

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> 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.

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## 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

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## 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 disclo-  
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           (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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