider not
11 subject to this title; and

12 (4) in the case of a service provider operating
13 in a foreign country, obtain the informed consent of
14 the individual involved prior to outsourcing such in-
15 dividual's personal health information to such pro-
16 vider.

17 (c) LIST OF PERSONS.—The Secretary shall maintain
18 a public list identifying health information persons that
19 have lost, stolen, disclosed, or used in an unauthorized
20 manner or for an unauthorized purpose the personal
21 health information of 1,000 or more individuals. The list
22 shall include how many individuals were affected by such
23 action and be displayed on the Web site of the Department
24 of Health and Human Services.

1 **SEC. 115. RISK MANAGEMENT.**

2 (a) IN GENERAL.—Each health information person
3 shall establish risk management and control processes to
4 protect against anticipated vulnerabilities to the privacy,
5 security, and integrity of personal health information that
6 the person accesses, holds, uses, or discloses.

7 (b) RISK ASSESSMENT.—A health information person
8 shall perform annual risk assessments of procedures, sys-
9 tems, or networks involved in the creation, accessing,
10 maintenance, retention, modification, recording, storage,
11 distribution, destruction, or other use or disclosure of per-
12 sonal health information. Such risk assessment shall in-
13 clude—

14 (1) identifying reasonably foreseeable internal
15 and external vulnerabilities that could result in inac-
16 curacy or in unauthorized access, disclosure, use, or
17 modification of personal health information, or of
18 systems containing personal health information;

19 (2) assessing the likelihood of and potential
20 damage from inaccuracy or from unauthorized ac-
21 cess, disclosure, use, or modification of personal
22 health information;

23 (3) assessing the sufficiency of policies, tech-
24 nologies, and safeguards in place to enable compli-
25 ance with individuals' informed consent to the ac-
26 cess, disclosure, use, or modification of their per-

1 sonal health information and minimize and control
2 risks from unauthorized access, disclosure, use, or
3 modification of individuals' personal health informa-
4 tion; and

5 (4) assessing the vulnerability of personal
6 health information during destruction and disposal
7 of such information, including through the disposal
8 or retirement of hardware.

9 (c) RISK MANAGEMENT.—A health information per-
10 son shall establish risk management and control proce-
11 dures designed to control risks such as those identified
12 in subsection (b). Such procedures shall include—

13 (1) a means for the detection and recording of
14 actual or attempted, unauthorized, fraudulent, or
15 otherwise unlawful access, disclosure, transmission,
16 modification, use, or loss of personal health informa-
17 tion;

18 (2) procedures for ensuring the secure disposal
19 of personal health information;

20 (3) a means for limiting physical access to
21 hardware, software, data storage technology, servers,
22 systems, or networks by unauthorized persons in
23 order to minimize the risk of information disclosure,
24 modification, transmission, access, use, or loss;

1 (4) providing appropriate risk management and
2 control training for employees; and

3 (5) carrying out annual testing of such risk
4 management and control procedures.

5 **SEC. 116. ACCOUNTING FOR DISCLOSURES AND USE.**

6 (a) **IN GENERAL.**—A health information person shall
7 establish and maintain, with respect to any personal
8 health information disclosure, a record of each disclosure
9 in accordance with regulations promulgated by the Sec-
10 retary in consultation with the Director of the Office of
11 Health Information Privacy. Such record shall include the
12 purpose of any disclosure and the identity of the specific
13 individual executing the disclosure, as well as the person
14 to which such information is disclosed.

15 (b) **MAINTENANCE OF RECORD.**—A record estab-
16 lished under subsection (a) shall be maintained for not less
17 than 6 years.

18 (c) **ELECTRONIC RECORDS.**—A health information
19 person shall, to the maximum extent practicable, maintain
20 an accessible electronic record concerning each access, use,
21 or disclosure, whether authorized or unauthorized and
22 whether successful or unsuccessful, of personal health in-
23 formation maintained by such person in electronic form.
24 The record shall include the identities of the specific indi-
25 viduals (or a way to identify such individuals, or informa-

1 tion helpful in determining the identities of such individ-
 2 uals) who access or seek to gain access to, use or seek
 3 to use, or disclose or seek to disclose, information suffi-
 4 cient to identify the personal health information sought
 5 or accessed, and other appropriate information.

6 (d) ACCESS TO RECORDS.—A health information per-
 7 son shall permit an individual who is the subject of per-
 8 sonal health information, or the individual’s designee, to
 9 inspect and copy the records created in subsections (a)
 10 and (c).

11 **Subtitle C—Use and Disclosure of** 12 **Personal Health Information**

13 **CHAPTER 1—GENERAL RESTRICTIONS**

14 **SEC. 121. GENERAL RULES REGARDING USE AND DISCLO-** 15 **SURE.**

16 (a) PROHIBITION.—

17 (1) GENERAL RULE.—A person may not dis-
 18 close, access, or use personal health information ex-
 19 cept as authorized under this title.

20 (2) RULE OF CONSTRUCTION.—Disclosure or
 21 use of health information that meets the standards
 22 of being de-identified health information shall not be
 23 construed as a disclosure or use of personal health
 24 information.

25 (b) SCOPE OF DISCLOSURE OR USE.—

1 (1) IN GENERAL.—A disclosure or use of per-
2 sonal health information under this subtitle shall be
3 limited to the minimum amount of information nec-
4 essary to accomplish the purpose for which the dis-
5 closure or use is made, such as the individual’s name
6 and address, date of service, place of service, type of
7 service, cost of service, and diagnosis.

8 (2) DETERMINATION.—The determination as to
9 what constitutes the minimum disclosure or use pos-
10 sible for purposes of paragraph (1) shall be made by
11 the individual or entity holding the information. The
12 minimum necessary standard is intended to be con-
13 sistent with, and not override, professional judgment
14 and standards.

15 (c) USE OR DISCLOSURE FOR PURPOSE ONLY.—

16 (1) IN GENERAL.—An authorized recipient (as
17 defined in paragraph (2)) of information pursuant to
18 this subtitle may use or disclose such information
19 solely to carry out the purpose for which the infor-
20 mation was disclosed, except as provided in section
21 143.

22 (2) AUTHORIZED RECIPIENT DEFINED.—In
23 paragraph (1), the term “authorized recipient”
24 means a person granted the authority by an indi-
25 vidual, in accordance with this title, to access, main-

1 tain, retain, modify, record, store, destroy, or other-
2 wise use the individual’s personal health information
3 through an authorized disclosure.

4 (d) NO GENERAL REQUIREMENT TO DISCLOSE.—
5 Nothing in this subtitle permitting the disclosure of per-
6 sonal health information shall be construed to require such
7 disclosure.

8 (e) IDENTIFICATION OF DISCLOSED INFORMATION AS
9 PERSONAL HEALTH INFORMATION.—Personal health in-
10 formation disclosed or used pursuant to this subtitle shall
11 be clearly identified and labeled as personal health infor-
12 mation that is subject to this title.

13 (f) DISCLOSURE OR USE BY AGENTS.—An agent,
14 employee, or affiliate of a health information person that
15 accesses, seeks to access, obtains, discloses, uses, or re-
16 ceives personal health information from such person, shall
17 be subject to this subtitle to the same extent as the person.

18 (g) DISCLOSURE OR USE BY OTHERS.—A person re-
19 ceiving personal health information initially held by a per-
20 son described in subsection (f) shall be subject to this sub-
21 title to the same extent as the person described in sub-
22 section (f).

23 (h) CREATION OF DE-IDENTIFIED INFORMATION.—
24 Notwithstanding subsection (c), but subject to the other
25 provisions of this section, a person described in subsection

1 (f) may disclose personal health information to an em-
2 ployee or other agent of the person for purposes of cre-
3 ating de-identified information.

4 (i) UNAUTHORIZED USE OR DISCLOSURE OF THE
5 DECRYPTION KEY.—The unauthorized disclosure of a
6 decryption key (as defined in section 171(7)) or other sec-
7 ondary or tertiary means for accessing personal health in-
8 formation shall be deemed for purposes of this subtitle to
9 be a disclosure of personal health information. The unau-
10 thorized use of a decryption key (or other secondary or
11 tertiary means for accessing personal health information)
12 or de-identified health information in order to identify an
13 individual is deemed for purposes of this subtitle to be dis-
14 closure of personal health information.

15 (j) NO WAIVER.—Except as provided in this title, an
16 informed consent or other authorization to disclose or use
17 personally identifiable health information executed by an
18 individual pursuant to this subtitle shall not be construed
19 as a waiver of any rights that the individual has under
20 other Federal or State laws, the rules of evidence, or com-
21 mon law.

22 (k) OPT-IN TO NETWORK SHARING.—

23 (1) IN GENERAL.—Before a health information
24 person may share personal health information,
25 through disclosure, access, use, or otherwise, with a

1 health information network or system, the individual
2 must opt in to the sharing of such information with
3 such network or system.

4 (2) HEALTH INFORMATION NETWORK OR SYS-
5 TEM DEFINED.—In this subsection, the term “health
6 information network or system” means an interoper-
7 able health information infrastructure consisting of
8 health information systems and other networks that
9 connect providers, consumers, and others involved in
10 supporting health and health care.

11 (1) DISPOSAL OF DATA.—To prevent the unauthor-
12 ized disclosure or use of personal health information, such
13 information, when disposed of, shall be de-identified, de-
14 stroyed, or expunged from any electronic, paper, or other
15 files and documents maintained by authorized persons to
16 make such information permanently unreadable and
17 undecipherable.

18 (m) OBLIGATIONS OF UNAUTHORIZED RECIPI-
19 ENTS.—A person that obtains, accesses, or receives per-
20 sonal health information and that is an unauthorized re-
21 cipient of such information may not access, maintain, re-
22 tain, modify, record, store, destroy, or otherwise use or
23 disclose such information for any purposes, and use or dis-
24 closure of personal health information under such cir-
25 cumstances shall be deemed for purposes of this subtitle

1 an unauthorized disclosure of personal health information,
2 unless the disclosure is for the purpose of informing the
3 Secretary, law enforcement authorities, or Congress of the
4 person's unauthorized receipt of the personal health infor-
5 mation.

6 **SEC. 122. INFORMED CONSENT FOR DISCLOSURE OF PER-**
7 **SONAL HEALTH INFORMATION FOR TREAT-**
8 **MENT AND PAYMENT.**

9 (a) REQUIREMENTS RELATING TO EMPLOYERS,
10 HEALTH PLANS, HEALTH OR LIFE INSURERS, UNIN-
11 SURED AND SELF-PAY INDIVIDUALS, AND PROVIDERS.—

12 (1) IN GENERAL.—An employer, health plan,
13 health or life insurer, or health care provider that
14 seeks to disclose personal health information in con-
15 nection with treatment or payment shall obtain in-
16 formed consent (as defined in section 171(19)) from
17 the subject of such personal health information that
18 satisfies the requirements of this section. A single
19 consent may authorize multiple disclosures.

20 (2) HEALTH PLANS, HEALTH OR LIFE INSUR-
21 ERS.—Every health plan or health or life insurer of-
22 fering enrollment to individual or nonemployer
23 groups shall, at the time of enrollment in the plan
24 or insurance, obtain an informed consent for the use
25 and disclosure of personal health information with

1 respect to each individual who is eligible to receive
2 care or benefits under the plan or insurance.

3 (3) UNINSURED AND SELF-PAY.—An origi-
4 nating provider that provides health care in other
5 than a network plan setting, or provides health care
6 to an uninsured individual, shall obtain an informed
7 consent for access to or use of personal health infor-
8 mation in providing health care or arranging for
9 health care from other providers or seeking payment
10 for the provision of health care services.

11 (4) PROVIDERS.—Every health care provider
12 that provides health care to an individual that has
13 not been given the appropriate prior consent under
14 this section, shall at the time of providing such care,
15 or at such time as is practicable if services are nec-
16 essary prior to the opportunity to obtain consent, ob-
17 tain an informed consent for the use and disclosure
18 of personal health information with respect to such
19 individual.

20 (b) REQUIREMENTS FOR INDIVIDUAL INFORMED
21 CONSENT.—To satisfy the requirements of this sub-
22 section, an informed consent from an individual to disclose
23 the individual's personal health information shall—

24 (1) identify, by general job description or other
25 functional description and by geographic location,

1 those persons that are authorized to disclose the in-
2 formation, including entities employed by a person
3 authorized to disclose the information;

4 (2) describe the specific nature of the informa-
5 tion to be disclosed;

6 (3) identify, by general job description or other
7 functional description and by geographic location,
8 those persons to which the information will be dis-
9 closed, including entities employed by a person to
10 which information is authorized to be disclosed;

11 (4) describe the purpose of the disclosures;

12 (5) permit the executing individual to indicate
13 that a particular person or class of persons (a group
14 of persons with similar roles or functions) listed on
15 the informed consent is not authorized to receive
16 personal health information concerning the indi-
17 vidual, except as provided for in subsection (c)(3);

18 (6) provide the means by which an individual
19 may indicate that some of the individual's personal
20 health information should be segregated and to what
21 persons or classes of persons such segregated infor-
22 mation may be disclosed;

23 (7) be subject to revocation by the individual
24 and indicate that the informed consent is valid until

1 revocation by the individual or until an event or date
2 specified;

3 (8)(A) be in writing, dated, and signed by the
4 individual; and

5 (B) not have been revoked under subsection (f);

6 (9) describe the procedure by which an indi-
7 vidual can amend an informed consent previously ob-
8 tained by a person;

9 (10) describe the extent to which the authorized
10 person will share information with sub-contracted
11 persons, and the geographic location of sub-con-
12 tracted persons, including those operating or located
13 overseas, except that the authorized person shall ob-
14 tain the informed consent of the individual involved
15 prior to outsourcing such individual's personal
16 health information to a sub-contracted person oper-
17 ating or located overseas; and

18 (11) describe the nature and probability of
19 harm to the individual resulting from the informed
20 consent for use or disclosure, consistent with the
21 principle of informed consent.

22 (c) LIMITATION ON INFORMED CONSENT.—

23 (1) IN GENERAL.—Subject to paragraphs (2)
24 and (3), a health information person that seeks in-
25 formed consent under this subtitle may not condition

1 the delivery of treatment or payment for services on
2 the receipt of such an informed consent.

3 (2) RIGHT TO REQUIRE SELF-PAYMENT.—

4 (A) IN GENERAL.—If an individual has re-
5 fused to provide an informed consent for disclo-
6 sure of administrative billing information (as
7 defined in subparagraph (B)) to a person and
8 such informed consent is necessary for a health
9 care provider to receive payment for services de-
10 livered, the health care provider may require
11 the individual to pay from their own funds for
12 the services.

13 (B) ADMINISTRATIVE BILLING INFORMA-
14 TION.—In subparagraph (A), the term “admin-
15 istrative billing information” means any of the
16 following forms of personal health information:

17 (i) Date of service, policy, patient
18 identifiers, and practitioner or facility iden-
19 tifiers.

20 (ii) Diagnostic codes, in accordance
21 with medicare billing codes, for which
22 treatment is being rendered or requested.

23 (iii) Complexity of service codes, indi-
24 cating duration of treatment.

25 (iv) Total billed charges.

1 (3) RIGHT OF HEALTH CARE PROVIDER TO RE-
2 QUIRE INFORMED CONSENT FOR TREATMENT PUR-
3 POSES.—If a health care provider that is seeking an
4 informed consent for disclosure of an individual’s
5 personal health information believes that the disclo-
6 sure of such information is necessary so as not to
7 endanger the health or treatment of the individual,
8 and if the withholding of services will not endanger
9 the life of the individual, the health care provider
10 may condition the provision of services upon the in-
11 dividual’s execution of an informed consent to dis-
12 close personal health information to the minimum
13 extent necessary.

14 (4) INFORMED CONSENTS FOR PAYMENT
15 UNDER CERTAIN CIRCUMSTANCES.—If an individual
16 is in a physical or mental condition such that the in-
17 dividual is not capable of authorizing the disclosure
18 of personal health information and no other arrange-
19 ments have been made to pay for the health care
20 services being rendered to the patient, such informa-
21 tion may be disclosed to a governmental authority to
22 the extent necessary to determine the individual’s
23 eligibility for, and to obtain, payment under a gov-
24 ernmental program for health care services provided
25 to the patient. The information may also be dis-

1 closed to another provider of health care or health
2 care service plan as necessary to assist the other
3 provider or health care service plan in obtaining pay-
4 ment for health care services rendered by that pro-
5 vider of health care or health care service plan to the
6 patient.

7 (d) MODEL INFORMED CONSENT.—The Secretary, in
8 consultation with the Director of the Office of Health In-
9 formation Privacy, after notice and opportunity for public
10 comment in accordance with section 553 of title 5, United
11 States Code, shall develop and disseminate model written
12 informed consents of the type described in this section,
13 which represent informed consent from the subject of such
14 personal health information that satisfies the require-
15 ments of this section, and model statements of the limita-
16 tions on informed consents. Any informed consent ob-
17 tained on a model informed consent form under this sec-
18 tion developed by the Secretary pursuant to the preceding
19 sentence shall be deemed to satisfy the requirements for
20 an informed consent under this section.

21 (e) SEGREGATION OF FILES.—A health information
22 person shall comply with the request of an individual who
23 is the subject of personal health information—

1 (1) to hide, mask, or mark separate any type or
2 amount of personal health information held by the
3 person; and

4 (2) to limit the use or disclosure of the seg-
5 regated health information within the person to
6 those specifically designated by the subject of the
7 personal health information.

8 (f) REVOCATION OF INFORMED CONSENT.—

9 (1) IN GENERAL.—An individual may revoke or
10 amend in writing an informed consent under this
11 section at any time, unless the disclosure that is the
12 subject of the consent is required to effectuate pay-
13 ment for health care that has been provided to the
14 individual and for which the individual has declined
15 or refused to pay from the individual's own funds.

16 (2) HEALTH PLAN.—With respect to a health
17 plan, the informed consent of an individual is
18 deemed to be revoked at the time of the cancellation
19 or non-renewal of enrollment in the health plan, ex-
20 cept as may be necessary to complete plan adminis-
21 tration and payment requirements related to the in-
22 dividual's period of enrollment.

23 (g) RECORD OF INDIVIDUAL'S INFORMED CONSENTS
24 AND REVOCATIONS.—Each person accessing, maintaining,
25 retaining, modifying, recording, storing, destroying, or

1 otherwise using personally identifiable or personal health
2 information for purposes of treatment or payment shall
3 maintain a record for a period of 6 years of each informed
4 consent by an individual and any revocation thereof, and
5 such record shall become part of the individual's health
6 record set.

7 **SEC. 123. INFORMED CONSENT AND AUTHORIZATION FOR**
8 **DISCLOSURE OF PERSONAL HEALTH INFOR-**
9 **MATION OTHER THAN FOR TREATMENT OR**
10 **PAYMENT.**

11 (a) IN GENERAL.—A health information person that
12 seeks to disclose personal health information for a purpose
13 other than treatment or payment shall obtain informed
14 consent. Such consent under this section shall be separate
15 from an informed consent provided under section 122.

16 (b) LIMITATION ON AUTHORIZATIONS.—A person
17 subject to section 122 may not condition the delivery of
18 treatment, or payment for services, on the receipt of an
19 informed consent or authorization described in this sec-
20 tion.

21 (c) MODEL INFORMED CONSENTS AND AUTHORIZA-
22 TIONS.—The Secretary, in consultation with the Director
23 of the Office of Health Information Privacy, after notice
24 and opportunity for public comment in accordance with
25 section 553 of title 5, United States Code, shall develop

1 and disseminate model informed consents of the type de-
2 scribed in subsection (a) and written authorizations of the
3 type described in subsections (d) and (e). Any consent or
4 authorization obtained on a respective model form shall
5 be deemed to meet the requirements under the respective
6 subsection.

7 (d) REQUIREMENT OF SEPARATE, ADDITIONAL AU-
8 THORIZATION FOR PERSONNEL DECISIONS.—A health in-
9 formation person subject to section 122 may not disclose
10 personal health information to any employees or agents
11 who are responsible for making employment, work assign-
12 ment, or other personnel decisions with respect to the sub-
13 ject of the information without a separate, additional writ-
14 ten authorization permitting such a disclosure.

15 (e) REQUIREMENT OF SEPARATE, ADDITIONAL AU-
16 THORIZATION FOR MARKETING.—

17 (1) IN GENERAL.—A health information person
18 may not disclose personal health information for
19 marketing purposes without a separate, additional
20 written authorization permitting such a disclosure.

21 (2) REQUIREMENTS.—In the case of a disclo-
22 sure of personal health information for marketing
23 purposes, a separate authorization required by para-
24 graph (1), to be valid, shall—

1 (A) state that one purpose of the disclo-
2 sure is for “marketing”;

3 (B) state that the purpose of the use or
4 disclosure involved is marketing;

5 (C) describe the specific marketing uses
6 and disclosures authorized, including whether
7 the personal health information involved—

8 (i) may be used for purposes internal
9 to the person;

10 (ii) may be disclosed to, and used by,
11 a business associate of the person; and

12 (iii) may be disclosed to, and used by,
13 any person or entity other than a business
14 associate of the person; and

15 (D) state that the use or disclosure of per-
16 sonal health information for marketing will di-
17 rectly result in remuneration to the person from
18 a third party, in any case in which a person ex-
19 pects, or reasonably should expect, that such re-
20 muneration will occur.

21 (3) MARKETING DEFINED.—

22 (A) IN GENERAL.—In this subsection, the
23 term “marketing” is a communication about a
24 product or service a purpose of which is to en-
25 courage recipients of the communication to pur-

1 chase or use the product or service in return for
2 direct or indirect compensation.

3 (B) EXCLUSIONS.—

4 (i) IN GENERAL.—Subject to clause
5 (ii), such term excludes the following ex-
6 ceptions:

7 (I) Communications made by per-
8 son for the purpose of describing the
9 entities participating in a provider
10 network or health plan network, and
11 communications made by a person for
12 the purpose of describing if and the
13 extent to which a product or service,
14 or payment for a product or service, is
15 provided by the person or included in
16 a benefit plan.

17 (II) Communications tailored to
18 the circumstances of a particular indi-
19 vidual, made by a health care provider
20 to an individual as part of the treat-
21 ment of the individual, and for the
22 purpose of furthering the treatment of
23 that individual.

24 (III) Communications tailored to
25 the circumstances of a particular indi-

1 vidual and made by a health care pro-
2 vider or health plan to an individual
3 in the course of managing or coordi-
4 nating the treatment of that indi-
5 vidual or for the purpose of directing
6 or recommending to that individual al-
7 ternative treatments, therapies, pro-
8 viders, or settings of care.

9 (ii) EXCEPTION.—Clause (i) shall not
10 apply, and a communication shall be con-
11 sidered marketing, if a person receives di-
12 rect or indirect remuneration from a third
13 party for making a written communication
14 otherwise described in subclause (I), (II),
15 or (III) of such clause.

16 (f) REQUIREMENT TO RELEASE PERSONAL HEALTH
17 INFORMATION TO CORONERS AND MEDICAL EXAM-
18 INERS.—

19 (1) IN GENERAL.—When a coroner or medical
20 examiner or their duly appointed deputies seek per-
21 sonal health information for the purpose of inquiry
22 into and determination of, the cause, manner, and
23 circumstances of an individual’s death, the health in-
24 formation person shall provide that individual’s per-
25 sonal health information to the coroner or medical

1 examiner or to the duly appointed deputies without
2 undue delay or consent by the deceased individual's
3 representative.

4 (2) PRODUCTION OF ADDITIONAL INFORMA-
5 TION.—If a coroner or medical examiner or their
6 duly appointed deputies receives health information
7 from a person referred to in paragraph (1), such
8 health information shall remain as personal health
9 information unless the health information is at-
10 tached to or otherwise made a part of a coroner's or
11 medical examiner's official report, in which case it
12 shall no longer be protected.

13 (3) EXEMPTION.—Health information attached
14 to or otherwise made a part of a coroner's or med-
15 ical examiner's official report shall be exempt from
16 the provisions of this title except as provided for in
17 this subsection.

18 (4) REIMBURSEMENT.—A person referred to in
19 paragraph (1) may request reimbursement from a
20 coroner or medical examiner for the reasonable costs
21 associated with inspection or copying of personal
22 health information maintained, retained, or stored
23 by such person.

24 (g) REVOCATION OR AMENDMENT OF CONSENT OR
25 AUTHORIZATION.—An individual may revoke or amend in

1 writing an informed consent or authorization under this
2 section at any time.

3 (h) ACTIONS.—It shall not be a violation of this title
4 with respect to the disclosure of personal health informa-
5 tion—

6 (1) if the disclosure was made based on a good
7 faith reliance on the individual’s informed consent or
8 authorization under this section at the time disclo-
9 sure was made;

10 (2) in a case in which the consent or authoriza-
11 tion is revoked, if the disclosing person had no ac-
12 tual or constructive notice of the revocation; or

13 (3) if the disclosure was for the purpose of pro-
14 tecting another individual from imminent physical
15 harm and is authorized under section 141.

16 (i) RECORD OF CONSENTS, AUTHORIZATIONS, AND
17 REVOCATIONS.—Each person accessing, maintaining, re-
18 taining, modifying, recording, storing, destroying, or oth-
19 erwise using personally identifiable or personal health in-
20 formation for purposes other than treatment or payment
21 shall maintain a record for a period of 6 years of each
22 informed consent and authorization by an individual and
23 any revocation thereof, and such record shall become part
24 of the individual’s health record set.

CHAPTER 2—EXCEPTIONS**SEC. 131. DISCLOSURE FOR LAW ENFORCEMENT, NATIONAL SECURITY, AND INTELLIGENCE PURPOSES.**

(a) ACCESS TO PERSONAL HEALTH INFORMATION FOR LAW ENFORCEMENT, NATIONAL SECURITY, AND INTELLIGENCE ACTIVITIES.—A health information person, or a person who receives personal health information pursuant to section 131, may disclose personal health information to—

(1) an investigative or law enforcement officer (as defined in subsection (k)) pursuant to a warrant issued under the Federal Rules of Criminal Procedure, an equivalent State warrant, a grand jury subpoena, civil subpoena, civil investigative demand, or a court order under limitations set forth in subsection (b); and

(2) an authorized Federal official for the conduct of lawful intelligence, counter-intelligence, and other national security activities authorized by the National Security Act (50 U.S.C. 401 et seq.) and implementing authority (Executive Order 12333), or otherwise by law.

1 (b) LIMITATION ON USE AND DISCLOSURE FOR NA-
2 TIONAL SECURITY, INTELLIGENCE, AND OTHER LAW EN-
3 FORCEMENT INQUIRIES.—

4 (1) IN GENERAL.—Personal health information
5 about an individual that is disclosed under this sec-
6 tion may not be used in, or disclosed to any entity
7 for use in, any administrative, civil, or criminal ac-
8 tion or investigation directed against the individual,
9 unless the action or investigation arises out of, or is
10 directly related to, the law enforcement, national se-
11 curity, or intelligence inquiry for which the informa-
12 tion was obtained.

13 (2) LAW ENFORCEMENT INQUIRY DEFINED.—
14 In paragraph (1), the term “law enforcement in-
15 quiry” means a lawful executive branch investigation
16 or official proceeding inquiring into a violation of, or
17 failure to comply with, any criminal or civil statute
18 or any regulation, rule, or order issued pursuant to
19 such a statute.

20 (c) REDACTIONS.—To the maximum extent prac-
21 ticable, and consistent with the requirements of due proc-
22 ess, a law enforcement agency shall redact personally iden-
23 tifying information from personal health information prior
24 to the public disclosure of such protected information in
25 a judicial or administrative proceeding.

1 (d) EXCEPTION.—This section shall not be construed
2 to limit or restrict the ability of law enforcement authori-
3 ties to gain information while in hot pursuit of a suspect
4 or if other exigent circumstances exist.

5 (e) INVESTIGATIVE OR LAW ENFORCEMENT OFFICER
6 DEFINED.—In this section, the term “investigative or law
7 enforcement officer” means any officer of the United
8 States or of a State or political subdivision thereof, who
9 is empowered by law to conduct investigations of, or to
10 make arrests for, civil or criminal offenses, and any attor-
11 ney authorized by law to prosecute or participate in the
12 prosecution of such offenses.

13 **SEC. 132. DISCLOSURE FOR PUBLIC HEALTH PURPOSES.**

14 (a) IN GENERAL.—A health information person may
15 disclose personal health information to a public health au-
16 thority (as defined in section 171(24)) or other entity au-
17 thorized by public health law, when receipt of such infor-
18 mation by the authority or other entity—

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

21 (2) is reasonably likely to achieve such purpose;

22 and

23 (3) is intended for a purpose that cannot be
24 achieved through the receipt or use of de-identified
25 health information.

1 (b) PUBLIC HEALTH PROTECTION DEFINED.—For
2 purposes of subsection (a), the term “public health pur-
3 pose” means a population-based activity or individual ef-
4 fort, authorized by law, the purpose of which is the preven-
5 tion of injury, disease, or premature mortality, or the pro-
6 motion of health, in a community, including—

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

10 (2) implementing public health policy;

11 (3) responding to public health needs and emer-
12 gencies; and

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

15 (c) LIMITATIONS.—The purpose of the disclosure de-
16 scribed in subsection (a) shall be of significant importance
17 such that it warrants the potential effect on, or risk to,
18 the privacy of individuals that the additional exposure of
19 personal health information might bring. Any infringe-
20 ment on the right to privacy under this section shall use
21 the least intrusive means that are tailored to minimize in-
22 trusion on the right to privacy.

1 **SEC. 133. REPORTING OF ABUSE AND NEGLECT TO PRO-**
2 **TECTION AND ADVOCACY AGENCIES.**

3 Any health information person may disclose personal
4 health information to a protection and advocacy agency
5 established under part C of title I of the Developmental
6 Disabilities Assistance and Bill of Rights Act (42 U.S.C.
7 6041 et seq.) or under the Protection and Advocacy for
8 Mentally Ill Individuals Act of 1986 (42 U.S.C. 10801 et
9 seq.) when such person reasonably believes that an indi-
10 vidual who is the subject of the personal health informa-
11 tion is vulnerable to abuse and neglect by an entity pro-
12 viding health or social services to the individual.

13 **SEC. 134. DISCLOSURE TO NEXT OF KIN AND DIRECTORY**
14 **INFORMATION.**

15 (a) NEXT OF KIN.—A health care provider, or a per-
16 son that receives personal health information under sec-
17 tion 141, may disclose personal health information about
18 health care services provided to an individual to the indi-
19 vidual's next of kin, or to another entity that the indi-
20 vidual has identified, if at the time of the treatment of
21 the individual—

22 (1) the individual—

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

1 (B) is in a physical or mental condition
2 such that the individual is not capable of object-
3 ing, and there are no prior indications that the
4 individual would object; and

5 (2) the information disclosed is relevant to
6 health care services currently being provided to that
7 individual.

8 (b) DIRECTORY INFORMATION.—

9 (1) DISCLOSURE.—

10 (A) IN GENERAL.—Except as provided in
11 paragraph (2), with respect to an individual
12 who is admitted as an inpatient to a health care
13 facility, a person described in subsection (a)
14 may disclose information described in subpara-
15 graph (B) about the individual to any entity if,
16 at the time of the admission, the individual—

17 (i) has been notified of the individ-
18 ual's right to object and has not objected
19 to the disclosure; or

20 (ii) is in a physical or mental condi-
21 tion such that the individual is not capable
22 of objecting and there are no prior indica-
23 tions that the individual would object.

1 (B) INFORMATION.—Information described
2 in this subparagraph is information that con-
3 sists only of 1 or more of the following items:

4 (i) The name of the individual who is
5 the subject of the information.

6 (ii) The general health status of the
7 individual, described as critical, poor, fair,
8 stable, or satisfactory or in terms denoting
9 similar conditions.

10 (iii) The location of the individual
11 within the health care facility to which the
12 individual is admitted.

13 (2) EXCEPTION.—Paragraph (1)(B)(iii) shall
14 not apply if disclosure of the location of the indi-
15 vidual would reveal specific information about the
16 physical or mental condition of the individual, unless
17 the individual expressly authorizes such disclosure.

18 (c) DIRECTORY OR NEXT-OF-KIN INFORMATION.—A
19 disclosure may not be made under this section if the dis-
20 closing person described in subsection (a) has reason to
21 believe that the disclosure of directory or next-of-kin infor-
22 mation could lead to the physical or mental harm of the
23 individual, unless the individual expressly authorizes such
24 disclosure.

1 CHAPTER 3—SPECIAL CIRCUMSTANCES**2 SEC. 141. EMERGENCY CIRCUMSTANCES.**

3 (a) GENERAL RULE.—In the event of a threat of im-
4 minent physical or mental harm to the subject of personal
5 health information, any person may, in order to allay or
6 remedy such threat, disclose personal health information
7 about such subject to a health care provider, health care
8 facility, law enforcement authority, or emergency medical
9 personnel, to the minimum extent necessary and only if
10 determined appropriate by a health care provider.

11 (b) HARM TO OTHERS.—Any person may disclose
12 personal health information about the subject of the infor-
13 mation where—

14 (1) such subject has made an identifiable threat
15 of serious injury or death with respect to an identifi-
16 able individual or group of individuals;

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

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

22 SEC. 142. HEALTH RESEARCH.

23 (a) REGULATIONS.—

24 (1) IN GENERAL.—The requirements and pro-
25 tections provided for under part 46 of title 45, Code

1 of Federal Regulations (as in effect on the date of
2 enactment of this Act), shall apply to all health re-
3 search.

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

7 (b) EVALUATION.—Not later than 24 months after
8 the date of the enactment of this Act, the Secretary shall
9 prepare and submit to Congress detailed recommendations
10 on whether informed consent should be required, and if
11 so, under what circumstances, before personal health in-
12 formation can be used for health research.

13 (c) RECOMMENDATIONS.—The recommendations re-
14 quired to be submitted under subsection (b) shall in-
15 clude—

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

22 (2) a list of all known breaches of health infor-
23 mation privacy over the past 5 years in research
24 projects approved by an institutional review board;

1 (3) a summary of how technology that both fa-
2 cilitates research and preserves privacy could be
3 used to obtain informed consent and strip identi-
4 fying data for the purpose of research;

5 (4) an analysis of State and Federal laws, med-
6 ical ethics, and ethics in the performance of health
7 research that examines requirements for the receipt
8 of informed consent; and

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

14 (d) CONSULTATION.—In carrying out this section,
15 the Secretary shall consult with individuals who have dis-
16 tinguished themselves in the fields of health research, pri-
17 vacy, related technology including electronic consent man-
18 agement tools, consumer interests in health information,
19 health data standards, and the provision of health services.

20 (e) CONGRESSIONAL NOTICE.—Not later than 6
21 months after the date on which the Secretary submits to
22 Congress the recommendations required under subsection
23 (b), the Secretary shall propose to implement such rec-
24 ommendations through regulations promulgated on the

1 record after opportunity for a hearing, and shall advise
2 the Congress of such proposal.

3 (f) OTHER REQUIREMENTS.—

4 (1) OBLIGATIONS OF THE RECIPIENT.—A per-
5 son who receives personal health information pursu-
6 ant to this section shall remove or destroy, at the
7 earliest opportunity consistent with the purposes of
8 the project involved, information that would enable
9 an individual to be identified, unless—

10 (A) an institutional review board has de-
11 termined that there is a health or research jus-
12 tification for the retention of such identifiers;

13 (B) an institutional review board has, to
14 the maximum extent practicable, attempted to
15 contact the individual to whom the identifiers
16 relate;

17 (C) upon being contacted pursuant to sub-
18 paragraph (B), the individual does not object to
19 the retention of such identifiers; and

20 (D) there is an adequate plan to protect
21 the identifiers from disclosure consistent with
22 this section.

23 (2) PERIODIC REVIEW AND TECHNICAL ASSIST-
24 ANCE.—

1 (A) INSTITUTIONAL REVIEW BOARD.—Any
2 institutional review board that authorizes re-
3 search under this section shall provide the Sec-
4 retary with the names and addresses of the in-
5 stitutional review board members.

6 (B) TECHNICAL ASSISTANCE.—The Sec-
7 retary shall provide technical assistance to insti-
8 tutional review boards described in this sub-
9 section.

10 (C) MONITORING.—The Secretary shall pe-
11 riodically monitor institutional review boards
12 described in this subsection, including with re-
13 spect to the privacy, security, and confiden-
14 tiality practices of such boards.

15 (D) REPORTS.—Not later than 3 years
16 after the date of enactment of this Act, the Sec-
17 retary shall report to Congress regarding the
18 activities of institutional review boards de-
19 scribed in this subsection.

20 (g) LIMITATION.—Nothing in this section shall be
21 construed to permit personal health information that is
22 received by a researcher under this section to be accessed
23 for purposes other than research or as authorized by the
24 individual that is the subject of such personal health infor-
25 mation.

1 **SEC. 143. HEALTH OVERSIGHT FUNCTIONS.**

2 (a) IN GENERAL.—A health information person may
3 disclose personal health information to a health oversight
4 agency (as defined in section 171(16)) to enable the agen-
5 cy to perform a health oversight function authorized by
6 law, if—

7 (1) the purpose for which the disclosure is to be
8 made cannot reasonably be accomplished without
9 personal health information;

10 (2) the purpose for which the disclosure is to be
11 made is of sufficient importance to warrant the ef-
12 fect on, or the risk to, the privacy of the individuals
13 that additional exposure of the information might
14 bring; and

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

17 (b) USE AND MAINTENANCE OF PERSONAL HEALTH
18 INFORMATION.—A health oversight agency that receives
19 personal health information under subsection (a)—

20 (1) shall, to the maximum extent practicable,
21 obtain the informed consent of the individual to
22 whom the personal health information relates before
23 using or disclosing the information;

24 (2) shall secure personal health information in
25 all work papers and all documents summarizing the
26 health oversight activity through technological, ad-

1 ministrative, and physical safeguards including cryp-
2 tographic-key based encryption;

3 (3) shall maintain in its records only such infor-
4 mation about an individual as is relevant and nec-
5 essary to accomplish the purpose for which the per-
6 sonal health information was obtained;

7 (4) using appropriate encryption measures,
8 shall maintain such information securely and limit
9 access to such information to those persons with a
10 legitimate need for access to carry out the purpose
11 for which the records were obtained; and

12 (5) shall remove or destroy the information that
13 allows subjects of personal health information to be
14 identified at the earliest time at which removal or
15 destruction can be accomplished, consistent with the
16 purpose of the health oversight activity.

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

23 **SEC. 144. INDIVIDUAL REPRESENTATIVES.**

24 (a) **IN GENERAL.**—Except as provided in subsections
25 (b) and (c), a person who is authorized by law (based on

1 grounds other than an individual's status as a minor), or
2 by an instrument recognized under law, to act as an agent,
3 attorney, proxy, or other legal representative of an indi-
4 vidual, may, to the extent so authorized, exercise and dis-
5 charge the rights of the individual under this title.

6 (b) HEALTH CARE POWER OF ATTORNEY.—A person
7 who is authorized by law (based on grounds other than
8 being a minor), or by an instrument recognized under law,
9 to make decisions about the provision of health care to
10 an individual who is incapacitated, may exercise and dis-
11 charge the rights of the individual under this title to the
12 extent necessary to effectuate the terms or purposes of
13 the grant of authority.

14 (c) INDIVIDUALS SUFFERING FROM CERTAIN MED-
15 ICAL CONDITIONS.—If a physician or other health care
16 provider determines that an individual, who has not been
17 declared to be legally incompetent, suffers from a medical
18 condition that prevents the individual from acting know-
19 ingly or effectively on the individual's own behalf, the right
20 of the individual to access or amend the health informa-
21 tion and to authorize disclosure under this title may be
22 exercised and discharged in the best interest of the indi-
23 vidual by—

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

1 (2) a person described in subsection (a) with re-
2 spect to the individual, but only if a person de-
3 scribed in paragraph (1) cannot be contacted after
4 a reasonable effort or if there is no individual who
5 fits the description in paragraph (1);

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

9 (4) the health care provider, but only if a per-
10 son described in paragraph (1), (2), or (3) cannot be
11 contacted after a reasonable effort.

12 (d) RIGHTS OF MINORS.—

13 (1) INDIVIDUALS WHO ARE 18 OR LEGALLY CA-
14 PABLE.—In the case of an individual—

15 (A) who is 18 years of age or older, all
16 rights of the individual under this title shall be
17 exercised by the individual; or

18 (B) who, acting alone, can consent to
19 health care without violating any applicable law,
20 and who has sought such care, the individual
21 shall exercise all rights of an individual under
22 this title with respect to personal health infor-
23 mation relating to such health care.

1 (2) INDIVIDUALS UNDER 18.—Except as pro-
2 vided in paragraph (1)(B), in the case of an indi-
3 vidual who is—

4 (A) under 14 years of age, all of the indi-
5 vidual’s rights under this title shall be exercised
6 through the parent or legal guardian; or

7 (B) 14 through 17 years of age, the rights
8 of inspection, supplementation, and modifica-
9 tion, and the right to authorize use and diselo-
10 sure of personal health information of the indi-
11 vidual shall be exercised by—

12 (i) the individual where no parent or
13 legal guardian exists;

14 (ii) the parent or legal guardian of the
15 individual; or

16 (iii) the individual if the parent or
17 legal guardian determined that the indi-
18 vidual has the sole right the control their
19 health information.

20 (e) DECEASED INDIVIDUALS.—

21 (1) APPLICATION OF ACT.—The provisions of
22 this title shall continue to apply to personal health
23 information concerning a deceased individual.

24 (2) EXERCISE OF RIGHTS ON BEHALF OF A DE-
25 CEASED INDIVIDUAL.—A person who is authorized

1 by law or by an instrument recognized under law, to
2 act as an executor or administrator of the estate of
3 a deceased individual, or otherwise to exercise the
4 rights of the deceased individual, may, to the extent
5 so authorized, exercise and discharge the rights of
6 such deceased individual under this title. If no such
7 designee has been authorized, the rights of the de-
8 ceased individual may be exercised as provided for in
9 subsection (c).

10 (3) IDENTIFICATION OF DECEASED INDI-
11 VIDUAL.—A person described in section 136(a) may
12 disclose personal health information if such dislo-
13 sure is necessary to assist in the identification of a
14 deceased individual.

15 **Subtitle D—Enforcement**

16 **SEC. 151. IN GENERAL.**

17 (a) CIVIL PENALTY.—A health information person
18 who the Secretary, in consultation with the Attorney Gen-
19 eral, determines has substantially and materially failed to
20 comply with this title shall be subject, in addition to any
21 other penalties that may be prescribed by law—

22 (1) in a case in which the violation relates to
23 subtitle A, B, or C, to a civil penalty of not more
24 than \$500 for each such violation, but not to exceed
25 \$5,000 in the aggregate for multiple violations;

1 (2) in a case in which the violation relates to
2 subtitle A, B, or C, to a civil penalty of not more
3 than \$10,000 for each such violation, but not to ex-
4 ceed \$50,000 in the aggregate for multiple viola-
5 tions; or

6 (3) in a case in which such violations have oc-
7 curred with such frequency as to constitute a gen-
8 eral business practice, to a civil penalty of not more
9 than \$100,000.

10 (b) CIVIL ACTION BY INDIVIDUALS.—

11 (1) IN GENERAL.—Any individual whose rights
12 under subtitle A, B, or C have been knowingly or
13 negligently violated may bring a civil action to re-
14 cover—

15 (A) such preliminary and equitable relief
16 as the court determines to be appropriate; and

17 (B) the greater of compensatory damages
18 or liquidated damages of \$5,000.

19 (2) ADDITIONAL REMEDIES.—The equitable re-
20 lief or damages that may be available under this sec-
21 tion shall be in addition to any other lawful remedy
22 or award that may be available.

23 **SEC. 152. ENFORCEMENT BY STATE ATTORNEYS GENERAL.**

24 (a) CIVIL ACTIONS.—In any case in which the attor-
25 ney general of a State or any State or local law enforce-

1 ment agency authorized by the State attorney general or
2 by State law to prosecute violations of consumer protec-
3 tion laws, has reason to believe that an interest of the resi-
4 dents of that State has been or is threatened or adversely
5 affected by the engagement of a person in a practice that
6 is prohibited under subtitle A, B, or C, the State or local
7 law enforcement agency on behalf of the residents of the
8 agency's jurisdiction, may bring a civil action on behalf
9 of the residents of the State or jurisdiction in a district
10 court of the United States of appropriate jurisdiction to—

11 (1) enjoin that act or practice;

12 (2) enforce compliance with the respective sub-
13 title; or

14 (3) obtain civil penalties in an amount cal-
15 culated by multiplying the number of violations by
16 an amount not greater than \$11,000.

17 For purposes of civil penalties under this subsection, each
18 day that a person is in violation of the requirements of
19 subtitle A, B, or C shall be treated as a separate violation,
20 up to a maximum civil penalty of \$5,000,000.

21 (b) RULE OF CONSTRUCTION.—For purposes of
22 bringing any civil action under subsection (a), nothing in
23 this subtitle regarding notification shall be construed to
24 prevent an attorney general of a State from exercising the

1 powers conferred on such attorney general by the laws of
2 that State to—

- 3 (1) conduct investigations;
- 4 (2) administer oaths or affirmations; or
- 5 (3) compel the attendance of witnesses or the
6 production of documentary and other evidence.

7 (c) VENUE; SERVICE OF PROCESS.—

8 (1) VENUE.—Any action brought under sub-
9 section (a) may be brought in the district court of
10 the United States that meets applicable require-
11 ments relating to venue under section 1391 of title
12 28, United States Code.

13 (2) SERVICE OF PROCESS.—In an action
14 brought under subsection (a), process may be served
15 in any district in which the defendant—

16 (A) is an inhabitant; or

17 (B) may be found.

18 **Subtitle E—Miscellaneous**

19 **SEC. 161. OFFICE OF HEALTH INFORMATION PRIVACY.**

20 (a) IN GENERAL.—The Secretary shall designate an
21 office within the Department of Health and Human Serv-
22 ices to be known as the Office of Health Information Pri-
23 vacy (referred to in this section as the “Office”). The Of-
24 fice shall be headed by a Director, who shall be appointed
25 by the Secretary.

1 (b) DUTIES.—The Director of the Office shall—

2 (1) receive and investigate complaints of alleged
3 violations of this title;

4 (2) provide for the conduct of audits where ap-
5 propriate;

6 (3) provide guidance to the Secretary on the
7 implementation of this Act;

8 (4) provide guidance to health care providers
9 and other relevant individuals concerning the man-
10 ner in which to interpret and implement the privacy
11 protections under this title (and the regulations pro-
12 mulgated under this title);

13 (5) prepare and submit the report described in
14 subsection (c);

15 (6) consult with, and provide recommendation
16 to, the Secretary concerning improvements in the
17 privacy and security of personal health information
18 and concerning medical privacy research needs; and

19 (7) carry out any other activities determined
20 appropriate by the Secretary.

21 (c) STANDARDS FOR CERTIFICATION.—

22 (1) ESTABLISHMENT.—Not later than 12
23 months after the date of enactment of this Act, the
24 Secretary, in consultation with the Director of the
25 Office and the Director of the Office of Civil Rights,

1 shall establish and implement standards for health
2 information technology products, including qualified
3 health information technology systems (as defined in
4 section 213), used to access, disclose, maintain,
5 store, distribute, transmit, amend, or dispose of per-
6 sonal health information in a manner that protects
7 the individual's right to privacy, confidentiality, and
8 security relating to that information.

9 (2) STAKEHOLDER PARTICIPATION.—In estab-
10 lishing the standards under paragraph (1), the Sec-
11 retary shall ensure the participation of various
12 stakeholders, including patients and consumer advo-
13 cates, privacy advocates, experts in information tech-
14 nology and information systems, and experts in
15 health care. The Secretary shall ensure that these
16 advocates and experts are equally represented, such
17 that the stakeholder process does not result in the
18 experts in information technology, information sys-
19 tems, and health care being disproportionately rep-
20 resented compared to advocates for the interests of
21 consumers and privacy proponents.

22 (d) REPORT ON COMPLIANCE.—Not later than Janu-
23 ary 1 of the first calendar year beginning more than 1
24 year after the establishment of the Office under subsection
25 (a), and every January 1 thereafter, the Secretary, in con-

1 sultation with the Director of the Office, shall prepare and
2 submit to Congress a report concerning the number of
3 complaints of alleged violations of subtitle A that are re-
4 ceived during the year for which the report is being pre-
5 pared. Such report shall describe the complaints and any
6 remedial action taken concerning such complaints and
7 shall be made available to the public on the Internet
8 website of the Department of Health and Human Services.

9 **SEC. 162. PROTECTION FOR WHISTLEBLOWERS.**

10 (a) PROHIBITION AGAINST DISCRIMINATION.—A
11 health information person may not—

12 (1) discharge, demote, suspend, threaten, har-
13 ass, retaliate against, or in any other manner dis-
14 criminate or cause any employer to discriminate
15 against an employee in the terms and conditions of
16 employment because of—

17 (A) the refusal of the employee to engage
18 in a violation of this title; or

19 (B) any lawful act the employee has com-
20 mitted or is about to commit, or which the
21 health information person perceives the em-
22 ployee to have committed, to provide informa-
23 tion or cause information to be provided, in-
24 cluding in the course of the employee's routine
25 job duties, to the individual's employer or to a

1 State or Federal official relating to an actual or
2 suspected violation of this title by any person,
3 including an employer or an employee of an em-
4 ployer; or

5 (2) adversely affect another person, directly or
6 indirectly, because such person has exercised a right
7 under this title, disclosed information relating to a
8 possible violation of subtitle A, B, or C or this sec-
9 tion, or associated with, or assisted, an individual in
10 the exercise of a right under this title.

11 (b) ENFORCEMENT ACTIONS.—

12 (1) IN GENERAL.—

13 (A) COMPLAINT WITH SECRETARY OF
14 LABOR.—Any employee or former employee who
15 alleges a violation of subsection (a) may seek
16 relief under subsection (c), by filing a complaint
17 with the Secretary of Labor.

18 (B) APPELLATE REVIEW IN CASE OF
19 FINAL ORDER.—Unless an employee brings an
20 action in district court under subparagraph (C),
21 any person adversely affected or aggrieved by a
22 final order of the Secretary of Labor with re-
23 spect to a complaint filed under subparagraph
24 (A) may obtain review of the order in the
25 United States court of appeals for the circuit in

1 which the violation, with respect to which the
2 order was issued, allegedly occurred or the cir-
3 cuit in which the complainant resided on the
4 date of such violation. The petition for review
5 must be filed not later than 60 days after the
6 date of the issuance of the final order. The re-
7 view shall conform to chapter 7 of title 5,
8 United States Code. The commencement of pro-
9 ceedings under this subparagraph shall not, un-
10 less ordered by the court, operate as a stay of
11 the order.

12 (C) DE NOVO REVIEW.—If the Secretary of
13 Labor has not issued a final decision within
14 180 days after the filing of the complaint, or
15 within 90 days after receiving any written de-
16 termination, the complainant may bring an ac-
17 tion at law or equity for de novo review in the
18 appropriate district court of the United States
19 with jurisdiction, which shall have jurisdiction
20 over such an action without regard to the
21 amount in controversy, and which action shall,
22 at the request of either party to such action, be
23 tried by the court with a jury.

24 (2) PROCEDURES.—

1 (A) IN GENERAL.—Except as provided in
2 this paragraph, the complaint procedures con-
3 tained in section 42121(b) of title 49, United
4 States Code, shall apply with respect to a com-
5 plaint filed under paragraph (1)(A).

6 (B) EXCEPTION.—With respect to a com-
7 plaint filed under paragraph (1)(A), the notifi-
8 cation provided for under section 42121(b)(1)
9 of title 49, United States Code, (as required
10 under subparagraph (A)) shall be made to the
11 person named in the complaint and to the em-
12 ployer.

13 (C) BURDEN OF PROOF.—The legal bur-
14 dens of proof contained in section 42121(b) of
15 title 49, United States Code, shall apply to any
16 action brought under this subsection.

17 (D) STATUTE OF LIMITATIONS.—A com-
18 plaint shall be filed under paragraph (1)(A) not
19 later than 2 years after the date on which the
20 alleged violation occurs.

21 (E) CIVIL ACTIONS TO ENFORCE.—If a
22 person fails to comply with an order issued by
23 the Secretary of Labor pursuant to the proce-
24 dures in section 42121(b) of title 49, United
25 States Code, the Secretary shall have the au-

1 thority described in section 42121(b)(5) of title
2 49, United States Code, to bring a civil action
3 to enforce the order in the district court of the
4 United States for the judicial district in which
5 the violation occurred.

6 (c) REMEDIES.—

7 (1) IN GENERAL.—If the Secretary of Labor or
8 the district court determines that a violation of sub-
9 section (a) has occurred, the Secretary or court shall
10 order any relief necessary to make the employee
11 whole.

12 (2) COMPENSATORY DAMAGES.—Relief in any
13 action under such subsection shall include—

14 (A) reinstatement of the employee to the
15 employee's former position with the same se-
16 niority status that the employee would have had
17 but for the discrimination;

18 (B) payment of the amount of back pay,
19 with interest, to which the employee is entitled;
20 and

21 (C) the payment of compensation for any
22 special damages sustained by the employee as a
23 result of the discrimination, including litigation
24 costs, expert witness fees, and reasonable attor-
25 ney fees.

1 (3) PUNITIVE DAMAGES.—Relief in any action
2 under such subsection may include punitive damages
3 in an amount not to exceed \$250,000.

4 (d) RIGHTS RETAINED BY THE EMPLOYEE.—Noth-
5 ing in this section shall be construed to diminish or elimi-
6 nate the rights, privileges, or remedies available to an em-
7 ployee under any Federal or State law, or under any col-
8 lective bargaining agreement.

9 (e) LIMITATION.—The protections of this section
10 shall not apply to any employee who—

11 (1) deliberately causes or participates in the al-
12 leged violation; or

13 (2) knowingly or recklessly provides materially
14 false information to an individual or entity described
15 in subsection (a).

16 (f) DEFINITIONS.—In this section:

17 (1) EMPLOY.—The term “employ” has the
18 meaning given such term under section 3(g) of the
19 Fair Labor Standards Act of 1938 (29 U.S.C.
20 203(g)) for the purposes of implementing the re-
21 quirements of that Act (29 U.S.C. 201, et seq.).

22 (2) EMPLOYEE.—The term “employee” means
23 an individual who is employed by an employer.

24 (3) EMPLOYER.—The term “employer” means
25 any person who employs employees, including any

1 person acting directly or indirectly in the interest of
2 any employer in relation to an employee and in-
3 cludes a public agency.

4 **SEC. 163. DEMONSTRATION GRANT FOR INDIVIDUALS WITH**
5 **LIMITED ENGLISH LANGUAGE PROFICIENCY**
6 **OR LIMITED HEALTH LITERACY.**

7 (a) IN GENERAL.—The Secretary shall award con-
8 tracts or competitive grants to eligible entities to support
9 demonstration projects that are designed to improve the
10 communication of information pertaining to health privacy
11 rights with individuals with limited English language pro-
12 ficiency and limited health literacy.

13 (b) PURPOSE.—It is the purpose of this section, to
14 promote the cultural competency of persons that access,
15 maintain, retain, modify, record, store, destroy, or other-
16 wise use or disclose personal health information, and to
17 enable such persons to better communicate privacy proce-
18 dures to non-English speakers, those with limited English
19 proficiency, and those with limited health literacy.

20 (c) ELIGIBLE ENTITIES.—In this section, the term
21 “eligible entity” means an organization or community-
22 based consortium that includes—

23 (1) individuals who are representatives of orga-
24 nizations serving or advocating for ethnic and racial
25 minorities, low income immigrant populations, and

1 others with limited English language proficiency and
2 limited health literacy;

3 (2) health care providers that provide care for
4 ethnic and racial minorities, low income immigrant
5 populations, and others with limited English lan-
6 guage proficiency and limited health literacy;

7 (3) community leaders and leaders of commu-
8 nity-based organizations; and

9 (4) experts and researchers in the areas of so-
10 cial and behavioral sciences, who have knowledge,
11 training, or practical experience in health policy, ad-
12 vocacy, cultural and linguistic competency, or other
13 relevant areas as determined by the Secretary.

14 (d) APPLICATION.—An eligible entity seeking a con-
15 tract or grant under this section shall submit an applica-
16 tion to the Secretary at such time, in such manner, and
17 containing such information as the Secretary may require.

18 (e) USE OF FUNDS.—An eligible entity shall use
19 amounts received under this section to carry out programs
20 and studies designed to help identify best practices in the
21 communication of privacy rights and procedures to ensure
22 comprehension by individuals with limited English pro-
23 ficiency and limited health literacy.

1 **SEC. 164. RELATIONSHIP TO OTHER LAWS.**

2 (a) FEDERAL AND STATE LAWS.—Nothing in this
3 Act shall be construed as preempting, superseding, or re-
4 pealing, explicitly or implicitly, other Federal or State laws
5 or regulations relating to personal health information or
6 relating to an individual’s access to personal health infor-
7 mation or health care services, if such laws or regulations
8 provide protections for the rights of individuals to the pri-
9 vacy of, and access to, their health information that is
10 greater than those provided for in this Act.

11 (b) PRIVILEGES.—Nothing in this Act shall be con-
12 strued to preempt or modify any provisions of State statu-
13 tory or common law to the extent that such law concerns
14 a privilege of a witness or person in a court of that State.
15 This Act shall not be construed to supersede or modify
16 any provision of Federal statutory or common law to the
17 extent such law concerns a privilege of a witness or entity
18 prior to a court proceeding or in a court of the United
19 States. Informed consent shall not be construed as a waiv-
20 er of any such privilege.

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

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

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

3 (3) regulates the disclosure or reporting of in-
4 formation concerning an individual's mental health;
5 or

6 (4) governs a minor's rights to access personal
7 health information or health care services.

8 (d) HEALTH INSURANCE PORTABILITY AND AC-
9 COUNTABILITY ACT.—The standards governing the pri-
10 vacy and security of individually identifiable health infor-
11 mation promulgated by the Secretary of Health and
12 Human Services under sections 262(a) and 264 of the
13 Health Insurance Portability and Accountability Act of
14 1996 shall remain in effect to the extent that they are
15 consistent with this title. The Secretary shall by rule
16 amend such Federal regulations as required to make such
17 regulations consistent with this title.

18 **SEC. 165. EFFECTIVE DATE.**

19 (a) EFFECTIVE DATE.—Unless specifically provided
20 for otherwise, this title shall take effect on the date that
21 is 12 months after the date of the promulgation of the
22 regulations required under subsection (b), or 30 months
23 after the date of enactment of this Act, whichever is ear-
24 lier.

1 (b) REGULATIONS.—Not later than 12 months after
2 the date of enactment of this Act, or as specifically pro-
3 vided for otherwise, the Secretary shall promulgate regula-
4 tions implementing this title.

5 **Subtitle F—General Definitions**

6 **SEC. 171. GENERAL DEFINITIONS.**

7 In this Act:

8 (1) AGENT.—The term “agent” means a person
9 that represents or acts for another person (a prin-
10 cipal) under a contract or relationship of agency, or
11 that functions to bring about, modify, affect, accept
12 performance of, or terminate, contractual obligations
13 between the principal and a third person. With re-
14 spect to an employer, such term includes the employ-
15 ees of the employer.

16 (2) AUTHORIZATION.—The term “authoriza-
17 tion” means the authority granted by an individual
18 that is the subject of personal health information, in
19 accordance with this title, for the disclosure or use
20 of the individual’s personal health information.

21 (3) BREACH.—The term “breach” means the
22 unauthorized acquisition, disclosure, or loss of per-
23 sonal health information which compromises the se-
24 curity, privacy, or integrity of personal health infor-
25 mation maintained by or on behalf of a person.

1 (4) CONFIDENTIALITY.—The term “confiden-
2 tiality” means the obligations of those who receive
3 information to respect the privacy interests of those
4 to whom the data relate.

5 (5) DE-IDENTIFIED HEALTH INFORMATION.—
6 The term “de-identified health information” means
7 any personal health information, with respect to
8 which—

9 (A) all personal identifiers, or other infor-
10 mation that may be used by itself or in com-
11 bination with other information which may be
12 available to re-identify (as defined in section
13 171(25)) the subject of the information (such
14 as geographic, credit, and financial information
15 and all of the identifiers enumerated at section
16 164.514(b)(2) of title 45 of the Code of Federal
17 Regulations (as in effect on January 1, 2008))
18 have been removed;

19 (B) a good faith effort has been made to
20 evaluate, minimize, and mitigate the risks of re-
21 identification of the subject of such information,
22 using commonly accepted scientific and statis-
23 tical standards and methods for minimizing risk
24 of disclosure; and

1 (C) there is no reasonable basis to believe
2 that the information can be used to identify an
3 individual.

4 (6) DISCLOSE.—The term “disclose” means to
5 release, publish, share, transfer, transmit, dissemi-
6 nate, show, permit access to, communicate (orally or
7 otherwise), re-identify, or otherwise divulge personal
8 health information to any person other than the in-
9 dividual who is the subject of such information.
10 Such term includes the initial disclosure and any
11 subsequent re-disclosure of personal health informa-
12 tion.

13 (7) DECRYPTION KEY.—The term “decryption
14 key” means the variable information used in or pro-
15 duced by a mathematical formula, code, or algo-
16 rithm, or any component thereof, used for
17 encryption (as defined in paragraph (10)) or
18 decryption of wire, electronic, or other communica-
19 tions or stored information.

20 (8) DIRECTOR OF THE OFFICE OF HEALTH IN-
21 FORMATION PRIVACY.—The term “Director of the
22 Office of Health Information Privacy” means such
23 Director as appointed under section 161.

24 (9) EMPLOYER.—Except as otherwise provided
25 in section 164, the term “employer” means a person

1 that is engaged in business affecting commerce and
2 that has employees.

3 (10) ENCRYPTION.—The term “encryption”—

4 (A) means the protection of data in elec-
5 tronic form, in storage or in transit, using an
6 encryption technology that has been adopted by
7 an established standards setting body which
8 renders such data indecipherable in the absence
9 of associated cryptographic keys necessary to
10 enable decryption of such data; and

11 (B) includes appropriate management and
12 safeguards of such cryptographic keys so as to
13 protect the integrity of the encryption.

14 (11) 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 or

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 (12) HEALTH CARE PROVIDER.—The term
8 “health care provider” means a person that, with re-
9 spect to a specific item of personal health informa-
10 tion, receives, accesses, maintains, retains, modifies,
11 records, stores, destroys, or otherwise uses or dis-
12 closes the information while acting in whole or in
13 part in the capacity of—

14 (A) an entity that is, or holds itself out to
15 be, licensed, certified, registered, or otherwise
16 authorized by Federal or State law to provide
17 an item or service that constitutes health care
18 in the ordinary course of business, or practice
19 of a profession;

20 (B) a contractor or other health care pro-
21 vider or facility authorized to provide items or
22 services related to diagnosis or treatment of a
23 health concern, including a hospital, nursing fa-
24 cility, allied health professional, and a facility

1 used or maintained by allied health profes-
2 sionals;

3 (C) a Federal or State program that di-
4 rectly provides items or services that constitute
5 health care to beneficiaries;

6 (D) an officer or employee or agent of a
7 person described in subparagraph (A) or (C)
8 who is engaged in the provision of health care
9 or who uses personal health information; or

10 (E) medical personnel in an emergency sit-
11 uation, including while communicating personal
12 health information by radio transmission or
13 other means.

14 (13) HEALTH INFORMATION PERSON.—The
15 term “health information person” means, in relation
16 to personal health information, a person, including a
17 health care provider, health researcher, health plan,
18 health insurer, health care clearinghouse, health
19 oversight agency, or public health authority, or such
20 person’s agent, officer, employee, or affiliate, that
21 accesses, maintains, retains, modifies, records,
22 stores, or otherwise holds, uses, or discloses such in-
23 formation.

24 (14) HEALTH PLAN.—

1 (A) IN GENERAL.—The term “health plan”
2 means—

3 (i) a group health plan (as defined in
4 section 2791(a)(1) of the Public Health
5 Service Act (42 U.S.C. 300gg–91(a)(1)));

6 (ii) health insurance coverage (as such
7 term is defined in section 2791(b)(1) of
8 the Public Health Service Act (42 U.S.C.
9 300gg–91(b)(1)); or

10 (iii) a safety net health plan (as de-
11 fined in subparagraph (B)).

12 (B) SAFETY NET HEALTH PLAN.—For
13 purposes of subparagraph (A)(iii), the term
14 “safety net health plan” means a managed care
15 organization, as defined in section
16 1932(a)(1)(B)(i) of the Social Security Act—

17 (i) that is exempt from or not subject
18 to Federal income tax, or that is owned by
19 an entity or entities exempt from or not
20 subject to Federal income tax; and

21 (ii) for which not less than 75 percent
22 of the enrolled population receives benefits
23 under a Federal health care program (as
24 defined in section 1128B(f)(1) of the So-
25 cial Security Act) or a health care plan or

1 program which is funded, in whole or in
2 part, by a State (other than a program for
3 government employees).

4 (15) HEALTH OR LIFE INSURER.—The term
5 “health or life insurer” means a health insurance
6 issuer (as defined in section 9805(b)(2) of the Inter-
7 nal Revenue Code of 1986) or a life insurance com-
8 pany (as defined in section 816 of such Code) and
9 includes the employees and agents of such a person.

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

12 (A) means a person that—

13 (i) performs or oversees the perform-
14 ance of an assessment, investigation, or
15 prosecution relating to compliance with
16 legal or fiscal standards relating to health
17 care fraud or fraudulent claims regarding
18 health care, health services or equipment,
19 related activities and items, or the effec-
20 tiveness of health privacy and security
21 measures; and

22 (ii) is a public executive branch agen-
23 cy, acting on behalf of a public executive
24 branch agency, acting pursuant to a re-
25 quirement of a public executive branch

1 agency, or carrying out activities under a
2 Federal or State law governing an assess-
3 ment, evaluation, determination, investiga-
4 tion, or prosecution described in clause (i);
5 and

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

8 (17) HEALTH RECORD SET.—The term “health
9 record set” means any item, collection, or grouping
10 of information that includes personal health infor-
11 mation, such as a medical record, electronic health
12 record, electronic medical record, personal health
13 record, or account of disclosure, use or access, that
14 is created, accessed, received, maintained, retained,
15 modified, recorded, stored, destroyed, or otherwise
16 used or disclosed by a health care provider, em-
17 ployer, insurer, health plan, health researcher, data
18 partner, or other person that relates to the health or
19 illness of the body, mind, or genome of an indi-
20 vidual.

21 (18) HEALTH RESEARCHER.—The term “health
22 researcher” means a person that is engaged in ac-
23 tivities conducted for the purpose of advancing pub-
24 lic knowledge and, with respect to a specific item of

1 personal health information, receives the informa-
2 tion—

3 (A) pursuant to section 142 (relating to
4 health research); or

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

9 (19) INFORMED CONSENT.—

10 (A) IN GENERAL.—Subject to subpara-
11 graph (B), the term “informed consent” means
12 the written authorization for use or disclosure
13 of personal health information by the individual
14 who is the subject of such information, condi-
15 tioned upon—

16 (i) that individual’s having been in-
17 formed of the nature and probability of
18 harm to the individual resulting from such
19 authorization; and

20 (ii) the authorization meeting the re-
21 quirements of section 122(b).

22 (B) THROUGH INFERENCE.—Informed
23 consent may be inferred, in the absence of a
24 contrary indication by the individual—

1 (i) to the extent necessary to provide
2 treatment and obtain payment for health
3 care in emergency situations;

4 (ii) to the extent necessary to provide
5 treatment and payment where a health
6 care provider is required by law to treat
7 the individual;

8 (iii) if the health care provider is un-
9 able to obtain informed consent due to
10 substantial barriers to communicating with
11 the individual and the provider reasonably
12 infers from the circumstances, based upon
13 the exercise of professional judgment, that
14 the individual does not object to the disclo-
15 sure or the disclosure is in the best inter-
16 est of the individual; and

17 (iv) to the extent the information is
18 necessary to carry out or otherwise imple-
19 ment a medical or mental health practi-
20 tioner's order or prescription for health
21 services, medical devices or supplies, or
22 pharmaceuticals.

23 (C) MULTIPLE USES AND DISCLOSURES.—
24 Informed consent may authorize multiple uses
25 or disclosures.

1 (20) OFFICE OF HEALTH INFORMATION PRI-
2 VACY.—The term “Office of Health Information Pri-
3 vacy” means the Office of Health Information Pri-
4 vacy designated under section 161.

5 (21) PERSON.—The term “person” means an
6 entity that is a government, governmental subdivi-
7 sion of an executive branch agency or authority, cor-
8 poration, company, association, firm, partnership,
9 society, estate, trust, joint venture, individual, indi-
10 vidual representative, tribal government, or any
11 other legal entity. Such term also includes the em-
12 ployees, contractors, agents, and affiliates of all legal
13 entities described in the preceding sentence, whether
14 or not they are acting in the capacity of their em-
15 ployment, contract, agency, or affiliation.

16 (22) PRIVACY.—The term “privacy” means an
17 individual’s right to control the acquisition, uses, or
18 disclosures of his or her identifiable health data.

19 (23) PERSONAL HEALTH INFORMATION.—

20 (A) IN GENERAL.—The term “personal
21 health information” means any information, in-
22 cluding genetic information, biometric informa-
23 tion, demographic information, and tissue sam-
24 ples collected from an individual, whether oral
25 or recorded in any form or medium, that—

1 (i) is created or received by a health
2 care provider, health researcher, health
3 plan, health or life insurer, medical or
4 health savings plan administrator, health
5 care clearinghouse, health oversight agen-
6 cy, public health authority, employer, data
7 partner, or other person or such person's
8 agent, officer, or employee; and

9 (ii)(I) relates to the past, present, or
10 future physical or mental health or condi-
11 tion of an individual (including individual
12 cells and their components), the provision
13 of health care to an individual, or the past,
14 present, or future payment for the provi-
15 sion of health care to an individual; and

16 (II)(aa) identifies an individual; or

17 (bb) with respect to which there is a
18 reasonable basis to believe that the infor-
19 mation can be used to identify an indi-
20 vidual.

21 (B) INCLUSION OF DECRYPTION KEY.—

22 The term “personal health information” in-
23 cludes any decryption key used for the
24 encryption or decryption of information de-
25 scribed in subparagraph (A).

1 (24) PUBLIC HEALTH AUTHORITY.—The term
2 “public health authority” means an authority or in-
3 strumentality of the United States, a tribal govern-
4 ment, a State, or a political subdivision of a State
5 that is—

6 (A) primarily responsible for public health
7 matters; and

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

11 (25) RE-IDENTIFY.—The term “re-identify”,
12 when used with respect to de-identified health infor-
13 mation, means an attempt, successful or otherwise,
14 to ascertain—

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

17 (B) the decryption key with respect to the
18 information (when undertaken with knowledge
19 that such key would allow for the identification
20 of the individual who is the subject of such in-
21 formation).

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

24 (27) SECURITY.—The term “security” means
25 physical, technological, or administrative safeguards

1 or tools used to protect identifiable health data from
2 unwarranted access or disclosure.

3 (28) SECURITY BREACH.—The term “security
4 breach” means the physical, structural, or sub-
5 stantive compromise of the security of personal
6 health information, through unauthorized disclosure,
7 use, or access, whether actual or attempted, result-
8 ing in the acquisition, access, or use of such infor-
9 mation by an unauthorized person. Such term does
10 not apply to good faith or accidental acquisition, or
11 disclosure of personal health information by an un-
12 authorized person, so long as no further use or dis-
13 closure is made by such person.

14 (29) SEGREGATE.—The term “segregate”
15 means to hide, mask, or mark separate a designated
16 subset of an individual’s personal health informa-
17 tion, or to place such a subset in a location that is
18 securely separated from the location used to store
19 other personal health information, such that access
20 to or use of any information so segregated may be
21 effectively limited to those persons that are author-
22 ized by the individual to access or use that seg-
23 regated information.

24 (30) SIGNED.—The term “signed” refers both
25 to signatures in ink and to electronic signatures that

1 are authenticated by the individual using an authen-
2 tication method approved by the Secretary.

3 (31) STATE.—The term “State” means each of
4 the several States, the District of Columbia, Puerto
5 Rico, the Virgin Islands, Guam, American Samoa,
6 and the Northern Mariana Islands.

7 (32) TO THE MAXIMUM EXTENT PRAC-
8 TICABLE.—The term “to the maximum extent prac-
9 ticable” means the level of compliance that a reason-
10 able person would deem technologically feasible so
11 long as such feasibility is periodically evaluated in
12 light of scientific advances.

13 (33) USE.—The term “use” means to create,
14 record, collect, access, obtain, store, maintain,
15 amend, correct, restore, modify, supplement, iden-
16 tify, re-identify, employ, apply, utilize, examine, ana-
17 lyze, detect, remove, destroy, dispose of, account for,
18 or monitor the flow of personal health information.

19 (34) WRITING; WRITTEN.—The terms “writing”
20 and “written” mean writing or written, respectively,
21 in either a paper-based or computer-based form, in-
22 cluding electronic and digital signatures.

1 **TITLE II—PROMOTION OF**
2 **HEALTH INFORMATION TECH-**
3 **NOLOGY**

4 **Subtitle A—Improving the Inter-**
5 **operability of Health Informa-**
6 **tion Technology**

7 **SEC. 201. OFFICE OF THE NATIONAL COORDINATOR OF**
8 **HEALTH INFORMATION TECHNOLOGY.**

9 (a) **ESTABLISHMENT.**—There is established within
10 the office of the Secretary, the Office of the National Co-
11 ordinator of Health Information Technology. The Na-
12 tional Coordinator shall be appointed by the Secretary in
13 consultation with the President, and shall report directly
14 to the Secretary.

15 (b) **PURPOSE.**—The Office of the National Coordi-
16 nator shall be responsible for—

17 (1) ensuring that key health information tech-
18 nology initiatives are coordinated across programs of
19 the Department of Health and Human Services;

20 (2) ensuring that health information technology
21 policies and programs of the Department of Health
22 and Human Services are coordinated with such poli-
23 cies and programs of other relevant Federal agencies
24 (including Federal commissions and advisory com-
25 mittees) with a goal of avoiding duplication of ef-

1 forts and of helping to ensure that each agency un-
2 dertakes activities primarily within the areas of its
3 greatest expertise and technical capability;

4 (3) reviewing Federal health information tech-
5 nology investments to ensure that Federal health in-
6 formation technology programs are meeting the ob-
7 jectives of the strategic plan published by the Office
8 of the National Coordinator of Health Information
9 Technology to establish a nationwide interoperable
10 health information technology infrastructure;

11 (4) providing comments and advice regarding
12 specific Federal health information technology pro-
13 grams, at the request of Office of Management and
14 Budget;

15 (5) enhancing the use of health information
16 technology to improve the quality of health care in
17 the prevention and management of chronic disease
18 and to address population health; and

19 (6) consulting with the Office of Health Infor-
20 mation Privacy to ensure that key health informa-
21 tion technology initiatives of the Department of
22 Health and Human Services and other Federal
23 agencies are consistent with the privacy, confiden-
24 tiality, and security requirements in title I.

1 (c) ROLE WITH AMERICAN HEALTH INFORMATION
2 COMMUNITY AND THE PARTNERSHIP FOR HEALTH CARE
3 IMPROVEMENT.—The Office of the National Coordinator
4 shall—

5 (1) serve as an ex officio member of the Amer-
6 ican Health Information Community established
7 under section 203, and act as a liaison between the
8 Federal Government and the Community;

9 (2) serve as an ex officio member of the Part-
10 nership and act as a liaison between the Federal
11 Government and the Partnership for Health Care
12 Improvement (established under section 202); and

13 (3) serve as a liaison between the Partnership
14 and the Community.

15 (d) REPORTS AND WEBSITE.—The Office of the Na-
16 tional Coordinator shall—

17 (1) develop and publish a strategic plan for im-
18 plementing a nationwide interoperable health infor-
19 mation technology infrastructure;

20 (2) maintain and frequently update an Internet
21 website that—

22 (A) publishes the schedule for the assess-
23 ment of standards for significant use cases;

24 (B) publishes the recommendations of the
25 American Health Information Community;

1 (C) publishes the recommendations of the
2 Partnership for Health Care Improvement;

3 (D) publishes quality measures;

4 (E) identifies sources of funds that will be
5 made available to facilitate the purchase of, or
6 enhance the utilization of, health information
7 technology systems, either through grants or
8 technical assistance; and

9 (F) publishes a plan for a transition of any
10 functions of the Office of the National Coordi-
11 nator that should be continued after September
12 30, 2014;

13 (3) prepare a report on the lessons learned
14 from major public and private health care systems
15 that have implemented health information tech-
16 nology systems, including an explanation of whether
17 the systems and practices developed by such systems
18 may be applicable to and usable in whole or in part
19 by other health care providers; and

20 (4) assess the impact of health information
21 technology in communities with health disparities
22 and identify practices to increase the adoption of
23 such technology by health care providers in such
24 communities.

1 (e) RULE OF CONSTRUCTION.—Nothing in this sec-
2 tion shall be construed as requiring the duplication of Fed-
3 eral efforts with respect to the establishment of the Office
4 of the National Coordinator of Health Information Tech-
5 nology, regardless of whether such efforts are carried out
6 before or after the date of the enactment of this title.

7 (f) AUTHORIZATION OF APPROPRIATIONS.—There is
8 authorized to be appropriated to carry out this section,
9 \$5,000,000 for each of fiscal years 2009 and 2010.

10 (g) SUNSET.—The provisions of this section shall not
11 apply after September 30, 2014.

12 **SEC. 202. PARTNERSHIP FOR HEALTH CARE IMPROVE-**
13 **MENT.**

14 (a) ESTABLISHMENT.—

15 (1) IN GENERAL.—There is established a pub-
16 lic-private Partnership for Health Care Improvement
17 (in this title referred to as the “Partnership”) to—

18 (A) provide advice to the Secretary and the
19 Nation and recommend specific actions to
20 achieve a nationwide interoperable health infor-
21 mation technology infrastructure;

22 (B) make recommendations concerning
23 standards, including privacy, security, and con-
24 fidentiality standards, implementation specifica-
25 tions, and certification criteria for the electronic

1 exchange of personal health information (in-
2 cluding for the reporting of quality data under
3 section 221) for adoption by the Federal Gov-
4 ernment and voluntary adoption by private enti-
5 ties that are consistent with the requirements of
6 title I;

7 (C) serve as a forum for the participation
8 of a broad range of stakeholders with specific
9 technical expertise in the development of stand-
10 ards, implementation specifications, and certifi-
11 cation criteria and protection of privacy and
12 data security to provide input on the effective
13 implementation of health information tech-
14 nology systems; and

15 (D) develop and maintain an Internet
16 website that—

17 (i) publishes established governance
18 rules (including a subsequent appointment
19 process);

20 (ii) publishes a business plan;

21 (iii) publishes meeting notices at least
22 14 days prior to each meeting;

23 (iv) publishes meeting agendas at
24 least 7 days prior to each meeting; and

1 (v) publishes meeting materials at
2 least 3 days prior to each meeting.

3 (2) LIMITATION.—The Partnership shall not
4 meet or take any action until an advisory committee
5 charter has been filed with the Secretary and with
6 the appropriate committees of the Senate and House
7 of Representatives for the American Health Infor-
8 mation Community described in section 203.

9 (b) MEMBERSHIP.—

10 (1) MEMBERS.—The members of the Partner-
11 ship shall consist of the following:

12 (A) APPOINTED MEMBERS.—The ap-
13 pointed members of the Partnership shall be
14 appointed as follows:

15 (i) 2 members shall be appointed by
16 the Secretary.

17 (ii) 1 member shall be appointed by
18 the majority leader of the Senate.

19 (iii) 1 member shall be appointed by
20 the minority leader of the Senate.

21 (iv) 1 member shall be appointed by
22 the Speaker of the House of Representa-
23 tives.

1 (v) 1 member shall be appointed by
2 the minority leader of the House of Rep-
3 resentatives.

4 (vi) Seven members shall be appointed
5 by the Comptroller General of whom—

6 (I) one member shall be a rep-
7 resentative of consumer or patient or-
8 ganizations;

9 (II) one member shall be a rep-
10 resentative of organizations with ex-
11 pertise in the protection of privacy;

12 (III) one member shall be a rep-
13 resentative of organizations with ex-
14 pertise in security;

15 (IV) one member shall be a rep-
16 resentative of health care providers;

17 (V) one member shall be a rep-
18 resentative of health plans or other
19 third party payers;

20 (VI) one member shall be a rep-
21 resentative of information technology
22 vendors; and

23 (VII) one member shall be a rep-
24 resentative of purchasers or employ-
25 ers.

1 (B) NATIONAL COORDINATOR.—The Na-
2 tional Coordinator shall be a member of the
3 Partnership and act as a liaison among the
4 Partnership, the community, and the Federal
5 Government.

6 (2) CHAIRPERSON AND VICE CHAIRPERSON.—
7 The Partnership shall designate one member to
8 serve as the chairperson and one member to serve as
9 the vice chairperson of the Partnership.

10 (3) PARTICIPATION.—Members shall be ap-
11 pointed under paragraph (1)(A), and the Partner-
12 ship shall develop procedures for conducting its ac-
13 tivities, so as to ensure a balance among various sec-
14 tors of the health care system so that no single sec-
15 tor unduly influences the recommendations of the
16 Partnership.

17 (4) TERMS.—Members appointed under para-
18 graph (1)(A) shall serve for 3 year terms, except
19 that any member appointed to fill a vacancy for an
20 unexpired term shall be appointed for the remainder
21 of such term. A member may serve for not to exceed
22 180 days after the expiration of such member's term
23 or until a successor has been appointed.

24 (5) OUTSIDE INVOLVEMENT.—The Partnership
25 shall ensure an adequate opportunity for the partici-

1 pation of outside advisors, including individuals with
2 expertise in—

3 (A) the protection of personal health infor-
4 mation privacy;

5 (B) personal health information security;

6 (C) health care quality and patient safety,
7 including individuals with expertise in utilizing
8 health information technology to improve health
9 care quality and patient safety;

10 (D) medical and clinical research data ex-
11 change; and

12 (E) developing health information tech-
13 nology standards and new health information
14 technology.

15 (6) QUORUM.—Two-thirds of the members of
16 the Partnership shall constitute a quorum for the
17 purpose of conducting votes.

18 (c) STANDARDS AND IMPLEMENTATION SPECIFICA-
19 TIONS.—

20 (1) SCHEDULE.—Not later than 90 days after
21 the date of enactment of this title, the Partnership
22 shall develop a schedule for the assessment of stand-
23 ards and implementation specifications under this
24 section. The Partnership shall update such schedule
25 annually. The Secretary shall publish such schedule

1 in the Federal Register and on the Internet website
2 of the Department of Health and Human Services.

3 (2) FIRST YEAR RECOMMENDATIONS.—Con-
4 sistent with the schedule published under paragraph
5 (1) and not later than 1 year after date of enact-
6 ment of this title, the Partnership shall recommend,
7 and the Secretary shall review, such standards and
8 implementation specifications.

9 (3) ONGOING RECOMMENDATIONS.—The Part-
10 nership shall review and modify, as appropriate but
11 at least annually, adopted standards and implemen-
12 tation specifications and continue to recommend ad-
13 ditional standards and implementation specifications,
14 consistent with the schedule published pursuant to
15 paragraph (1). The Secretary shall review such
16 modifications and recommendations.

17 (4) RECOGNITION OF PRIVATE ENTITIES.—The
18 Partnership, in consultation with the Secretary, may
19 recognize a private entity or entities for the purpose
20 of developing and updating standards and implemen-
21 tation specifications to achieve uniform and con-
22 sistent implementation of the standards adopted by
23 the President under this title. Such entity or entities
24 shall make recommendations to the Partnership con-
25 sistent with this section.

1 (5) PUBLICATION.—All recommendations made
2 by the Partnership pursuant to this section shall be
3 published in the Federal Register and on the Inter-
4 net website of the Office of the National Coordi-
5 nator.

6 (6) REQUIREMENT FOR CERTAIN REC-
7 COMMENDATIONS.—The Partnership may not issue
8 any recommendation that affects an individual’s
9 right to health information privacy unless such rec-
10 ommendation receives the affirmative support of the
11 consumer or patient organization representative of
12 the Partnership appointed under subsection
13 (b)(1)(A)(vi)(I).

14 (7) PILOT TESTING.—The Secretary may con-
15 duct, or recognize a private entity or entities to con-
16 duct, a pilot project to test the standards and imple-
17 mentation specifications developed under this section
18 in order to provide for the efficient implementation
19 of the standards and implementation specifications
20 described in this subsection prior to issuing such
21 recommendations.

22 (8) PUBLIC INPUT.—The Partnership shall con-
23 duct open public meetings and develop a process to
24 allow for public comment on the schedule and rec-
25 ommendations described in this section. Such proc-

1 ess shall ensure that such comments will be sub-
2 mitted within 30 days of the publication of a rec-
3 ommendation under this section.

4 (9) FEDERAL ACTION.—Not later than 90 days
5 after the issuance of a recommendation from the
6 Partnership under this subsection, the Secretary, in
7 collaboration with representatives of other relevant
8 Federal agencies as determined appropriate by the
9 President, shall jointly review such recommendation.
10 If appropriate, the President shall provide for the
11 adoption by the Federal Government of any stand-
12 ard or implementation specification contained in
13 such recommendation only after providing an oppor-
14 tunity for public comment in accordance with section
15 553 of title 5, United States Code. Such determina-
16 tion shall be published in the Federal Register and
17 on the Internet website of the Office of the National
18 Coordinator within 30 days after such determination
19 is made.

20 (10) CONSISTENCY.—The standards and imple-
21 mentation specifications described in this subsection
22 shall be consistent with the privacy protections in
23 title I and the standards for information trans-
24 actions and data elements developed pursuant to the
25 regulations promulgated under section 264(c) of the

1 Health Insurance Portability and Accountability Act
2 of 1996.

3 (d) CERTIFICATION.—

4 (1) DEVELOPING CRITERIA.—The Partnership,
5 in consultation with the Secretary, may recognize a
6 private entity or entities for the purpose of devel-
7 oping and recommending to the Partnership criteria
8 to certify that appropriate categories of health infor-
9 mation technology products that claim to be in com-
10 pliance with applicable standards and implementa-
11 tion specifications adopted under this title have es-
12 tablished such compliance.

13 (2) ADOPTION OF CRITERIA.—The Secretary,
14 based upon the recommendations of the Partnership,
15 shall review, and if appropriate, adopt such criteria.

16 (3) CONDUCTING CERTIFICATION.—The Sec-
17 retary may recognize a private entity or entities to
18 conduct the certifications described under paragraph
19 (1) using the criteria adopted by the Secretary
20 under this subsection.

21 (e) RULE OF CONSTRUCTION.—Nothing in this sec-
22 tion shall be construed as disrupting existing activities de-
23 scribed in subsection (c) or (d).

24 (f) REQUIREMENT TO CONSIDER RECOMMENDA-
25 TIONS.—In carrying out the activities described in sub-

1 sections (c) and (d), the Partnership shall adopt and inte-
2 grate the recommendations of the American Health Infor-
3 mation Community that are adopted by the Secretary.

4 (g) AUTHORIZATION OF APPROPRIATIONS.—There
5 are authorized to be appropriated to carry out this section,
6 \$2,000,000 for each of the fiscal years 2009 and 2010.

7 **SEC. 203. AMERICAN HEALTH INFORMATION COMMUNITY**
8 **POLICIES.**

9 (a) ESTABLISHMENT.—There is established a com-
10 mittee to be known as the American Health Information
11 Community (in this section referred to as the “Commu-
12 nity”). The Community shall—

13 (1) provide advice to the Secretary and the
14 heads of any relevant Federal agencies concerning
15 the policy considerations related to health informa-
16 tion technology;

17 (2) not later than 1 year after the date of en-
18 actment of this title, and annually thereafter, make
19 recommendations concerning a policy framework for
20 the development and adoption of a nationwide inter-
21 operable health information technology infrastruc-
22 ture;

23 (3) not later than 1 year after the date of en-
24 actment of this title, and annually thereafter, make
25 recommendation concerning national policies for

1 adoption by the Federal Government, and voluntary
2 adoption by private entities, to support the wide-
3 spread adoption of health information technology,
4 including—

5 (A) the protection of personal health infor-
6 mation, including policies concerning the indi-
7 vidual's ability to control the acquisition, uses,
8 and disclosures of personal health information;

9 (B) methods to protect personal health in-
10 formation from improper use and disclosures
11 and methods to notify patients if their personal
12 health information is wrongfully disclosed;

13 (C) methods to facilitate and secure access
14 to such individual's personal health information;

15 (D) the appropriate uses of a nationwide
16 personal health information infrastructure in-
17 cluding—

18 (i) the collection of quality data and
19 public reporting;

20 (ii) biosurveillance and public health;

21 (iii) medical and clinical research; and

22 (iv) drug safety;

23 (E) fostering the public understanding of
24 health information technology;

1 (F) strategies to enhance the use of health
2 information technology in preventing and man-
3 aging chronic disease;

4 (G) policies to incorporate the input of em-
5 ployees of health care providers in the design
6 and implementation of health information tech-
7 nology systems; and

8 (H) other policies determined to be nec-
9 essary by the Community; and

10 (4) serve as a forum for the participation of a
11 broad range of stakeholders to provide input on im-
12 proving the effective implementation of health infor-
13 mation technology systems.

14 The Community may not make any recommendation that
15 affects an individual's right to health information privacy
16 unless the recommendation receives the affirmative sup-
17 port of the consumer or patient organization representa-
18 tive appointed under subsection (c)(1)(A)(viii)(I).

19 (b) PUBLICATION.—All recommendations made by
20 the Community pursuant to this section shall be published
21 in the Federal Register and on the Internet website of the
22 National Coordinator. The Secretary shall review all rec-
23 ommendations and determine which recommendations
24 shall be endorsed by the Federal Government and such
25 determination shall be published on the Internet website

1 of the Office of the National Coordinator after an oppor-
2 tunity for public comment in accordance with section 553
3 of title 5, United States Code.

4 (c) MEMBERSHIP.—

5 (1) MEMBERS.—The members of the Commu-
6 nity shall consist of the following:

7 (A) APPOINTED MEMBERS.—The ap-
8 pointed members of the Community shall be ap-
9 pointed as follows:

10 (i) 3 members shall be appointed by
11 the Secretary, 1 of whom shall be a rep-
12 resentative from the Department of Health
13 and Human Services.

14 (ii) 1 member shall be appointed by
15 the Secretary of Veterans Affairs who shall
16 represent the Department of Veterans Af-
17 fairs.

18 (iii) 1 member shall be appointed by
19 the Secretary of Defense who shall rep-
20 resent the Department of Defense.

21 (iv) 1 member shall be appointed by
22 the majority leader of the Senate.

23 (v) 1 member shall be appointed by
24 the minority leader of the Senate.

1 (vi) 1 member shall be appointed by
2 the Speaker of the House of Representa-
3 tives.

4 (vii) 1 member shall be appointed by
5 the minority leader of the House of Rep-
6 resentatives.

7 (viii) Nine members shall be ap-
8 pointed by the Comptroller General of
9 whom—

10 (I) one member shall be advo-
11 cates for patients or consumers;

12 (II) one member shall represent
13 health care providers;

14 (III) one member shall be from a
15 labor organization representing health
16 care workers;

17 (IV) one member shall have ex-
18 pertise in the protection of privacy
19 and data security;

20 (V) one member shall have exper-
21 tise in improving the health of vulner-
22 able populations;

23 (VI) one member shall represent
24 health plans or other third party pay-
25 ers;

1 (VII) one member shall represent
2 information technology vendors;

3 (VIII) one member shall rep-
4 resent purchasers or employers; and

5 (IX) one member shall have ex-
6 pertise in health care quality measure-
7 ment and reporting.

8 (B) NATIONAL COORDINATOR.—The Na-
9 tional Coordinator shall be a member of the
10 Community and act as a liaison among the
11 Community, the partnership, and the Federal
12 Government.

13 (2) CHAIRPERSON AND VICE CHAIRPERSON.—
14 The Community shall designate one member to serve
15 as the chairperson and one member to serve as the
16 vice chairperson of the Community.

17 (3) PARTICIPATION.—The members of the
18 Community appointed under paragraph (1) shall
19 represent a balance among various sectors of the
20 health care system so that no single sector unduly
21 influences the recommendations of the Community.

22 (4) TERMS.—

23 (A) IN GENERAL.—The terms of members
24 of the Community shall be for 3 years except
25 that the Comptroller General shall designate

1 staggered terms for the members first ap-
2 pointed.

3 (B) VACANCIES.—Any member appointed
4 to fill a vacancy in the membership of the Com-
5 munity that occurs prior to the expiration of
6 the term for which the member’s predecessor
7 was appointed shall be appointed only for the
8 remainder of that term. A member may serve
9 after the expiration of that member’s term until
10 a successor has been appointed. A vacancy in
11 the Community shall be filled in the manner in
12 which the original appointment was made.

13 (5) OUTSIDE INVOLVEMENT.—The Community
14 shall ensure an adequate opportunity for the partici-
15 pation of outside advisors, including individuals with
16 expertise in—

17 (A) the protection of health information
18 privacy and security;

19 (B) improving the health of vulnerable
20 populations;

21 (C) health care quality and patient safety,
22 including individuals with expertise in measure-
23 ment and the use of health information tech-
24 nology to capture data to improve health care
25 quality and patient safety;

1 (D) ethics, including the ethical standards
2 of professional medical and mental health prac-
3 titioner associations;

4 (E) medical and clinical research data ex-
5 change;

6 (F) developing health information tech-
7 nology standards and new health information
8 technology; and

9 (G) the operation of a State or local health
10 information network.

11 (6) QUORUM.—Ten members of the Community
12 shall constitute a quorum for purposes of voting, but
13 a lesser number of members may meet and hold
14 hearings.

15 (d) FEDERAL AGENCIES.—

16 (1) STAFF OF OTHER FEDERAL AGENCIES.—
17 Upon the request of the Community, the head of any
18 Federal agency may detail, without reimbursement,
19 any of the personnel of such agency to the Commu-
20 nity to assist in carrying out the duties of the Com-
21 munity. Any such detail shall not interrupt or other-
22 wise affect the civil service status or privileges of the
23 Federal employee involved.

24 (2) TECHNICAL ASSISTANCE.—Upon the re-
25 quest of the Community, the head of a Federal

1 agency shall provide such technical assistance to the
2 Community as the Community determines to be nec-
3 essary to carry out its duties.

4 (3) OTHER RESOURCES.—The Community shall
5 have reasonable access to materials, resources, sta-
6 tistical data, and other information from the Library
7 of Congress and agencies and elected representatives
8 of the executive and legislative branches of the Fed-
9 eral Government. The chairperson or vice chair-
10 person of the Community shall make requests for
11 such access in writing when necessary.

12 (e) APPLICATION OF FACCA.—The Federal Advisory
13 Committee Act (5 U.S.C. App.) shall apply to the Commu-
14 nity, except that the term provided for under section
15 14(a)(2) of such Act shall be not longer than 7 years.

16 (f) SUNSET.—The provisions of this section shall not
17 apply after September 20, 2014.

18 (g) AUTHORIZATION OF APPROPRIATIONS.—There is
19 authorized to be appropriated to carry out this section,
20 \$2,000,000 for each of fiscal years 2009 and 2010.

21 **SEC. 204. RESEARCH ACCESS TO HEALTH CARE DATA AND**
22 **REPORTING ON PERFORMANCE.**

23 The Secretary shall permit researchers that meet cri-
24 teria used to evaluate the appropriateness of the release

1 data for research purpose (as established by the Sec-
2 retary) to—

3 (1) have access to all Federal health care data;

4 and

5 (2) report on the performance of health care
6 providers and suppliers, including reporting in a
7 provider- or supplier-identifiable format.

8 **Subtitle B—Facilitating the Wide-**
9 **spread Adoption of Interoper-**
10 **able Health Information Tech-**
11 **nology**

12 **SEC. 211. FACILITATING THE WIDESPREAD ADOPTION OF**
13 **INTEROPERABLE HEALTH INFORMATION**
14 **TECHNOLOGY.**

15 (a) **COMPETITIVE GRANTS FOR ADOPTION OF TECH-**
16 **NOLOGY.—**

17 (1) **IN GENERAL.—**The Secretary may award
18 competitive grants to eligible entities to facilitate the
19 purchase and enhance the utilization of qualified
20 health information technology systems (as defined in
21 section 213) to improve the quality and efficiency of
22 health care.

23 (2) **ELIGIBILITY.—**To be eligible to receive a
24 grant under paragraph (1) an entity shall—

1 (A) submit to the Secretary an application
2 at such time, in such manner, and containing
3 such information as the Secretary may require;

4 (B) submit to the Secretary a strategic
5 plan for the implementation of data sharing
6 and interoperability measures;

7 (C) adopt the standards adopted by the
8 Federal Government under section 301;

9 (D) implement the measures adopted
10 under section 221 and report to the Secretary
11 on such measures;

12 (E) comply with the requirements of title
13 I;

14 (F) take into account the input of employ-
15 ees and staff who are directly involved in pa-
16 tient care of such health care providers in the
17 design, implementation, and use of qualified
18 health information technology systems;

19 (G) demonstrate significant financial need;

20 (H) provide matching funds in accordance
21 with paragraph (4); and

22 (I) be a—

23 (i) public or not for profit hospital;

1 (ii) federally qualified health center
2 (as defined in section 1861(aa)(4) of the
3 Social Security Act);

4 (iii) individual or group practice (or a
5 consortium thereof); or

6 (iv) another health care provider not
7 described in clause (i) or (ii);

8 that serves medically underserved communities.

9 (3) USE OF FUNDS.—Amounts received under a
10 grant under this subsection shall be used to—

11 (A) facilitate the purchase of qualified
12 health information technology systems;

13 (B) train personnel in the use of such sys-
14 tems;

15 (C) enhance the utilization of qualified
16 health information technology systems (which
17 may include activities to increase the awareness
18 among consumers of health care privacy protec-
19 tions); or

20 (D) improve the prevention and manage-
21 ment of chronic disease.

22 (4) MATCHING REQUIREMENT.—To be eligible
23 for a grant under this subsection an entity shall con-
24 tribute non-Federal contributions to the costs of car-
25 rying out the activities for which the grant is award-

1 ed in an amount equal to \$1 for each \$3 of Federal
2 funds provided under the grant.

3 (5) PREFERENCE IN AWARDING GRANTS.—In
4 awarding grants under this subsection the Secretary
5 shall give preference to—

6 (A) eligible entities that will improve the
7 degree to which such entity will link the quali-
8 fied health information technology system to
9 local or regional health information plan or
10 plans; and

11 (B) with respect to awards made for the
12 purpose of providing care in an outpatient med-
13 ical setting, entities that organize their prac-
14 tices as a patient-centered medical home.

15 (b) COMPETITIVE GRANTS FOR THE DEVELOPMENT
16 OF STATE LOAN PROGRAMS TO FACILITATE THE WIDE-
17 SPREAD ADOPTION OF HEALTH INFORMATION TECH-
18 NOLOGY.—

19 (1) IN GENERAL.—The Secretary may award
20 competitive grants to States for the establishment of
21 State programs for loans to health care providers to
22 facilitate the purchase and enhance the utilization of
23 qualified health information technology.

24 (2) ESTABLISHMENT OF FUND.—To be eligible
25 to receive a competitive grant under this subsection,

1 a State shall establish a qualified health information
2 technology loan fund (referred to in this subsection
3 as a “State loan fund”) and comply with the other
4 requirements contained in this subsection. Amounts
5 received under a grant under this subsection shall be
6 deposited in the State loan fund established by the
7 State. No funds authorized by other provisions of
8 this title to be used for other purposes specified in
9 this title shall be deposited in any such State loan
10 fund.

11 (3) ELIGIBILITY.—To be eligible to receive a
12 grant under paragraph (1) a State shall—

13 (A) submit to the Secretary an application
14 at such time, in such manner, and containing
15 such information as the Secretary may require;

16 (B) submit to the Secretary a strategic
17 plan in accordance with paragraph (4);

18 (C) establish a qualified health information
19 technology loan fund in accordance with para-
20 graph (2);

21 (D) require that health care providers re-
22 ceiving loans under the grant—

23 (i) link, to the extent practicable, the
24 qualified health information system to a

1 local or regional health information net-
2 work;

3 (ii) consult, as needed, with the
4 Health Information Technology Resource
5 Center established in section 914(d) to ac-
6 cess the knowledge and experience of exist-
7 ing initiatives regarding the successful im-
8 plementation and effective use of health in-
9 formation technology;

10 (iii) agree to notify individuals if their
11 personal health information is wrongfully
12 disclosed; and

13 (iv) take into account the input of em-
14 ployees and staff who are directly involved
15 in patient care of such health care pro-
16 viders in the design and implementation
17 and use of qualified health information
18 technology systems;

19 (E) require that health care providers re-
20 ceiving loans under the grant adopt the stand-
21 ards adopted by the Federal Government under
22 section 301;

23 (F) require that health care providers re-
24 ceiving loans under the grant implement the

1 measures adopted under section 221 and report
2 to the Secretary on such measures; and

3 (G) provide matching funds in accordance
4 with paragraph (8).

5 (4) STRATEGIC PLAN.—

6 (A) IN GENERAL.—A State that receives a
7 grant under this subsection shall annually pre-
8 pare a strategic plan that identifies the in-
9 tended uses of amounts available to the State
10 loan fund of the State.

11 (B) CONTENTS.—A strategic plan under
12 subparagraph (A) shall include—

13 (i) a list of the projects to be assisted
14 through the State loan fund in the first
15 fiscal year that begins after the date on
16 which the plan is submitted;

17 (ii) a description of the criteria and
18 methods established for the distribution of
19 funds from the State loan fund;

20 (iii) a description of the financial sta-
21 tus of the State loan fund and the short-
22 term and long-term goals of the State loan
23 fund; and

24 (iv) a description of the strategies the
25 State will use to address challenges in the

1 adoption of health information technology
2 due to limited broadband access.

3 (5) USE OF FUNDS.—

4 (A) IN GENERAL.—Amounts deposited in a
5 State loan fund, including loan repayments and
6 interest earned on such amounts, shall be used
7 only for awarding loans or loan guarantees, or
8 as a source of reserve and security for leveraged
9 loans, the proceeds of which are deposited in
10 the State loan fund established under para-
11 graph (1). Loans under this section may be
12 used by a health care provider to—

13 (i) facilitate the purchase of qualified
14 health information technology systems;

15 (ii) enhance the utilization of qualified
16 health information technology systems
17 (which may include activities to increase
18 the awareness among consumers of health
19 care of privacy protections and privacy
20 rights); or

21 (iii) train personnel in the use of such
22 systems.

23 (B) LIMITATION.—Amounts received by a
24 State under this subsection may not be used—

1 (i) for the purchase or other acquisi-
2 tion of any health information technology
3 system that is not a qualified health infor-
4 mation technology system;

5 (ii) to conduct activities for which
6 Federal funds are expended under this
7 title, or the amendments made by this
8 title; or

9 (iii) for any purpose other than mak-
10 ing loans to eligible entities under this sec-
11 tion.

12 (6) TYPES OF ASSISTANCE.—Except as other-
13 wise limited by applicable State law, amounts depos-
14 ited into a State loan fund under this subsection
15 may only be used for the following:

16 (A) To award loans that comply with the
17 following:

18 (i) The interest rate for each loan
19 shall be less than or equal to the market
20 interest rate.

21 (ii) The principal and interest pay-
22 ments on each loan shall commence not
23 later than 1 year after the date on which
24 the loan was awarded, and each loan shall

1 be fully amortized not later than 10 years
2 after such date.

3 (iii) The State loan fund shall be
4 credited with all payments of principal and
5 interest on each loan awarded from the
6 fund.

7 (B) To guarantee, or purchase insurance
8 for, a local obligation (all of the proceeds of
9 which finance a project eligible for assistance
10 under this subsection) if the guarantee or pur-
11 chase would improve credit market access or re-
12 duce the interest rate applicable to the obliga-
13 tion involved.

14 (C) As a source of revenue or security for
15 the payment of principal and interest on rev-
16 enue or general obligation bonds issued by the
17 State if the proceeds of the sale of the bonds
18 will be deposited into the State loan fund.

19 (D) To earn interest on the amounts de-
20 posited into the State loan fund.

21 (7) ADMINISTRATION OF STATE LOAN
22 FUNDS.—

23 (A) COMBINED FINANCIAL ADMINISTRA-
24 TION.—A State may (as a convenience and to
25 avoid unnecessary administrative costs) com-

1 bine, in accordance with State law, the financial
2 administration of a State loan fund established
3 under this subsection with the financial admin-
4 istration of any other revolving fund established
5 by the State if not otherwise prohibited by the
6 law under which the State loan fund was estab-
7 lished.

8 (B) COST OF ADMINISTERING FUND.—

9 Each State may annually use not to exceed 4
10 percent of the funds provided to the State
11 under a grant under this subsection to pay the
12 reasonable costs of the administration of the
13 programs under this section, including the re-
14 covery of reasonable costs expended to establish
15 a State loan fund which are incurred after the
16 date of enactment of this title.

17 (C) GUIDANCE AND REGULATIONS.—The

18 Secretary shall publish guidance and promul-
19 gate regulations as may be necessary to carry
20 out the provisions of this subsection, includ-
21 ing—

22 (i) provisions to ensure that each
23 State commits and expends funds allotted
24 to the State under this subsection as effi-

1 ciently as possible in accordance with this
2 title and applicable State laws; and

3 (ii) guidance to prevent waste, fraud,
4 and abuse.

5 (D) PRIVATE SECTOR CONTRIBUTIONS.—

6 (i) IN GENERAL.—A State loan fund
7 established under this subsection may ac-
8 cept contributions from private sector enti-
9 ties, except that such entities may not
10 specify the recipient or recipients of any
11 loan issued under this subsection.

12 (ii) AVAILABILITY OF INFORMA-
13 TION.—A State shall make publicly avail-
14 able the identity of, and amount contrib-
15 uted by, any private sector entity under
16 clause (i) and may issue letters of com-
17 mendation or make other awards (that
18 have no financial value) to any such entity.

19 (8) MATCHING REQUIREMENTS.—

20 (A) IN GENERAL.—The Secretary may not
21 make a grant under paragraph (1) to a State
22 unless the State agrees to make available (di-
23 rectly or through donations from public or pri-
24 vate entities) non-Federal contributions in cash
25 toward the costs of the State program to be im-

1 plemented under the grant in an amount equal
2 to not less than \$1 for each \$1 of Federal
3 funds provided under the grant.

4 (B) DETERMINATION OF AMOUNT OF NON-
5 FEDERAL CONTRIBUTION.—In determining the
6 amount of non-Federal contributions that a
7 State has provided pursuant to subparagraph
8 (A), the Secretary may not include any
9 amounts provided to the State by the Federal
10 Government.

11 (9) PREFERENCE IN AWARDING GRANTS.—The
12 Secretary may give a preference in awarding grants
13 under this subsection to States that adopt value-
14 based purchasing programs to improve health care
15 quality.

16 (10) REPORTS.—The Secretary shall annually
17 submit to the Committee on Health, Education,
18 Labor, and Pensions and the Committee on Finance
19 of the Senate, and the Committee on Energy and
20 Commerce and the Committee on Ways and Means
21 of the House of Representatives, a report summa-
22 rizing the reports received by the Secretary from
23 each State that receives a grant under this sub-
24 section.

1 (c) COMPETITIVE GRANTS FOR THE IMPLEMENTA-
2 TION OF REGIONAL OR LOCAL HEALTH INFORMATION
3 TECHNOLOGY PLANS.—

4 (1) IN GENERAL.—The Secretary may award
5 competitive grants to eligible entities to implement
6 regional or local health information plans to improve
7 health care quality and efficiency through the elec-
8 tronic exchange of personal health information pur-
9 suant to the standards, implementation specifica-
10 tions and certification criteria, and other require-
11 ments adopted by the Secretary under section 221.

12 (2) ELIGIBILITY.—To be eligible to receive a
13 grant under paragraph (1) an entity, which may be
14 a health record bank or trust, shall—

15 (A) demonstrate financial need to the Sec-
16 retary;

17 (B) demonstrate that one of its principal
18 missions or purposes is to use information tech-
19 nology to improve health care quality and effi-
20 ciency;

21 (C) adopt bylaws, memoranda of under-
22 standing, or other charter documents that dem-
23 onstrate that the governance structure and de-
24 cision making processes of such entity allow for

1 participation on an ongoing basis by multiple
2 stakeholders within a community, including—

3 (i) health care providers (including
4 health care providers that provide services
5 to low income and underserved popu-
6 lations);

7 (ii) pharmacists or pharmacies;

8 (iii) health plans;

9 (iv) health centers (as defined in sec-
10 tion 330(b)) and federally qualified health
11 centers (as defined in section 1861(aa)(4)
12 of the Social Security Act) and rural
13 health clinics (as defined in section
14 1861(aa) of the Social Security Act), if
15 such centers or clinics are present in the
16 community served by the entity;

17 (v) patient or consumer organizations;

18 (vi) organizations dedicated to im-
19 proving the health of vulnerable popu-
20 lations;

21 (vii) employers;

22 (viii) State or local health depart-
23 ments; and

1 (ix) any other health care providers or
2 other entities, as determined appropriate
3 by the Secretary;

4 (D) demonstrate the participation, to the
5 extent practicable, of stakeholders in the elec-
6 tronic exchange of personal health information
7 within the local or regional plan pursuant to
8 subparagraph (C);

9 (E) adopt nondiscrimination and conflict of
10 interest policies that demonstrate a commit-
11 ment to open, fair, and nondiscriminatory par-
12 ticipation in the health information plan by all
13 stakeholders;

14 (F) adopt the standards adopted by the
15 Secretary under section 301;

16 (G) require that health care providers re-
17 ceiving such grants—

18 (i) implement the measures adopted
19 under section 221 and report to the Sec-
20 retary on such measures; and

21 (ii) take into account the input of em-
22 ployees and staff who are directly involved
23 in patient care of such health care pro-
24 viders in the design, implementation, and

1 use of health information technology sys-
2 tems;

3 (H) agree to comply with the requirements
4 of title I;

5 (I) facilitate the electronic exchange of per-
6 sonal health information within the local or re-
7 gional area and among local and regional areas;

8 (J) prepare and submit to the Secretary an
9 application in accordance with paragraph (3);

10 (K) agree to provide matching funds in ac-
11 cordance with paragraph (5); and

12 (L) reduce barriers to the implementation
13 of health information technology by providers.

14 (3) APPLICATION.—

15 (A) IN GENERAL.—To be eligible to receive
16 a grant under paragraph (1), an entity shall
17 submit to the Secretary an application at such
18 time, in such manner, and containing such in-
19 formation as the Secretary may require.

20 (B) REQUIRED INFORMATION.—At a min-
21 imum, an application submitted under this
22 paragraph shall include—

23 (i) clearly identified short-term and
24 long-term objectives of the regional or local
25 health information plan;

1 (ii) a technology plan that complies
2 with the standards, implementation speci-
3 fications, and certification criteria adopted
4 under section 202(c)(6) and that includes
5 a descriptive and reasoned estimate of
6 costs of the hardware, software, training,
7 and consulting services necessary to imple-
8 ment the regional or local health informa-
9 tion plan;

10 (iii) a strategy that includes initiatives
11 to improve health care quality and effi-
12 ciency, including the use and reporting of
13 health care quality measures adopted
14 under section 221;

15 (iv) a plan that describes provisions to
16 encourage the implementation of the elec-
17 tronic exchange of personal health infor-
18 mation by all health care providers partici-
19 pating in the health information plan;

20 (v) a plan to ensure the privacy and
21 security of personal health information
22 that is consistent with the requirements of
23 title I;

24 (vi) a governance plan that defines
25 the manner in which the stakeholders shall

1 jointly make policy and operational deci-
2 sions on an ongoing basis;

3 (vii) a financial or business plan that
4 describes—

5 (I) the sustain ability of the plan;

6 (II) the financial costs and bene-
7 fits of the plan; and

8 (III) the entities to which such
9 costs and benefits will accrue;

10 (viii) a description of whether the
11 State in which the entity resides has re-
12 ceived a grant under section 319D of the
13 Public Health Service Act, alone or as a
14 part of a consortium, and if the State has
15 received such a grant, how the entity will
16 coordinate the activities funded under such
17 section 319D with the system under this
18 section; and

19 (ix) in the case of an applicant entity
20 that is unable to demonstrate the partici-
21 pation of all stakeholders pursuant to
22 paragraph (2)(C), the justification from
23 the entity for any such nonparticipation.

24 (4) USE OF FUNDS.—Amounts received under a
25 grant under paragraph (1) shall be used to establish

1 and implement a regional or local health information
2 plan in accordance with this subsection.

3 (5) MATCHING REQUIREMENT.—

4 (A) IN GENERAL.—The Secretary may not
5 make a grant under this subsection to an entity
6 unless the entity agrees that, with respect to
7 the costs to be incurred by the entity in car-
8 rying out the network program for which the
9 grant was awarded, the entity will make avail-
10 able (directly or through donations from public
11 or private entities) non-Federal contributions
12 toward such costs in an amount equal to not
13 less than 50 percent of such costs (\$1 for each
14 \$2 of Federal funds provided under the grant).

15 (B) DETERMINATION OF AMOUNT CON-
16 TRIBUTED.—Non-Federal contributions re-
17 quired under subparagraph (A) may be in cash
18 or in kind, fairly evaluated, including equip-
19 ment, technology, or services. Amounts provided
20 by the Federal Government, or services assisted
21 or subsidized to any significant extent by the
22 Federal Government, may not be included in
23 determining the amount of such non-Federal
24 contributions.

1 (6) HEALTH RECORD BANK OR TRUST DE-
2 FINED.—In this section, the term “health record
3 bank or trust” means an independent organization
4 that provides a secure electronic repository for stor-
5 ing and maintaining an individual’s lifetime health
6 and medical records from multiple sources and en-
7 suring that the individual always has complete con-
8 trol over who accesses their information.

9 (d) REPORTS.—Not later than 1 year after the date
10 on which the first grant is awarded under this section,
11 and annually thereafter during the grant period, an entity
12 that receives a grant under this section shall submit to
13 the Secretary a report on the activities carried out under
14 the grant involved. Each such report shall include—

15 (1) a description of the financial costs and ben-
16 efits of the project involved and of the entities to
17 which such costs and benefits accrue;

18 (2) an analysis of the impact of the project on
19 health care quality and safety;

20 (3) a description of any reduction in duplicative
21 or unnecessary care as a result of the project in-
22 volved; and

23 (4) other information as required by the Sec-
24 retary.

25 (e) AUTHORIZATION OF APPROPRIATIONS.—

1 (B) a school of nursing; or

2 (C) an institution with a graduate medical
3 education program;

4 (3) provide for the collection of data regarding
5 the effectiveness of the demonstration project to be
6 funded under the grant in improving the safety of
7 patients and the efficiency of health care delivery;
8 and

9 (4) provide matching funds in accordance with
10 subsection (d).

11 (c) USE OF FUNDS.—

12 (1) IN GENERAL.—With respect to a grant
13 under subsection (a), an eligible entity or consortium
14 shall use amounts received under the grant in col-
15 laboration with 2 or more disciplines.

16 (2) LIMITATION.—An eligible entity or consor-
17 tium shall not award a grant under subsection (a)
18 to purchase hardware, software, or services.

19 (d) MATCHING FUNDS.—

20 (1) IN GENERAL.—The Secretary may award a
21 grant to an entity under or consortium this section
22 only if the entity of consortium agrees to make avail-
23 able non-Federal contributions toward the costs of
24 the program to be funded under the grant in an

1 amount that is not less than \$1 for each \$2 of Fed-
2 eral funds provided under the grant.

3 (2) DETERMINATION OF AMOUNT CONTRIB-
4 UTED.—Non-Federal contributions under paragraph
5 (1) may be in cash or in kind, fairly evaluated, in-
6 cluding equipment or services. Amounts provided by
7 the Federal Government, or services assisted or sub-
8 sidized to any significant extent by the Federal Gov-
9 ernment, may not be included in determining the
10 amount of such contributions.

11 (e) EVALUATION.—The Secretary shall take such ac-
12 tion as may be necessary to evaluate the projects funded
13 under this section and publish, make available, and dis-
14 seminate the results of such evaluations on as wide a basis
15 as is practicable.

16 (f) REPORTS.—Not later than 1 year after the date
17 of enactment of this title, and annually thereafter, the Sec-
18 retary shall submit to the Committee on Health, Edu-
19 cation, Labor, and Pensions and the Committee on Fi-
20 nance of the Senate, and the Committee on Energy and
21 Commerce and the Committee on Ways and Means of the
22 House of Representatives a report that—

23 (1) describes the specific projects established
24 under this section; and

1 (2) contains recommendations for Congress
2 based on the evaluation conducted under subsection
3 (e).

4 (g) AUTHORIZATION OF APPROPRIATIONS.—There is
5 authorized to be appropriated to carry out this section,
6 \$2,000,000 for each of fiscal years 2009 and 2010.

7 (h) SUNSET.—This provisions of this section shall not
8 apply after September 30, 2012.

9 **SEC. 213. QUALIFIED HEALTH INFORMATION TECHNOLOGY**
10 **SYSTEM DEFINED.**

11 In this subtitle, the term “qualified health informa-
12 tion technology system” means a computerized system (in-
13 cluding hardware and software) that—

14 (1) safeguards the privacy, security, and con-
15 fidentiality of personal health information in accord-
16 ance with the requirements of title I;

17 (2) maintains and provides permitted access to
18 health information in an electronic format;

19 (3) with respect to personal health information
20 maintained in a designated record set, preserves an
21 audit trail of each individual that has gained access
22 to such record set;

23 (4) incorporates decision support to reduce
24 medical errors and enhance health care quality;

1 (5) complies with the standards adopted by the
2 Federal Government under section 202;

3 (6) has the ability to transmit and exchange in-
4 formation to other health information technology
5 systems and, to the extent feasible, public health in-
6 formation technology systems; and

7 (7) allows for the reporting of quality measures
8 adopted under section 221.

9 **Subtitle C—Improving the Quality**
10 **of Health Care**

11 **SEC. 221. FOSTERING DEVELOPMENT AND USE OF HEALTH**
12 **CARE QUALITY MEASURES.**

13 (a) IN GENERAL.—The Secretary shall provide for
14 the development and use of health care quality measures
15 (referred to in this title as “quality measures”) for the
16 purpose of measuring the quality and efficiency of health
17 care that patients receive.

18 (b) DESIGNATION OF, AND ARRANGEMENT WITH,
19 ORGANIZATION.—

20 (1) IN GENERAL.—Not later than 90 days after
21 the date of enactment of this title, the Secretary
22 shall designate, and have in effect an arrangement
23 with, a single organization that meets the require-
24 ments of subsection (c) under which such organiza-
25 tion shall promote the development of quality meas-

1 ures and provide the Secretary with advice and rec-
2 ommendations on the key elements and priorities of
3 a national system for healthcare performance meas-
4 urement.

5 (2) RESPONSIBILITIES.—The responsibilities to
6 be performed by the organization designated under
7 paragraph (1) (in this title referred to as the “des-
8 ignated organization”) shall include—

9 (A) establishing and managing an inte-
10 grated national strategy and process for setting
11 priorities and goals in establishing quality
12 measures;

13 (B) coordinating and harmonizing the de-
14 velopment and testing of such measures;

15 (C) establishing standards for the develop-
16 ment and testing of such measures;

17 (D) endorsing national consensus quality
18 measures;

19 (E) recommending, in collaboration with
20 multi-stakeholder groups, quality measures to
21 the Secretary for adoption and use;

22 (F) promoting the development and use of
23 electronic health records that contain the
24 functionality for automated collection, aggrega-

1 tion, and transmission of performance measure-
2 ment information; and

3 (G) providing recommendations and advice
4 to the Partnership for Health Care Improve-
5 ment regarding the integration of quality meas-
6 ures into the certification process outlined
7 under section 202 and the American Health In-
8 formation Community regarding national poli-
9 cies outlined under section 203.

10 (c) REQUIREMENTS DESCRIBED.—The requirements
11 described in this subsection are the following:

12 (1) PRIVATE ENTITY.—The organization shall
13 be a private nonprofit entity that is governed by a
14 board of directors and an individual who is des-
15 ignated as president and chief executive officer.

16 (2) BOARD MEMBERSHIP.—The members of the
17 board of directors of the entity shall include rep-
18 resentatives of—

19 (A) health care providers or groups rep-
20 resenting providers;

21 (B) health plans or groups representing
22 health plans;

23 (C) patients or consumers enrolled in such
24 plans or groups representing individuals en-
25 rolled in such plans;

1 (D) health care purchasers and employers
2 or groups representing purchasers or employers;
3 and

4 (E) organizations that develop health in-
5 formation technology standards and new health
6 information technology.

7 (3) OTHER MEMBERSHIP REQUIREMENTS.—
8 The membership of the board of directors of the en-
9 tity shall be representative of individuals with expe-
10 rience with—

11 (A) urban health care issues;

12 (B) safety net health care issues;

13 (C) rural or frontier health care issues;

14 (D) quality and safety issues;

15 (E) State or local health programs;

16 (F) individuals or entities skilled in the
17 conduct and interpretation of biomedical, health
18 services, and health economics research and
19 with expertise in outcomes and effectiveness re-
20 search and technology assessment;

21 (G) individuals or entities involved in the
22 development and establishment of standards
23 and certification for health information tech-
24 nology systems and clinical data; and

1 (H) members of the medical and mental
2 health professions with expertise in standards
3 of professional ethics.

4 (4) OPEN AND TRANSPARENT.—With respect to
5 matters related to the arrangement with the Sec-
6 retary under subsection (a)(1), the organization
7 shall conduct its business in an open and trans-
8 parent manner, and provide the opportunity for pub-
9 lic comment and ensure a balance among disparate
10 stakeholders, so that no member organization unduly
11 influences the work of the organization.

12 (5) VOLUNTARY CONSENSUS STANDARDS SET-
13 TING ORGANIZATIONS.—The organization shall oper-
14 ate as a voluntary consensus standards setting orga-
15 nization as defined for purposes of section 12(d) of
16 the National Technology Transfer and Advancement
17 Act of 1995 (Public Law 104–113) and Office of
18 Management and Budget Revised Circular A–119
19 (published in the Federal Register on February 10,
20 1998).

21 (6) PARTICIPATION.—If the organization re-
22 quires a fee for membership, the organization shall
23 ensure that such fee is not a substantial barrier to
24 participation in the entity’s activities related to the
25 arrangement with the Secretary.

1 (d) REQUIREMENTS FOR MEASURES.—The quality
2 measures developed under this title shall comply with the
3 following:

4 (1) MEASURES.—The designated organization,
5 in promoting the development of quality measures
6 under this title, shall ensure that such measures—

7 (A) are evidence-based, reliable, and valid;

8 (B) include—

9 (i) measures of clinical processes and
10 outcomes, patient experience, efficiency,
11 and equity; and

12 (ii) measures to assess effectiveness,
13 timeliness, patient self-management, pa-
14 tient centeredness, and safety; and

15 (C) include measures of underuse and
16 overuse.

17 (2) PRIORITIES.—In carrying out its respon-
18 sibilities under this section, the designated organiza-
19 tion shall ensure that priority is given to—

20 (A) measures that preserve access to qual-
21 ity health care by protecting the privacy and se-
22 curity of personal health information;

23 (B) measures with the greatest potential
24 impact for improving the performance and effi-
25 ciency of care;

1 (C) measures that may be rapidly imple-
2 mented by group health plans, health insurance
3 issuers, physicians, hospitals, nursing homes,
4 long-term care providers, and other providers;

5 (D) measures which may inform health
6 care decisions made by consumers and patients;

7 (E) measures that apply to multiple serv-
8 ices furnished by different providers during an
9 episode of care;

10 (F) measures that can be integrated into
11 certification process described in section 202;
12 and

13 (G) measures that may be integrated into
14 the decision support function of qualified health
15 information technology as defined by this title.

16 (3) RISK ADJUSTMENT.—The designated orga-
17 nization, in consultation with performance measure
18 developers and other stakeholders, shall establish
19 procedures to ensure that quality measures take into
20 account differences in patient health status, patient
21 characteristics, and geographic location, as appro-
22 priate.

23 (4) MAINTENANCE.—The designated organiza-
24 tion, in consultation with owners and developers of
25 quality measures, shall require the owners or devel-

1 opers of quality measures to update and enhance
2 such measures, including the development of more
3 accurate and precise specifications, and retire exist-
4 ing outdated measures. Such updating shall occur
5 not more often than once during each 12-month pe-
6 riod, except in the case of emergency circumstances
7 requiring a more immediate update to a measure.

8 (e) **GRANTS FOR PERFORMANCE MEASURE DEVEL-**
9 **OPMENT.**—The Secretary, acting through the Agency for
10 Healthcare Research and Quality, may award grants, in
11 amounts not to exceed \$50,000 each, to organizations to
12 support the development and testing of quality measures
13 that meet the standards established by the designated or-
14 ganization.

15 **SEC. 222. ADOPTION AND USE OF QUALITY MEASURES; RE-**
16 **PORTING.**

17 (a) **IN GENERAL.**—For purposes of carrying out ac-
18 tivities authorized or required by this title to ensure the
19 use of quality measures and to foster uniformity between
20 health care quality measures utilized by private entities,
21 the Secretary shall—

22 (1) select quality measures for adoption and
23 use, from quality measures recommended by multi-
24 stakeholder groups and endorsed by the designated
25 organization; and

1 (2) ensure that standards adopted under sec-
2 tion 301 integrate the quality measures endorsed,
3 adopted, and utilized under this section.

4 (b) RELATIONSHIP WITH PROGRAMS UNDER THE
5 SOCIAL SECURITY ACT.—The Secretary shall ensure that
6 the quality measures adopted under this section—

7 (1) complement quality measures developed by
8 the Secretary under programs administered by the
9 Secretary under the Social Security Act, including
10 programs under titles XVIII, XIX, and XXI of such
11 Act; and

12 (2) do not conflict with the needs and priorities
13 of the programs under titles XVIII, XIX, and XXI
14 of such Act, as set forth by the Administrator of the
15 Centers for Medicare & Medicaid Services.

16 (c) REPORTING.—The Secretary shall implement pro-
17 cedures, consistent with generally accepted standards, to
18 enable the Department of Health and Human Services to
19 accept the electronic submission of data for purposes of
20 performance measurement, including at the provider level,
21 using the quality measures developed, endorsed, and
22 adopted pursuant to this title.

23 (d) DISSEMINATION OF INFORMATION.—In order to
24 make comparative performance information available to
25 health care consumers, health professionals, public health

1 officials, oversight organizations, researchers, and other
2 appropriate individuals and entities, after consultation
3 with multi-stakeholder groups, the Secretary shall promul-
4 gate regulations to provide for the dissemination, aggrega-
5 tion, and analysis of quality measures collected pursuant
6 to this title.

7 **Subtitle D—Miscellaneous** 8 **Provisions**

9 **SEC. 231. HEALTH INFORMATION TECHNOLOGY RESOURCE** 10 **CENTER.**

11 Section 914 of the Public Health Service Act (42
12 U.S.C. 299b–3) is amended by adding at the end the fol-
13 lowing:

14 “(d) HEALTH INFORMATION TECHNOLOGY RE-
15 SOURCE CENTER.—

16 “(1) IN GENERAL.—The Secretary, acting
17 through the Director, shall develop a Health Infor-
18 mation Technology Resource Center (referred to in
19 this subsection as the ‘Center’) to provide technical
20 assistance and develop best practices to support and
21 accelerate efforts to adopt, implement, and effec-
22 tively use interoperable health information tech-
23 nology in compliance with sections 202 and 221 of
24 the TRUST in Health Information Act of 2008.

1 “(2) PURPOSES.—The purposes of the Center
2 are to—

3 “(A) provide a forum for the exchange of
4 knowledge and experience;

5 “(B) accelerate the transfer of lessons
6 learned from existing public and private sector
7 initiatives, including those currently receiving
8 Federal financial support;

9 “(C) assemble, analyze, and widely dis-
10 seminate evidence and experience related to the
11 adoption, implementation, and effective use of
12 interoperable health information technology;

13 “(D) provide for the establishment of re-
14 gional and local health information networks to
15 facilitate the development of interoperability
16 across health care settings and improve the
17 quality of health care;

18 “(E) provide for the development of solu-
19 tions to barriers to the exchange of electronic
20 health information; and

21 “(F) conduct other activities identified by
22 the States, local, or regional health information
23 networks, or health care stakeholders as a focus
24 for developing and sharing best practices.

1 “(3) SUPPORT FOR ACTIVITIES.—To provide
2 support for the activities of the Center, the Director
3 shall modify the requirements, if necessary, that
4 apply to the National Resource Center for Health
5 Information Technology to provide the necessary in-
6 frastructure to support the duties and activities of
7 the Center and facilitate information exchange
8 across the public and private sectors.

9 “(4) RULE OF CONSTRUCTION.—Nothing in
10 this subsection shall be construed to require the du-
11 plication of Federal efforts with respect to the estab-
12 lishment of the Center, regardless of whether such
13 efforts were carried out prior to or after the enact-
14 ment of this subsection.

15 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
16 is authorized to be appropriated, such sums as may be
17 necessary for each of fiscal years 2009 and 2010 to carry
18 out this section.”.

19 **SEC. 232. FACILITATING THE PROVISION OF TELEHEALTH**
20 **SERVICES ACROSS STATE LINES.**

21 Section 330L of the Public Health Service Act (42
22 U.S.C. 254c-18) is amended to read as follows:

1 **“SEC. 330L. TELEMEDICINE; INCENTIVE GRANTS REGARD-**
 2 **ING COORDINATION AMONG STATES.**

3 “(a) FACILITATING THE PROVISION OF TELE-
 4 HEALTH SERVICES ACROSS STATE LINES.—The Sec-
 5 retary may make grants to States that have adopted re-
 6 gional State reciprocity agreements for practitioner licen-
 7 sure, in order to expedite the provision of telehealth serv-
 8 ices across State lines.

9 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
 10 purpose of carrying out subsection (a), there are author-
 11 ized to be appropriated such sums as may be necessary
 12 for each of the fiscal years 2009 and 2010.”.

13 **Subtitle E—Definitions**

14 **SEC. 241. DEFINITIONS.**

15 In this title, the following terms, defined in section
 16 171, have the meanings given such terms in such section:
 17 Breach , confidentiality, de-identified health information,
 18 disclose, Director of the Office of Health Information Pri-
 19 vacy, employer, health care, health care provider, Office
 20 of Health Information Privacy, privacy, personal health
 21 information, Secretary, security, State, and use.

22 **TITLE III—ADDITIONAL**
 23 **PROVISIONS**

24 **SEC. 301. FEDERAL PURCHASING AND DATA COLLECTION**
 25 **BY CMS AND OTHER FEDERAL AGENCIES.**

26 (a) COORDINATION OF FEDERAL SPENDING.—

1 (1) IN GENERAL.—Not later than 1 year after
2 the adoption by the President of a recommendation
3 under section 202(c)(6), the Administrator of the
4 Center for Medicare & Medicaid Services and the
5 head of any other Federal agency shall not expend
6 Federal funds for the purchase of any new health in-
7 formation technology or health information tech-
8 nology system for clinical care or for the electronic
9 retrieval, storage, or exchange of personal health in-
10 formation if such technology or system is not con-
11 sistent with applicable standards adopted by the
12 Federal Government under section 202.

13 (2) RULE OF CONSTRUCTION.—Nothing in
14 paragraph (1) shall be construed to restrict the pur-
15 chase of minor (as determined by the Secretary)
16 hardware or software components in order to mod-
17 ify, correct a deficiency in, or extend the life of exist-
18 ing hardware or software.

19 (b) VOLUNTARY ADOPTION.—

20 (1) IN GENERAL.—Any standards and imple-
21 mentation specifications adopted by the Federal
22 Government under section 202(c) shall be voluntary
23 with respect to private entities.

24 (2) REQUIREMENT.—Private entities that enter
25 into a contract with the Federal Government shall

1 adopt the standards and implementation specifica-
2 tions adopted by the Federal Government under this
3 section for the purpose of activities under such Fed-
4 eral contract.

5 (3) RULE OF CONSTRUCTION.—Nothing in this
6 section shall be construed to require that a private
7 entity that enters into a contract with the Federal
8 Government adopt the standards and implementa-
9 tion specifications adopted by the Federal Govern-
10 ment under this section with respect to activities not
11 related to the contract.

12 (c) COORDINATION OF FEDERAL DATA COLLEC-
13 TION.—Not later than 3 years after the adoption by the
14 Federal Government of a recommendation as provided for
15 in section 202(c), all Federal agencies (including the Cen-
16 ter for Medicare & Medicaid Services) collecting health
17 data in an electronic format for the purposes of quality
18 reporting, surveillance, epidemiology, adverse event report-
19 ing, research, or for other purposes determined appro-
20 priate by the Secretary, shall comply with the standards
21 and implementation specifications adopted under such
22 subsection.

1 **SEC. 302. ENSURING HEALTH CARE PROVIDERS PARTICI-**
2 **PATING IN THE MEDICARE PROGRAM MAY**
3 **MAINTAIN HEALTH INFORMATION IN ELEC-**
4 **TRONIC FORM.**

5 Section 1871 of the Social Security Act (42 U.S.C.
6 1395hh) is amended by adding at the end the following
7 new subsection:

8 “(g)(1) Any provider of services or supplier shall be
9 deemed as meeting any requirement for the maintenance
10 of data in paper form under this title (whether or not for
11 purposes of management, billing, reporting, reimburse-
12 ment, or otherwise) if the required data is maintained in
13 an electronic form.

14 “(2) Nothing in this subsection shall be construed as
15 requiring health care providers to maintain or submit data
16 in electronic form.”.

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