

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. 6357
OFFERED BY M . _____**

Strike all after the enacting clause and insert the following:

1 SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Protecting Records, Optimizing Treatment, and Easing
4 Communication through Healthcare Technology Act of
5 2008” or the “PRO(TECH)T Act of 2008”.

6 (b) TABLE OF CONTENTS.—The table of contents of
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—HEALTH INFORMATION TECHNOLOGY

Subtitle A—Promotion of Health Information Technology

PART I—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

Sec. 101. ONCHIT; standards development and adoption; health information technology resource center.

“TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND
QUALITY

“Sec. 3000. Definitions.

“Subtitle A—Promotion of Health Information Technology

“Sec. 3001. Office of the National Coordinator for Health Information Technology.

“Sec. 3002. HIT Policy Committee.

“Sec. 3003. HIT Standards Committee.

“Sec. 3004. Process for adoption of endorsed recommendations.

“Sec. 3005. Application and use of adopted standards and implementation specifications by Federal agencies.

“Sec. 3006. Voluntary application and use of adopted standards and implementation specifications by private entities.

“Sec. 3007. Health Information Technology Resource Center.

Sec. 102. Transitions.

PART II—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

Sec. 111. Coordination of Federal activities with adopted standards and implementation specifications.

Sec. 112. Application to private entities.

Sec. 113. Study and reports.

Subtitle B—Incentives for the Use of Health Information Technology

Sec. 121. Grant, loan, and demonstration programs.

“Subtitle B—Incentives for the Use of Health Information Technology

“Sec. 3011. Grants and loans To facilitate the widespread adoption of qualified health information technology.

“Sec. 3012. Demonstration program to integrate information technology into clinical education.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

Sec. 201. National Institute for Standards and Technology testing.

Sec. 202. Research and development programs.

TITLE III—PRIVACY AND SECURITY PROVISIONS

Sec. 300. Definitions.

Subtitle A—Security Provisions

Sec. 301. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions.

Sec. 302. Notification in the case of breach.

Sec. 303. Education on Health Information Privacy and report on compliance.

Subtitle B—Improved Privacy Provisions and Additional Security Provisions

Sec. 311. Application of penalties to business associates of covered entities for violations of privacy contract requirements.

Sec. 312. Restrictions on certain disclosures and sales of health information; accounting of certain protected health information disclosures; access to certain information in electronic format.

Sec. 313. Conditions on certain contacts as part of health care operations.

Sec. 314. Study on application of privacy and security requirements to non-HIPAA covered entities.

Sec. 315. Temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities.

Sec. 316. Business associate contracts required for certain entities.

Sec. 317. Guidance on implementation specification to de-identify protected health information.

Sec. 318. GAO report on treatment disclosures.

Sec. 319. Clarification of application of wrongful disclosures criminal penalties.

Sec. 320. Improved enforcement.

Subtitle A—Relationship to Other Laws; Regulatory References; Effective Date

- Sec. 1. Relationship to other laws.
- Sec. 2. Regulatory references.
- Sec. 3. Effective date.

1 **TITLE I—HEALTH INFORMATION**
2 **TECHNOLOGY**

3 **Subtitle A—Promotion of Health**
4 **Information Technology**

5 **PART I—IMPROVING HEALTH CARE QUALITY,**
6 **SAFETY, AND EFFICIENCY**

7 **SEC. 101. ONCHIT; STANDARDS DEVELOPMENT AND ADOPTI-**
8 **ON; HEALTH INFORMATION TECHNOLOGY**
9 **RESOURCE CENTER.**

10 (a) IN GENERAL.—The Public Health Service Act
11 (42 U.S.C. 201 et seq.) is amended by adding at the end
12 the following:

13 **“TITLE XXX—HEALTH INFORMA-**
14 **TION TECHNOLOGY AND**
15 **QUALITY**

16 **“SEC. 3000. DEFINITIONS.**

17 “In this title:

18 “(1) ENTERPRISE INTEGRATION.—The term
19 ‘enterprise integration’ means the electronic linkage
20 of health care providers, health plans, the govern-
21 ment, and other interested parties, to enable the
22 electronic exchange and use of health information

1 among all the components in the health care infra-
2 structure in accordance with applicable law, and
3 such term includes related application protocols and
4 other related standards.

5 “(2) HEALTH CARE PROVIDER.—The term
6 ‘health care provider’ means a hospital, skilled nurs-
7 ing facility, nursing facility, home health entity,
8 health care clinic, Federally qualified health center,
9 group practice (as defined in section 1877(h)(4) of
10 the Social Security Act), a pharmacist, a pharmacy,
11 a laboratory, a physician (as defined in section
12 1861(r) of the Social Security Act), a practitioner
13 (as described in section 1842(b)(18)(C) of the Social
14 Security Act), a provider operated by, or under con-
15 tract with, the Indian Health Service or by an In-
16 dian tribe (as defined in the Indian Self-Determina-
17 tion and Education Assistance Act), tribal organiza-
18 tion, or urban Indian organization (as defined in
19 section 4 of the Indian Health Care Improvement
20 Act), a rural health clinic, and any other category of
21 facility or clinician determined appropriate by the
22 Secretary.

23 “(3) HEALTH INFORMATION.—The term ‘health
24 information’ has the meaning given such term in
25 section 1171(4) of the Social Security Act.

1 “(4) HEALTH INFORMATION TECHNOLOGY.—
2 The term ‘health information technology’ means
3 hardware, software, integrated technologies and re-
4 lated licenses, intellectual property, upgrades, and
5 packaged solutions sold as services that are specifi-
6 cally designed for use by health care entities for the
7 electronic creation, maintenance, or exchange of
8 health information.

9 “(5) HEALTH PLAN.—The term ‘health plan’
10 has the meaning given such term in section 1171(5)
11 of the Social Security Act.

12 “(6) HIT POLICY COMMITTEE.—The term ‘HIT
13 Policy Committee’ means such Committee estab-
14 lished under section 3002(a).

15 “(7) HIT STANDARDS COMMITTEE.—The term
16 ‘HIT Standards Committee’ means such Committee
17 established under section 3003(a).

18 “(8) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
19 FORMATION.—The term ‘individually identifiable
20 health information’ has the meaning given such term
21 in section 1171(6) of the Social Security Act.

22 “(9) LABORATORY.—The term ‘laboratory’ has
23 the meaning given such term in section 353(a).

24 “(10) NATIONAL COORDINATOR.—The term
25 ‘National Coordinator’ means the head of the Office

1 of the National Coordinator for Health Information
2 Technology established under section 3001(a).

3 “(11) PHARMACIST.—The term ‘pharmacist’
4 has the meaning given such term in section 804(2)
5 of the Federal Food, Drug, and Cosmetic Act.

6 “(12) STATE.—The term ‘State’ means each of
7 the several States, the District of Columbia, Puerto
8 Rico, the Virgin Islands, Guam, American Samoa,
9 and the Northern Mariana Islands.

10 **“Subtitle A—Promotion of Health** 11 **Information Technology**

12 **“SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR** 13 **HEALTH INFORMATION TECHNOLOGY.**

14 “(a) ESTABLISHMENT.—There is established within
15 the Department of Health and Human Services an Office
16 of the National Coordinator for Health Information Tech-
17 nology (referred to in this section as the ‘Office’). The Of-
18 fice shall be headed by a National Coordinator who shall
19 be appointed by the Secretary and shall report directly to
20 the Secretary.

21 “(b) PURPOSE.—The National Coordinator shall per-
22 form the duties under subsection (c) in a manner con-
23 sistent with the development of a nationwide health infor-
24 mation technology infrastructure that allows for the elec-
25 tronic use and exchange of information and that—

1 “(1) ensures that each patient’s health informa-
2 tion is secure and protected, in accordance with ap-
3 plicable law;

4 “(2) improves health care quality, reduces med-
5 ical errors, and advances the delivery of patient-cen-
6 tered medical care;

7 “(3) reduces health care costs resulting from
8 inefficiency, medical errors, inappropriate care, du-
9 plicative care, and incomplete information;

10 “(4) ensures that appropriate information to
11 help guide medical decisions is available at the time
12 and place of care;

13 “(5) ensures the inclusion of meaningful public
14 input in such development of such infrastructure;

15 “(6) improves the coordination of care and in-
16 formation among hospitals, laboratories, physician
17 offices, and other entities through an effective infra-
18 structure for the secure and authorized exchange of
19 health care information;

20 “(7) improves public health reporting and facili-
21 tates the early identification and rapid response to
22 public health threats and emergencies, including bio-
23 terror events and infectious disease outbreaks;

24 “(8) facilitates health and clinical research and
25 health care quality;

1 “(9) promotes prevention of chronic diseases;

2 “(10) promotes a more effective marketplace,
3 greater competition, greater systems analysis, in-
4 creased consumer choice, and improved outcomes in
5 health care services; and

6 “(11) improves efforts to reduce health dispari-
7 ties.

8 “(c) DUTIES OF THE NATIONAL COORDINATOR.—

9 “(1) STANDARDS.—The National Coordinator
10 shall review and determine whether to endorse each
11 standard, implementation specification, and certifi-
12 cation criterion for the electronic exchange and use
13 of health information that is recommended by the
14 HIT Standards Committee under section 3003 for
15 purposes of adoption under section 3004(b). The Co-
16 ordinator shall make such determination, and report
17 to the Secretary such determination, not later than
18 90 days after the date the recommendation is re-
19 ceived by the Coordinator.

20 “(2) HIT POLICY COORDINATION.—The Na-
21 tional Coordinator shall coordinate health informa-
22 tion technology policy and programs of the Depart-
23 ment with those of other relevant executive branch
24 agencies with a goal of avoiding duplication of ef-
25 forts and of helping to ensure that each agency un-

1 dertakes health information technology activities pri-
2 marily within the areas of its greatest expertise and
3 technical capability.

4 “(3) STRATEGIC PLAN.—

5 “(A) IN GENERAL.—The National Coordi-
6 nator shall, in consultation with other appro-
7 priate Federal agencies (including the National
8 Institute of Standards and Technology), main-
9 tain and update a strategic plan with specific
10 objectives, milestones, and metrics for the fol-
11 lowing:

12 “(i) The electronic exchange and use
13 of health information and the enterprise
14 integration of such information.

15 “(ii) The utilization of an electronic
16 health record for each person in the United
17 States by 2014.

18 “(iii) The incorporation of privacy and
19 security protections for the electronic ex-
20 change of an individual’s individually iden-
21 tifiable health information.

22 “(iv) Ensuring security methods to
23 ensure appropriate authorization and elec-
24 tronic authentication of health information
25 and specifying technologies or methodolo-

1 gies for rendering health information unus-
2 able, unreadable, or indecipherable.

3 “(v) Specifying a framework for co-
4 ordination and flow of recommendations
5 and policies under this subtitle among the
6 Secretary, the National Coordinator, the
7 HIT Policy Committee, the HIT Standards
8 Committee, and other health information
9 exchanges and other relevant entities.

10 “(vi) Methods to foster the public un-
11 derstanding of health information tech-
12 nology.

13 “(vii) Strategies to enhance the use of
14 health information technology in improving
15 the quality of health care, reducing medical
16 errors, reducing health disparities, and in
17 improving the continuity of care among
18 health care settings.

19 “(B) COLLABORATION.—The strategic
20 plan shall be developed and updated through
21 collaboration of public and private interests.

22 “(C) MEASURABLE OUTCOME GOALS.—
23 The strategic plan shall include measurable out-
24 come goals.

1 “(D) PUBLICATION.—The National Coor-
2 dinator shall publish the strategic plan, includ-
3 ing all updates.

4 “(4) WEBSITE.—The National Coordinator
5 shall maintain and frequently update an Internet
6 website on which there is posted information that in-
7 cludes the following:

8 “(A) The schedule developed by the HIT
9 Standards Committee under section 3003(b)(3).

10 “(B) The recommendations of the HIT
11 Policy Committee under section 3002.

12 “(C) Recommendations of the HIT Stand-
13 ards Committee under section 3003.

14 “(D) Sources of Federal grant funds and
15 technical assistance that are available to facili-
16 tate the purchase of, or enhance the utilization
17 of, health information technology systems.

18 “(E) The report prepared by the National
19 Coordinator under paragraph (5).

20 “(F) The assessment by the National Co-
21 ordinator under paragraph (6).

22 “(G) The evaluation by the National Coor-
23 dinator under paragraph (7).

24 “(H) The annual estimate of resources re-
25 quired under paragraph (8).

1 “(5) IMPLEMENTATION REPORT.—The National
2 Coordinator shall prepare a report that identifies
3 lessons learned from major public and private health
4 care systems in their implementation of health infor-
5 mation technology systems, including information on
6 whether the systems and practices developed by such
7 systems may be applicable to and usable in whole or
8 in part by other health care providers.

9 “(6) ASSESSMENT OF IMPACT OF HIT ON COM-
10 MUNITIES WITH HEALTH DISPARITIES AND UNIN-
11 SURED, UNDERINSURED, AND MEDICALLY UNDER-
12 SERVED AREAS.—The National Coordinator shall as-
13 sess and publish the impact of health information
14 technology in communities with health disparities
15 and in areas that serve uninsured, underinsured,
16 and medically underserved individuals (including
17 urban and rural areas) and identify practices to in-
18 crease the adoption of such technology by health
19 care providers in such communities.

20 “(7) EVALUATION OF BENEFITS AND COSTS OF
21 THE ELECTRONIC USE AND EXCHANGE OF HEALTH
22 INFORMATION.—The National Coordinator shall
23 evaluate and publish evidence on the benefits and
24 costs of the electronic use and exchange of health in-

1 formation and assess to whom these benefits and
2 costs accrue.

3 “(8) RESOURCE REQUIREMENTS.—The Na-
4 tional Coordinator shall estimate and publish re-
5 sources required annually to reach the goal of utili-
6 zation of an electronic health record for each person
7 in the United States by 2014, including the required
8 level of Federal funding, expectations for regional,
9 State, and private investment, and the expected con-
10 tributions by volunteers to activities for the utiliza-
11 tion of such records.

12 “(9) CERTIFICATION.—

13 “(A) IN GENERAL.—The National Coordi-
14 nator, in consultation with the Director of the
15 National Institute of Standards and Tech-
16 nology, shall develop a program (either directly
17 or by contract) for the voluntary certification of
18 health information technology as being in com-
19 pliance with applicable certification criteria
20 adopted under this subtitle. Such program shall
21 include testing of the technology in accordance
22 with section 201(b) of the PRO(TECH)T Act
23 of 2008.

24 “(B) CERTIFICATION CRITERIA DE-
25 SCRIBED.—In this title, the term ‘certification

1 criteria' means, with respect to standards and
2 implementation specifications for health infor-
3 mation technology, criteria to establish that the
4 technology meets such standards and implemen-
5 tation specifications.

6 “(d) DETAIL OF FEDERAL EMPLOYEES.—

7 “(1) IN GENERAL.—Upon the request of the
8 National Coordinator, the head of any Federal agen-
9 cy is authorized to detail, with or without reimburse-
10 ment from the Office, any of the personnel of such
11 agency to the Office to assist it in carrying out its
12 duties under this section.

13 “(2) EFFECT OF DETAIL.—Any detail of per-
14 sonnel under paragraph (1) shall—

15 “(A) not interrupt or otherwise affect the
16 civil service status or privileges of the Federal
17 employee; and

18 “(B) be in addition to any other staff of
19 the Department employed by the National Co-
20 ordinator.

21 “(3) ACCEPTANCE OF DETAILEES.—Notwith-
22 standing any other provision of law, the Office may
23 accept detailed personnel from other Federal agen-
24 cies without regard to whether the agency described
25 under paragraph (1) is reimbursed.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this section
3 \$66,000,000 for fiscal year 2009.

4 **“SEC. 3002. HIT POLICY COMMITTEE.**

5 “(a) ESTABLISHMENT.—There is established a HIT
6 Policy Committee to make policy recommendations to the
7 National Coordinator relating to the implementation of a
8 nationwide health information technology infrastructure,
9 including implementation of the strategic plan described
10 in section 3001(e)(3).

11 “(b) DUTIES.—

12 “(1) RECOMMENDATIONS ON HEALTH INFOR-
13 MATION TECHNOLOGY INFRASTRUCTURE.—Not later
14 than 1 year after the date of the enactment of this
15 title, the HIT Policy Committee shall recommend a
16 policy framework for the development and adoption
17 of a nationwide health information technology infra-
18 structure that permits the electronic exchange and
19 use of health information as is consistent with the
20 strategic plan under section 3001(e)(3) and that in-
21 cludes the recommendations under paragraph (2).
22 Annually thereafter the Committee shall update such
23 recommendations and make new recommendations
24 as appropriate.

1 “(2) SPECIFIC AREAS OF STANDARD DEVELOP-
2 MENT.—

3 “(A) IN GENERAL.—The HIT Policy Com-
4 mittee shall recommend the areas in which
5 standards, implementation specifications, and
6 certification criteria are needed for the elec-
7 tronic exchange and use of health information
8 for purposes of adoption under section 3004(b)
9 and shall recommend an order of priority for
10 the development, harmonization, and recogni-
11 tion of such standards, specifications, and cri-
12 teria among the areas so recommended. Such
13 standards and implementation specifications
14 shall include named standards, architectures,
15 and software schemes for the authentication
16 and security of individually identifiable health
17 information and other information as needed to
18 ensure the reproducible development of common
19 solutions across disparate entities.

20 “(B) AREAS REQUIRED FOR CONSIDER-
21 ATION.—For purposes of subparagraph (A), the
22 HIT Policy Committee shall make recommenda-
23 tions for at least the following areas:

24 “(i) Technologies that protect the pri-
25 vacy of health information and promote se-

1 curity, including for the segmentation and
2 protection from disclosure of specific and
3 sensitive individually identifiable health in-
4 formation, in accordance with applicable
5 law, and for the use and disclosure of lim-
6 ited data sets (as defined for purposes of
7 regulations promulgated under section
8 264(c) of the Health Insurance Portability
9 and Accountability Act of 1996) of such
10 information.

11 “(ii) A nationwide health information
12 technology infrastructure that allows for
13 the electronic use and exchange of health
14 information.

15 “(iii) The utilization of an electronic
16 health record for each person in the United
17 States by 2014.

18 “(iv) Technologies that allow for an
19 accounting of disclosures made by a cov-
20 ered entity (as defined for purposes of reg-
21 ulations promulgated under section 264(c)
22 of the Health Insurance Portability and
23 Accountability Act of 1996) for purposes
24 of treatment, payment, and health care op-

1 erations (as such terms are defined for
2 purposes of such regulations).

3 “(C) OTHER AREAS FOR CONSIDER-
4 ATION.—In making recommendations under
5 subparagraph (A), the HIT Policy Committee
6 may consider the following additional areas:

7 “(i) The appropriate uses of a nation-
8 wide health information infrastructure, in-
9 cluding for purposes of—

10 “(I) the collection of quality data
11 and public reporting;

12 “(II) biosurveillance and public
13 health;

14 “(III) medical and clinical re-
15 search; and

16 “(IV) drug safety.

17 “(ii) Self-service technologies that fa-
18 cilitate the use and exchange of patient in-
19 formation and reduce wait times.

20 “(iii) Telemedicine technologies, in
21 order to reduce travel requirements for pa-
22 tients in remote areas.

23 “(iv) Technologies that facilitate home
24 health care and the monitoring of patients
25 recuperating at home.

1 “(v) Technologies that help reduce
2 medical errors.

3 “(vi) Technologies that facilitate the
4 continuity of care among health settings.

5 “(vii) Technologies that meet the
6 needs of diverse populations.

7 “(viii) Any other technology that the
8 HIT Policy Committee finds to be among
9 the technologies with the greatest potential
10 to improve the quality and efficiency of
11 health care.

12 “(3) FORUM.—The HIT Policy Committee shall
13 serve as a forum for broad stakeholder input with
14 specific expertise in policies relating to the matters
15 described in paragraphs (1) and (2).

16 “(4) WEBSITE.—The HIT Policy Committee
17 shall develop and maintain an Internet website on
18 which there is posted information that includes the
19 following:

20 “(A) Established governance rules.

21 “(B) A business plan.

22 “(C) Meeting notices at least 14 days prior
23 to each meeting.

24 “(D) Meeting agendas at least 7 days prior
25 to each meeting.

1 “(E) Meeting materials at least 3 days
2 prior to each meeting.

3 “(c) MEMBERSHIP.—

4 “(1) APPOINTMENTS.—The HIT Policy Com-
5 mittee shall be composed of members to be ap-
6 pointed as follows:

7 “(A) 3 members shall be appointed by the
8 Secretary, 1 of whom shall be appointed to rep-
9 resent the Department of Health and Human
10 Services and 1 of whom shall be a public health
11 official.

12 “(B) 1 member shall be appointed by the
13 majority leader of the Senate.

14 “(C) 1 member shall be appointed by the
15 minority leader of the Senate.

16 “(D) 1 member shall be appointed by the
17 Speaker of the House of Representatives.

18 “(E) 1 member shall be appointed by the
19 minority leader of the House of Representa-
20 tives.

21 “(F) Such other members as shall be ap-
22 pointed by the President as representatives of
23 other relevant Federal agencies.

1 “(G) 11 members shall be appointed by the
2 Comptroller General of the United States of
3 whom—

4 “(i) 1 member shall be an advocate
5 for patients or consumers;

6 “(ii) 2 members shall represent health
7 care providers, one of which shall be a phy-
8 sician;

9 “(iii) 1 member shall be from a labor
10 organization representing health care
11 workers;

12 “(iv) 1 member shall have expertise in
13 privacy and security;

14 “(v) 1 member shall have expertise in
15 improving the health of vulnerable popu-
16 lations;

17 “(vi) 1 member shall be from the
18 health research community;

19 “(vii) 1 member shall represent health
20 plans or other third-party payers;

21 “(viii) 1 member shall represent infor-
22 mation technology vendors;

23 “(ix) 1 member shall represent pur-
24 chasers or employers; and

1 “(x) 1 member shall have expertise in
2 health care quality measurement and re-
3 porting.

4 “(2) NATIONAL COORDINATOR.—The National
5 Coordinator shall be a member of the HIT Policy
6 Committee and act as a liaison among the HIT Pol-
7 icy Committee, the HIT Standards Committee, and
8 the Federal Government.

9 “(3) CHAIRPERSON AND VICE CHAIRPERSON.—
10 The HIT Policy Committee shall designate 1 mem-
11 ber to serve as the chairperson and 1 member to
12 serve as the vice chairperson of the HIT Policy
13 Committee.

14 “(4) PARTICIPATION.—The members of the
15 HIT Policy Committee appointed under paragraph
16 (1) shall represent a balance among various sectors
17 of the health care system so that no single sector
18 unduly influences the recommendations of such
19 Committee.

20 “(5) TERMS.—

21 “(A) IN GENERAL.—The terms of mem-
22 bers of the HIT Policy Committee appointed
23 under paragraph (1) shall be 3 years except
24 that the Comptroller General of the United
25 States shall designate staggered terms for the

1 members first appointed under paragraph
2 (1)(G).

3 “(B) VACANCIES.—Any member appointed
4 to fill a vacancy in the membership of the HIT
5 Policy Committee that occurs prior to the expi-
6 ration of the term for which the member’s pred-
7 ecessor was appointed shall be appointed only
8 for the remainder of that term. A member may
9 serve after the expiration of that member’s
10 term until a successor has been appointed. A
11 vacancy in the HIT Policy Committee shall be
12 filled in the manner in which the original ap-
13 pointment was made.

14 “(6) OUTSIDE INVOLVEMENT.—The HIT Policy
15 Committee shall ensure an adequate opportunity for
16 the participation in activities of the Committee of
17 outside advisors, including individuals with expertise
18 in the development of policies for the electronic ex-
19 change and use of health information, including in
20 the areas of health information privacy and security.

21 “(7) QUORUM.—Ten members of the HIT Pol-
22 icy Committee shall constitute a quorum for pur-
23 poses of voting, but a lesser number of members
24 may meet and hold hearings.

1 “(d) APPLICATION OF FACA.—The Federal Advisory
2 Committee Act (5 U.S.C. App.), other than section 14 of
3 such Act, shall apply to the HIT Policy Committee.

4 “(e) PUBLICATION.—The Secretary shall provide for
5 publication in the Federal Register and the posting on the
6 Internet website of the Office of the National Coordinator
7 for Health Information Technology of all policy rec-
8 ommendations made by the HIT Policy Committee under
9 this section.

10 **“SEC. 3003. HIT STANDARDS COMMITTEE.**

11 “(a) ESTABLISHMENT.—There is established a com-
12 mittee to be known as the HIT Standards Committee to
13 recommend to the National Coordinator standards, imple-
14 mentation specifications, and certification criteria for the
15 electronic exchange and use of health information for pur-
16 poses of adoption under section 3004(b), consistent with
17 the implementation of the strategic plan described in sec-
18 tion 3001(c)(3).

19 “(b) DUTIES.—

20 “(1) STANDARD DEVELOPMENT.—

21 “(A) IN GENERAL.—Beginning not later
22 than 1 year after the date of the enactment of
23 this title, the HIT Standards Committee shall
24 recommend to the National Coordinator stand-
25 ards, implementation specifications, and certifi-

1 cation criteria described in subsection (a) that
2 have been developed, harmonized, or recognized
3 by the Committee. Annually thereafter the
4 Committee shall update such recommendations
5 and make new recommendations as appropriate,
6 including in response to a notification sent
7 under section 3004(b)(2). Such recommenda-
8 tions shall be consistent with the latest rec-
9 ommendations made by the HIT Policy Com-
10 mittee.

11 “(B) PILOT TESTING OF STANDARDS AND
12 IMPLEMENTATION SPECIFICATIONS.—In the de-
13 velopment, harmonization, or recognition of
14 standards and implementation specifications,
15 the HIT Standards Committee, as appropriate,
16 shall provide for the testing of such standards
17 and specifications by the National Institute for
18 Standards and Technology under section 201 of
19 the PRO(TECH)T Act of 2008.

20 “(C) CONSISTENCY.—The standards, im-
21 plementation specifications, and certification
22 criteria recommended under this subsection
23 shall be consistent with the standards for infor-
24 mation transactions and data elements adopted

1 pursuant to section 1173 of the Social Security
2 Act.

3 “(2) FORUM.—The HIT Standards Committee
4 shall serve as a forum for the participation of a
5 broad range of stakeholders to provide input on the
6 development, harmonization, and recognition of
7 standards, implementation specifications, and certifi-
8 cation criteria necessary for the development and
9 adoption of a nationwide health information tech-
10 nology infrastructure that allows for the electronic
11 use and exchange of health information.

12 “(3) SCHEDULE.—Not later than 90 days after
13 the date of the enactment of this title, the HIT
14 Standards Committee shall develop a schedule for
15 the assessment of policy recommendations developed
16 by the HIT Policy Committee under section 3002.
17 The HIT Standards Committee shall update such
18 schedule annually. The Secretary shall publish such
19 schedule in the Federal Register.

20 “(4) PUBLIC INPUT.—The HIT Standards
21 Committee shall conduct open public meetings and
22 develop a process to allow for public comment on the
23 schedule described in paragraph (3) and rec-
24 ommendations described in this subsection. Under
25 such process comments shall be submitted in a time-

1 ly manner after the date of publication of a rec-
2 ommendation under this subsection.

3 “(5) WEBSITE.—The HIT Standards Com-
4 mittee shall develop and maintain an Internet
5 website on which there is posted information that in-
6 cludes the following:

7 “(A) Established governance rules.

8 “(B) A business plan.

9 “(C) Meeting notices at least 14 days prior
10 to each meeting.

11 “(D) Meeting agendas at least 7 days prior
12 to each meeting.

13 “(E) Meeting materials at least 3 days
14 prior to each meeting.

15 “(6) REQUIREMENT TO INTEGRATE REC-
16 OMMENDATIONS.—In carrying out the activities
17 under this section, the HIT Standards Committee
18 shall integrate the recommendations of the HIT Pol-
19 icy Committee.

20 “(c) MEMBERSHIP.—

21 “(1) APPOINTMENTS.—The HIT Standards
22 Committee shall be composed of members to be ap-
23 pointed as follows:

24 “(A) 2 members shall be appointed by the
25 Secretary.

1 “(B) 1 member shall be appointed by the
2 majority leader of the Senate.

3 “(C) 1 member shall be appointed by the
4 minority leader of the Senate.

5 “(D) 1 member shall be appointed by the
6 Speaker of the House of Representatives.

7 “(E) 1 member shall be appointed by the
8 minority leader of the House of Representa-
9 tives.

10 “(F) 9 members shall be appointed by the
11 Comptroller General of the United States of
12 whom—

13 “(i) 1 member shall be a representa-
14 tive of consumer or patient organizations;

15 “(ii) 1 member shall be a representa-
16 tive of organizations with expertise in pri-
17 vacy;

18 “(iii) 1 member shall be a representa-
19 tive of organizations with expertise in secu-
20 rity;

21 “(iv) 2 members shall be a representa-
22 tive of health care providers, one of which
23 shall be a physician;

1 “(v) 1 member shall be a representa-
2 tive of health plans or other third party
3 payers;

4 “(vi) 1 member shall be a representa-
5 tive of information technology vendors;

6 “(vii) 1 member shall be a representa-
7 tive of purchasers or employers; and

8 “(viii) 1 member shall be a represent-
9 ative of the health research community.

10 “(G) 1 member shall be appointed by the
11 Director of the National Institute for Standards
12 and Technology.

13 “(2) NATIONAL COORDINATOR.—The National
14 Coordinator shall be a member of the HIT Stand-
15 ards Committee and act as a liaison among the HIT
16 Standards Committee, the HIT Policy Committee,
17 and the Federal government.

18 “(3) CHAIRPERSON AND VICE CHAIRPERSON.—
19 The HIT Standards Committee shall designate 1
20 member to serve as the chairperson and 1 member
21 to serve as the vice chairperson of the Committee.

22 “(4) PARTICIPATION.—The members of the
23 HIT Standards Committee appointed under para-
24 graph (1) shall represent a balance among various
25 sectors of the health care system so that no single

1 sector unduly influences the recommendations of
2 such Committee.

3 “(5) TERMS.—

4 “(A) IN GENERAL.—The terms of mem-
5 bers of the HIT Standards Committee ap-
6 pointed under paragraph (1) shall be 3 years
7 except that the Comptroller General of the
8 United States shall designate staggered terms
9 for the members first appointed under para-
10 graph (1)(F).

11 “(B) VACANCIES.—Any member appointed
12 to fill a vacancy in the membership of the HIT
13 Standards Committee that occurs prior to the
14 expiration of the term for which the member’s
15 predecessor was appointed shall be appointed
16 only for the remainder of that term. A member
17 may serve after the expiration of that member’s
18 term until a successor has been appointed. A
19 vacancy in the HIT Standards Committee shall
20 be filled in the manner in which the original ap-
21 pointment was made.

22 “(6) OUTSIDE INVOLVEMENT.—The HIT
23 Standards Committee shall ensure an adequate op-
24 portunity for the participation in activities of the
25 Committee of outside advisors, including individuals

1 with expertise in the development of standards for
2 the electronic exchange and use of health informa-
3 tion, including in the areas of health information
4 privacy and security.

5 “(7) QUORUM.—Eight members of the HIT
6 Standards Committee shall constitute a quorum for
7 purposes of voting, but a lesser number of members
8 may meet and hold hearings.

9 “(d) APPLICATION OF FACCA.—The Federal Advisory
10 Committee Act (5 U.S.C. App.), other than section 14,
11 shall apply to the HIT Standards Committee.

12 “(e) PUBLICATION.—The Secretary shall provide for
13 publication in the Federal Register and the posting on the
14 Internet website of the Office of the National Coordinator
15 for Health Information Technology of all recommenda-
16 tions made by the HIT Standards Committee under this
17 section.

18 **“SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED REC-**
19 **COMMENDATIONS.**

20 “(a) REVIEW OF ENDORSED STANDARDS, SPECI-
21 FICATIONS, AND CRITERIA.—Not later than 90 days after
22 the date of receipt of standards, implementation specifica-
23 tions, or certification criteria endorsed under section
24 3001(c), the Secretary, in consultation with representa-
25 tives of other relevant Federal agencies, shall jointly re-

1 view such standards, specifications, or criteria and shall
2 determine whether or not to propose adoption of such
3 standards, specifications, or criteria.

4 “(b) DETERMINATION TO ADOPT STANDARDS, SPEC-
5 IFICATIONS, AND CRITERIA.—If the Secretary deter-
6 mines—

7 “(1) to propose adoption of any grouping of
8 such standards, specifications, or criteria, the Sec-
9 retary shall, through a rulemaking process, deter-
10 mine whether or not to adopt such grouping of
11 standards, specifications, or criteria; or

12 “(2) not to propose adoption of any grouping of
13 standards, specifications, or criteria, the Secretary
14 shall notify the National Coordinator and the HIT
15 Standards Committee in writing of such determina-
16 tion and the reasons for not proposing the adoption
17 of such recommendation.

18 “(c) PUBLICATION.—The Secretary shall provide for
19 publication in the Federal Register of all determinations
20 made by the Secretary under subsection (a).

21 **“SEC. 3005. APPLICATION AND USE OF ADOPTED STAND-**
22 **ARDS AND IMPLEMENTATION SPECIFICA-**
23 **TIONS BY FEDERAL AGENCIES.**

24 “For requirements relating to the application and use
25 by Federal agencies of the standards and implementation

1 specifications adopted under section 3004(b), see section
2 111 of the PRO(TECH)T Act of 2008.

3 **“SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPT-**
4 **ED STANDARDS AND IMPLEMENTATION**
5 **SPECIFICATIONS BY PRIVATE ENTITIES.**

6 “(a) IN GENERAL.—Except as provided under section
7 112 of the PRO(TECH)T Act of 2008, any standard or
8 implementation specification adopted under section
9 3004(b) shall be voluntary with respect to private entities.

10 “(b) RULE OF CONSTRUCTION.—Nothing in this sub-
11 title shall be construed to require that a private entity that
12 enters into a contract with the Federal Government apply
13 or use the standards and implementation specifications
14 adopted under section 3004(b) with respect to activities
15 not related to the contract.

16 **“SEC. 3007. HEALTH INFORMATION TECHNOLOGY RE-**
17 **SOURCE CENTER.**

18 “(a) DEVELOPMENT.—

19 “(1) IN GENERAL.—The National Coordinator
20 shall develop a Health Information Technology Re-
21 source Center to provide technical assistance and de-
22 velop best practices to support and accelerate efforts
23 to adopt, implement, and effectively use health infor-
24 mation technology that allows for the electronic ex-
25 change and use of information in compliance with

1 standards, implementation specifications, and certifi-
2 cation criteria adopted under section 3004(b).

3 “(2) PURPOSES.—The purpose of the Center is
4 to—

5 “(A) provide a forum for the exchange of
6 knowledge and experience;

7 “(B) accelerate the transfer of lessons
8 learned from existing public and private sector
9 initiatives, including those currently receiving
10 Federal financial support;

11 “(C) assemble, analyze, and widely dis-
12 seminate evidence and experience related to the
13 adoption, implementation, and effective use of
14 health information technology that allows for
15 the electronic exchange and use of information;

16 “(D) provide technical assistance for the
17 establishment and evaluation of regional and
18 local health information networks to facilitate
19 the electronic exchange of information across
20 health care settings and improve the quality of
21 health care;

22 “(E) provide technical assistance for the
23 development and dissemination of solutions to
24 barriers to the exchange of electronic health in-
25 formation;

1 “(F) learn about effective strategies to
2 adopt and utilize health information technology
3 in medically underserved communities;

4 “(G) conduct other activities identified by
5 the States, local or regional health information
6 networks, or health care stakeholders as a focus
7 for developing and sharing best practices; and

8 “(H) provide technical assistance to pro-
9 mote adoption and utilization of health informa-
10 tion technology by health care providers, includ-
11 ing in medically underserved communities.

12 “(b) TECHNICAL ASSISTANCE TELEPHONE NUMBER
13 OR WEBSITE.—The National Coordinator shall establish
14 a toll-free telephone number or Internet website to provide
15 health care providers with a single point of contact to—

16 “(1) learn about Federal grants and technical
17 assistance services related to the electronic exchange
18 and use of health information;

19 “(2) learn about standards, implementation
20 specifications, and certification criteria adopted
21 under section 3004(b);

22 “(3) learn about regional and local health infor-
23 mation networks for assistance with health informa-
24 tion technology; and

1 “(4) disseminate additional information deter-
2 mined by the National Coordinator.”.

3 **SEC. 102. TRANSITIONS.**

4 (a) ONCHIT.—To the extent consistent with section
5 3001 of the Public Health Service Act, as added by section
6 101, all functions, personnel, assets, liabilities, and admin-
7 istrative actions applicable to the National Coordinator for
8 Health Information Technology appointed under Execu-
9 tive Order 13335 or the Office of such National Coordi-
10 nator on the date before the date of the enactment of this
11 Act shall be transferred to the National Coordinator ap-
12 pointed under section 3001(a) of such Act and the Office
13 of such National Coordinator as of the date of the enact-
14 ment of this Act.

15 (b) AHIC.—

16 (1) To the extent consistent with sections 3002
17 and 3003 of the Public Health Service Act, as added
18 by section 101, all functions, personnel, assets, and
19 liabilities applicable to the American Health Infor-
20 mation Community created in response to Executive
21 Order 13335 as of the day before the date of the en-
22 actment of this Act shall be transferred to the HIT
23 Policy Committee or the HIT Standards Committee,
24 established under section 3002(a) or 3003(a) of such

1 Act, as appropriate, as of the date of the enactment
2 of this Act.

3 (2) In carrying out section 3003(b)(1)(A) of the
4 Public Health Service Act, as so added, until rec-
5 ommendations are made by the HIT Policy Com-
6 mittee, recommendations of the HIT Standards
7 Committee shall be consistent with the most recent
8 recommendations made by the American Health In-
9 formation Community.

10 (c) RULES OF CONSTRUCTION.—

11 (1) ONCHIT.—Nothing in section 3001 of the
12 Public Health Service Act, as added by section 101,
13 or subsection (a) shall be construed as requiring the
14 creation of a new entity to the extent that the Office
15 of the National Coordinator for Health Information
16 Technology established pursuant to Executive Order
17 13335 is consistent with the provisions of such sec-
18 tion 3001.

19 (2) AHIC.—Nothing in sections 3002 or 3003
20 of the Public Health Service Act, as added by sec-
21 tion 101, or subsection (b) shall be construed as re-
22 quiring the creation of a new entity to the extent
23 that the American Health Information Community
24 created in response to Executive Order 13335 is

1 consistent with the provisions of such sections 3002
2 and 3003.

3 **PART II—APPLICATION AND USE OF ADOPTED**
4 **HEALTH INFORMATION TECHNOLOGY**
5 **STANDARDS; REPORTS**

6 **SEC. 111. COORDINATION OF FEDERAL ACTIVITIES WITH**
7 **ADOPTED STANDARDS AND IMPLEMENTA-**
8 **TION SPECIFICATIONS.**

9 (a) SPENDING ON HEALTH INFORMATION TECH-
10 NOLOGY SYSTEMS.—As each agency (as defined in the Ex-
11 ecutive Order issued on August 22, 2006, relating to pro-
12 moting quality and efficient health care in Federal govern-
13 ment administered or sponsored health care programs) im-
14 plements, acquires, or upgrades health information tech-
15 nology systems used for the direct exchange of individually
16 identifiable health information between agencies and with
17 non-Federal entities, it shall utilize, where available,
18 health information technology systems and products that
19 meet standards and implementation specifications adopted
20 under section 3004(b) of the Public Health Service Act,
21 as added by section 101.

22 (b) FEDERAL INFORMATION COLLECTION ACTIVI-
23 TIES.—With respect to a standard or implementation
24 specification adopted under section 3004(b) of the Public
25 Health Service Act, as added by section 101, the President

1 shall take measures to ensure that Federal activities in-
2 volving the broad collection and submission of health in-
3 formation are consistent with such standard or specifica-
4 tion, respectively, within three years after the date of such
5 adoption.

6 (c) APPLICATION OF DEFINITIONS.—The definitions
7 contained in section 3000 of the Public Health Service
8 Act, as added by section 101, shall apply for purposes of
9 this part.

10 **SEC. 112. APPLICATION TO PRIVATE ENTITIES.**

11 Each agency (as defined in such Executive Order
12 issued on August 22, 2006, relating to promoting quality
13 and efficient health care in Federal government adminis-
14 tered or sponsored health care programs) shall require in
15 contracts or agreements with health care providers, health
16 plans, or health insurance issuers that as each provider,
17 plan, or issuer implements, acquires, or upgrades health
18 information technology systems, it shall utilize, where
19 available, health information technology systems and prod-
20 ucts that meet standards and implementation specifica-
21 tions adopted under section 3004(b) of the Public Health
22 Service Act, as added by section 101.

23 **SEC. 113. STUDY AND REPORTS.**

24 (a) REPORT ON ADOPTION OF NATIONWIDE SYS-
25 TEM.—Not later than 2 years after the date of the enact-

1 ment of this Act and annually thereafter, the Secretary
2 of Health and Human Services shall submit to the Com-
3 mittee on Health, Education, Labor, and Pensions and the
4 Committee on Commerce, Science, and Transportation of
5 the Senate and the Committee on Energy and Commerce
6 and the Committee on Science and Technology of the
7 House of Representatives a report that—

8 (1) describes the specific actions that have been
9 taken by the Federal Government and private enti-
10 ties to facilitate the adoption of a nationwide system
11 for the electronic use and exchange of health infor-
12 mation;

13 (2) describes barriers to the adoption of such a
14 nationwide system; and

15 (3) contains recommendations to achieve full
16 implementation of such a nationwide system.

17 (b) REIMBURSEMENT INCENTIVE STUDY AND RE-
18 PORT.—

19 (1) STUDY.—The Secretary of Health and
20 Human Services shall carry out, or contract with a
21 private entity to carry out, a study that examines
22 methods to create efficient reimbursement incentives
23 for improving health care quality in Federally quali-
24 fied health centers, rural health clinics, and free
25 clinics.

1 (2) REPORT.—Not later than 2 years after the
2 date of the enactment of this Act, the Secretary of
3 Health and Human Services shall submit to the
4 Committee on Health, Education, Labor, and Pen-
5 sions and the Committee on Commerce, Science, and
6 Transportation of the Senate and the Committee on
7 Energy and Commerce and the Committee on
8 Science and Technology of the House of Representa-
9 tives a report on the study carried out under para-
10 graph (1).

11 **Subtitle B—Incentives for the Use**
12 **of Health Information Technology**

13 **SEC. 121. GRANT, LOAN, AND DEMONSTRATION PROGRAMS.**

14 Title XXX of the Public Health Service Act, as added
15 by section 101, is amended by adding at the end the fol-
16 lowing new subtitle:

17 **“Subtitle B—Incentives for the Use**
18 **of Health Information Technology**

19 **“SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDE-**
20 **SPREAD ADOPTION OF QUALIFIED HEALTH**
21 **INFORMATION TECHNOLOGY.**

22 “(a) COMPETITIVE GRANTS TO FACILITATE THE
23 WIDESPREAD ADOPTION OF HEALTH INFORMATION
24 TECHNOLOGY.—

1 “(1) IN GENERAL.—The National Coordinator
2 may award competitive grants to eligible entities to
3 purchase qualified health information technology.

4 “(2) QUALIFIED HEALTH INFORMATION TECH-
5 NOLOGY.—For purposes of this section, the term
6 ‘qualified health information technology’ means
7 health information technology that consists of hard-
8 ware, software, or the provision of support services
9 and that—

10 “(A) enables the protection of health infor-
11 mation, in accordance with applicable law;

12 “(B) is (or is necessary for the operation
13 of) an electronic health records system, includ-
14 ing the provision of decision support and physi-
15 cian order entry for medications;

16 “(C) has the ability to allow timely and
17 permissible access to patient information and to
18 transmit and exchange health information
19 among providers, patients, or insurers; and

20 “(D) is certified under the program devel-
21 oped under section 3001(c)(9) to be in compli-
22 ance with any applicable standards and imple-
23 mentation specifications adopted under section
24 3004(b).

1 “(3) ELIGIBILITY.—To be eligible to receive a
2 grant under paragraph (1) an entity shall—

3 “(A) submit to the National Coordinator
4 an application at such time and in such manner
5 as the National Coordinator may require, and
6 containing—

7 “(i) a plan on how the entity intends
8 to maintain and support the qualified
9 health information technology that would
10 be purchased with amounts under such
11 grant, including the type of resources ex-
12 pected to be involved; and

13 “(ii) such other information as the
14 National Coordinator may require;

15 “(B) submit to the National Coordinator a
16 plan for how qualified health information tech-
17 nology purchased by the entity will result in the
18 electronic exchange and use of health informa-
19 tion;

20 “(C) be—

21 “(i) a not for profit hospital or a Fed-
22 erally qualified health center (as defined in
23 section 1861(aa)(4) of the Social Security
24 Act);

1 “(ii) an individual or group practice;

2 or

3 “(iii) another health care provider,

4 such as a rural health clinic, not described

5 in clause (i) or (ii);

6 “(D) demonstrate significant financial

7 need;

8 “(E) agree to notify individuals in accord-

9 ance with section 302 of the PRO(TECH)T Act

10 of 2008 (relating to notifications in the case of

11 breaches);

12 “(F) provide matching funds in accordance

13 with paragraph (5);

14 “(G) consult with the Health Information

15 Technology Resource Center established under

16 section 3007 to access the knowledge and expe-

17 rience of existing initiatives regarding the suc-

18 cessful implementation and effective use of

19 health information technology; and

20 “(H) link, to the extent practicable, to one

21 or more local or regional health information

22 plans.

23 “(4) USE OF FUNDS.—Amounts received under

24 a grant under this subsection shall be used to facili-

1 tate the purchase of qualified health information
2 technology.

3 “(5) MATCHING REQUIREMENT.—To be eligible
4 for a grant under this subsection an entity shall con-
5 tribute non-Federal contributions to the costs of car-
6 rying out the activities for which the grant is award-
7 ed in an amount equal to \$1 for each \$3 of Federal
8 funds provided under the grant.

9 “(6) PREFERENCE IN AWARDING GRANTS.—In
10 awarding grants under this subsection the National
11 Coordinator shall give preference to the following eli-
12 gible entities:

13 “(A) Small health care providers.

14 “(B) Entities that are located in rural and
15 other areas that serve uninsured, underinsured,
16 and medically underserved individuals (regard-
17 less of whether such area is urban or rural).

18 “(C) Nonprofit health care providers.

19 “(7) ADDITIONAL SOURCES OF FUNDING FOR
20 HEALTH INFORMATION TECHNOLOGY.—Funding
21 made available under this subsection is in addition
22 to funding which may be used toward the acquisition
23 and utilization of health information technology
24 under other law, which includes the following:

1 “(A) Medicaid transformation grants
2 under section 1903(z) of the Social Security
3 Act.

4 “(B) Grants or funding available through
5 the Agency for Healthcare Research and Qual-
6 ity.

7 “(C) Grants or funding that may be avail-
8 able through the Health Resources and Services
9 Administration for investment in health infor-
10 mation technologies or telehealth.

11 “(D) Grants or funding that may be avail-
12 able through the Department of Agriculture’s
13 Rural Development Telecommunications Pro-
14 gram for investment in telemedicine.

15 “(b) COMPETITIVE GRANTS TO STATES AND INDIAN
16 TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO
17 FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED
18 HEALTH INFORMATION TECHNOLOGY.—

19 “(1) IN GENERAL.—The National Coordinator
20 may award competitive grants to eligible entities for
21 the establishment of programs for loans to health
22 care providers to purchase qualified health informa-
23 tion technology.

24 “(2) ELIGIBLE ENTITY DEFINED.—For pur-
25 poses of this subsection, the term ‘eligible entity’

1 means a State or Indian tribe (as defined in the In-
2 dian Self-Determination and Education Assistance
3 Act) that—

4 “(A) submits to the National Coordinator
5 an application at such time, in such manner,
6 and containing such information as the Na-
7 tional Coordinator may require;

8 “(B) submits to the National Coordinator
9 a strategic plan in accordance with paragraph
10 (4) and provides to the National Coordinator
11 assurances that the entity will update such plan
12 annually in accordance with such paragraph;

13 “(C) provides assurances to the National
14 Coordinator that the entity will establish a
15 Loan Fund in accordance with paragraph (3);

16 “(D) provides assurances to the National
17 Coordinator that the entity will not provide a
18 loan from the Loan Fund to a health care pro-
19 vider unless the provider meets each of the con-
20 ditions described in paragraph (5); and

21 “(E) agrees to provide matching funds in
22 accordance with paragraph (9).

23 “(3) ESTABLISHMENT OF FUND.—For purposes
24 of paragraph (2)(C), an eligible entity shall establish
25 a qualified health information technology loan fund

1 (referred to in this subsection as a ‘Loan Fund’)
2 and comply with the other requirements contained in
3 this section. A grant to an eligible entity under this
4 subsection shall be deposited in the Loan Fund es-
5 tablished by the eligible entity. No funds authorized
6 by other provisions of this subtitle to be used for
7 other purposes specified in this subtitle shall be de-
8 posited in any Loan Fund.

9 “(4) STRATEGIC PLAN.—

10 “(A) IN GENERAL.—For purposes of para-
11 graph (2)(B), a strategic plan of an eligible en-
12 tity under this paragraph shall identify the in-
13 tended uses of amounts available to the Loan
14 Fund of such entity.

15 “(B) CONTENTS.—A strategic plan under
16 subparagraph (A), with respect to a Loan Fund
17 of an eligible entity, shall include for a year the
18 following:

19 “(i) A list of the projects to be as-
20 sisted through the Loan Fund during such
21 year.

22 “(ii) A description of the criteria and
23 methods established for the distribution of
24 funds from the Loan Fund during the
25 year.

1 “(iii) A description of the financial
2 status of the Loan Fund as of the date of
3 submission of the plan.

4 “(iv) The short-term and long-term
5 goals of the Loan Fund.

6 “(5) HEALTH CARE PROVIDER CONDITIONS FOR
7 RECEIPT OF LOANS.—For purposes of paragraph
8 (2)(D), the conditions described in this paragraph,
9 with respect to a health care provider that seeks a
10 loan from a Loan Fund established under this sub-
11 section, are the following:

12 “(A) The health care provider links, to the
13 extent practicable, to one or more local or re-
14 gional health information networks.

15 “(B) The health care provider consults
16 with the Health Information Technology Re-
17 source Center established under section 3007 to
18 access the knowledge and experience of existing
19 initiatives regarding the successful implementa-
20 tion and effective use of health information
21 technology.

22 “(C) The health care provider agrees to
23 notify individuals in accordance with section
24 302 of the PRO(TECH)T Act of 2008 (relating
25 to notifications in the case of breaches).

1 “(D) The health care provider submits to
2 the State or Indian tribe involved a plan on how
3 the health care provider intends to maintain
4 and support the qualified health information
5 technology that would be purchased with such
6 loan, including the type of resources expected to
7 be involved and any such other information as
8 the State or Indian Tribe, respectively, may re-
9 quire.

10 “(6) USE OF FUNDS.—

11 “(A) IN GENERAL.—Amounts deposited in
12 a Loan Fund, including loan repayments and
13 interest earned on such amounts, shall be used
14 only for awarding loans or loan guarantees,
15 making reimbursements described in paragraph
16 (8)(D)(i), or as a source of reserve and security
17 for leveraged loans, the proceeds of which are
18 deposited in the Loan Fund established under
19 paragraph (1). Loans under this section may be
20 used by a health care provider to purchase
21 qualified health information technology.

22 “(B) LIMITATION.—Amounts received by
23 an eligible entity under this subsection may not
24 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; or

5 “(ii) to conduct activities for which
6 Federal funds are expended under this
7 title.

8 “(7) TYPES OF ASSISTANCE.—Except as other-
9 wise limited by applicable State law, amounts depos-
10 ited into a Loan Fund under this subsection may
11 only be used for the following:

12 “(A) To award loans that comply with the
13 following:

14 “(i) The interest rate for each loan
15 shall not exceed the market interest rate.

16 “(ii) The principal and interest pay-
17 ments on each loan shall commence not
18 later than 1 year after the date the loan
19 was awarded, and each loan shall be fully
20 amortized not later than 10 years after the
21 date of the loan.

22 “(iii) The Loan Fund shall be cred-
23 ited with all payments of principal and in-
24 terest on each loan awarded from the Loan
25 Fund.

1 “(B) To guarantee, or purchase insurance
2 for, a local obligation (all of the proceeds of
3 which finance a project eligible for assistance
4 under this subsection) if the guarantee or pur-
5 chase would improve credit market access or re-
6 duce the interest rate applicable to the obliga-
7 tion involved.

8 “(C) As a source of revenue or security for
9 the payment of principal and interest on rev-
10 enue or general obligation bonds issued by the
11 eligible entity if the proceeds of the sale of the
12 bonds will be deposited into the Loan Fund.

13 “(D) To earn interest on the amounts de-
14 posited into the Loan Fund.

15 “(E) To make reimbursements described in
16 paragraph (8)(D)(i).

17 “(8) ADMINISTRATION OF LOAN FUNDS.—

18 “(A) COMBINED FINANCIAL ADMINISTRA-
19 TION.—An eligible entity may (as a convenience
20 and to avoid unnecessary administrative costs)
21 combine, in accordance with applicable State
22 law, the financial administration of a Loan
23 Fund established under this subsection with the
24 financial administration of any other revolving
25 fund established by the entity if otherwise not

1 prohibited by the law under which the Loan
2 Fund was established.

3 “(B) COST OF ADMINISTERING FUND.—
4 Each eligible entity may annually use not to ex-
5 ceed 4 percent of the funds provided to the en-
6 tity under a grant under this subsection to pay
7 the reasonable costs of the administration of
8 the programs under this section, including the
9 recovery of reasonable costs expended to estab-
10 lish a Loan Fund which are incurred after the
11 date of the enactment of this title.

12 “(C) GUIDANCE AND REGULATIONS.—The
13 National Coordinator shall publish guidance
14 and promulgate regulations as may be nec-
15 essary to carry out the provisions of this sub-
16 section, including—

17 “(i) provisions to ensure that each eli-
18 gible entity commits and expends funds al-
19 lotted to the entity under this subsection
20 as efficiently as possible in accordance with
21 this title and applicable State laws; and

22 “(ii) guidance to prevent waste, fraud,
23 and abuse.

24 “(D) PRIVATE SECTOR CONTRIBUTIONS.—

1 “(i) IN GENERAL.—A Loan Fund es-
2 tablished under this subsection may accept
3 contributions from private sector entities,
4 except that such entities may not specify
5 the recipient or recipients of any loan
6 issued under this subsection. An eligible
7 entity may agree to reimburse a private
8 sector entity for any contribution made
9 under this subparagraph, except that the
10 amount of such reimbursement may not be
11 greater than the principal amount of the
12 contribution made.

13 “(ii) AVAILABILITY OF INFORMA-
14 TION.—An eligible entity shall make pub-
15 licly available the identity of, and amount
16 contributed by, any private sector entity
17 under clause (i) and may issue letters of
18 commendation or make other awards (that
19 have no financial value) to any such entity.

20 “(9) MATCHING REQUIREMENTS.—

21 “(A) IN GENERAL.—The National Coordi-
22 nator may not make a grant under paragraph
23 (1) to an eligible entity unless the entity agrees
24 to make available (directly or through donations
25 from public or private entities) non-Federal

1 contributions in cash to the costs of carrying
2 out the activities for which the grant is awarded
3 in an amount equal to not less than \$1 for each
4 \$1 of Federal funds provided under the grant.

5 “(B) DETERMINATION OF AMOUNT OF
6 NON-FEDERAL CONTRIBUTION.—In determining
7 the amount of non-Federal contributions that
8 an eligible entity has provided pursuant to sub-
9 paragraph (A), the National Coordinator may
10 not include any amounts provided to the entity
11 by the Federal Government.

12 “(10) REPORTS.—The National Coordinator
13 shall annually submit to the Committee on Health,
14 Education, Labor, and Pensions and the Committee
15 on Finance of the Senate, and the Committee on
16 Energy and Commerce of the House of Representa-
17 tives, a report summarizing the reports received by
18 the National Coordinator from each eligible entity
19 that receives a grant under this subsection.

20 “(c) COMPETITIVE GRANTS FOR THE IMPLEMENTA-
21 TION OF REGIONAL OR LOCAL HEALTH INFORMATION
22 TECHNOLOGY PLANS.—

23 “(1) IN GENERAL.—The National Coordinator
24 may award competitive grants to eligible entities to
25 implement regional or local health information plans

1 to improve health care quality and efficiency through
2 the electronic exchange and use of health informa-
3 tion.

4 “(2) ELIGIBILITY.—To be eligible to receive a
5 grant under paragraph (1) an entity shall—

6 “(A) facilitate the electronic exchange and
7 use of health information within the local or re-
8 gional area and among local and regional areas;

9 “(B) demonstrate financial need to the Na-
10 tional Coordinator;

11 “(C) demonstrate that one of its principal
12 missions or purposes is to use information tech-
13 nology to improve health care quality and effi-
14 ciency;

15 “(D) adopt bylaws, memoranda of under-
16 standing, or other charter documents that dem-
17 onstrate that the governance structure and de-
18 cisionmaking processes of such entity allow for
19 participation on an ongoing basis by multiple
20 stakeholders within a community, including—

21 “(i) physicians (as defined in section
22 1861(r) of the Social Security Act), includ-
23 ing physicians that provide services to low
24 income populations and populations that
25 are uninsured, underinsured, and medically

1 underserved (including such populations in
2 urban and rural areas);

3 “(ii) hospitals (including hospitals
4 that provide services to low income and un-
5 derserved populations);

6 “(iii) pharmacists and pharmacies;

7 “(iv) health plans;

8 “(v) health centers (as defined in sec-
9 tion 330(b)) and Federally qualified health
10 centers (as defined in section 1861(aa)(4)
11 of the Social Security Act);

12 “(vi) rural health clinics (as defined in
13 section 1861(aa) of the Social Security
14 Act);

15 “(vii) patient or consumer organiza-
16 tions that reflect the population to be
17 served;

18 “(viii) employers;

19 “(ix) public health agencies; and

20 “(x) such other health care providers
21 or other entities, as determined appro-
22 priate by the National Coordinator;

23 “(E) demonstrate the participation, to the
24 extent practicable, of stakeholders in the elec-
25 tronic exchange and use of health information

1 within the local or regional health information
2 plan pursuant to subparagraph (D);

3 “(F) adopt nondiscrimination and conflict
4 of interest policies that demonstrate a commit-
5 ment to open, fair, and nondiscriminatory par-
6 ticipation in the regional or local health infor-
7 mation plan by all stakeholders;

8 “(G) comply with applicable standards and
9 implementation specifications adopted under
10 subtitle A of this title;

11 “(H) prepare and submit to the National
12 Coordinator an application in accordance with
13 paragraph (3); and

14 “(I) agree to provide matching funds in ac-
15 cordance with paragraph (6).

16 “(3) APPLICATION.—

17 “(A) IN GENERAL.—To be eligible to re-
18 ceive a grant under paragraph (1), an entity
19 shall submit to the National Coordinator an ap-
20 plication at such time, in such manner, and
21 containing such information (in addition to in-
22 formation required under subparagraph (B)), as
23 the National Coordinator may require.

1 “(B) REQUIRED INFORMATION.—At a
2 minimum, an application submitted under this
3 paragraph shall include—

4 “(i) clearly identified short-term and
5 long-term objectives of the regional or local
6 health information plan;

7 “(ii) an estimate of costs of the hard-
8 ware, software, training, and other services
9 necessary to implement the regional or
10 local health information plan;

11 “(iii) a strategy that includes initia-
12 tives to improve health care quality and ef-
13 ficiency;

14 “(iv) a plan that describes provisions
15 to encourage the electronic exchange and
16 use of health information by all physicians,
17 including single physician practices and
18 small physician groups, participating in the
19 health information plan;

20 “(v) a plan to ensure the privacy and
21 security of individually identifiable health
22 information that is consistent with applica-
23 ble Federal and State law;

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 sustainability of the
6 plan;

7 “(II) the financial costs and ben-
8 efits of the plan; and

9 “(III) the entities to which such
10 costs and benefits will accrue;

11 “(viii) a plan on how the entity in-
12 volved intends to maintain and support the
13 regional or local health information plan,
14 including the type of resources expected to
15 be involved; and

16 “(ix) in the case of an applicant that
17 is unable to demonstrate the participation
18 of all stakeholders pursuant to paragraph
19 (2)(D), the justification from the entity for
20 any such nonparticipation.

21 “(4) USE OF FUNDS.—Amounts received under
22 a grant under paragraph (1) shall be used to estab-
23 lish and implement a regional or local health infor-
24 mation plan in accordance with this subsection.

1 “(5) PREFERENCE.—In awarding grants under
2 paragraph (1), the Secretary shall give preference to
3 eligible entities that intend to use amounts received
4 under a grant to establish or implement a regional
5 or local health information plan that encompasses
6 communities with health disparities or areas that
7 serve uninsured, underinsured, and medically under-
8 served individuals (including urban and rural areas).

9 “(6) MATCHING REQUIREMENT.—

10 “(A) IN GENERAL.—The National Coordi-
11 nator may not make a grant under this sub-
12 section to an entity unless the entity agrees
13 that, with respect to the costs of carrying out
14 the activities for which the grant is awarded,
15 the entity will make available (directly or
16 through donations from public or private enti-
17 ties) non-Federal contributions toward such
18 costs in an amount equal to not less than 50
19 percent of such costs (\$1 for each \$2 of Federal
20 funds provided under the grant).

21 “(B) DETERMINATION OF AMOUNT CON-
22 TRIBUTED.—Non-Federal contributions re-
23 quired under subparagraph (A) may be in cash
24 or in kind, fairly evaluated, including equip-
25 ment, technology, or services. Amounts provided

1 by the Federal Government, or services assisted
2 or subsidized to any significant extent by the
3 Federal Government, may not be included in
4 determining the amount of such non-Federal
5 contributions.

6 “(d) REPORTS.—Not later than 1 year after the date
7 on which the first grant is awarded under this section,
8 and annually thereafter during the grant period, an entity
9 that receives a grant under this section shall submit to
10 the National Coordinator a report on the activities carried
11 out under the grant involved. Each such report shall in-
12 clude—

13 “(1) a description of the financial costs and
14 benefits of the project involved and of the entities to
15 which such costs and benefits accrue;

16 “(2) an analysis of the impact of the project on
17 health care quality and safety;

18 “(3) a description of any reduction in duplica-
19 tive or unnecessary care as a result of the project in-
20 volved;

21 “(4) a description of the efforts of recipients
22 under this section to facilitate secure patient access
23 to health information;

24 “(5) an analysis of the effectiveness of the
25 project involved on ensuring the privacy and security

1 of individually identifiable health information in ac-
2 cordance with applicable Federal and State law; and

3 “(6) other information as required by the Na-
4 tional Coordinator.

5 “(e) REQUIREMENT TO IMPROVE QUALITY OF CARE
6 AND DECREASE IN COSTS.—The National Coordinator
7 shall annually evaluate the activities conducted under this
8 section and shall, in awarding grants, implement the les-
9 sons learned from such evaluation in a manner so that
10 awards made subsequent to each such evaluation are made
11 in a manner that, in the determination of the National
12 Coordinator, will result in the greatest improvement in
13 quality of care and decrease in costs.

14 “(f) LIMITATION.—An eligible entity may only receive
15 one non-renewable grant under subsection (a), one non-
16 renewable grant under subsection (b), and one non-renew-
17 able grant under subsection (c).

18 “(g) SMALL HEALTH CARE PROVIDER.—For pur-
19 poses of this section, the term ‘small health care provider’
20 means a health care provider that has an average of 10
21 or fewer full-time equivalent employees during the period
22 involved.

23 “(h) AUTHORIZATION OF APPROPRIATIONS.—

24 “(1) IN GENERAL.—For the purpose of car-
25 rying out subsections (a) through (d), there is au-

1 thorized to be appropriated \$115,000,000 for each
2 of the fiscal years 2009 through 2013.

3 “(2) AVAILABILITY.—Amounts appropriated
4 under paragraph (1) shall remain available through
5 fiscal year 2013.

6 **“SEC. 3012. DEMONSTRATION PROGRAM TO INTEGRATE IN-**
7 **FORMATION TECHNOLOGY INTO CLINICAL**
8 **EDUCATION.**

9 “(a) IN GENERAL.—The Secretary may award grants
10 under this section to carry out demonstration projects to
11 develop academic curricula integrating qualified health in-
12 formation technology in the clinical education of health
13 professionals. Such awards shall be made on a competitive
14 basis and pursuant to peer review.

15 “(b) ELIGIBILITY.—To be eligible to receive a grant
16 under subsection (a), an entity shall—

17 “(1) submit to the Secretary an application at
18 such time, in such manner, and containing such in-
19 formation as the Secretary may require;

20 “(2) submit to the Secretary a strategic plan
21 for integrating qualified health information tech-
22 nology in the clinical education of health profes-
23 sionals to reduce medical errors and enhance health
24 care quality;

25 “(3) be—

1 “(A) a school of medicine, osteopathic
2 medicine, dentistry, or pharmacy, or a graduate
3 program in behavioral or mental health;

4 “(B) a graduate school of nursing or phy-
5 sician assistant studies;

6 “(C) a consortium of two or more schools
7 described in subparagraph (A) or (B); or

8 “(D) an institution with a graduate med-
9 ical education program in medicine, osteopathic
10 medicine, dentistry, pharmacy, nursing, or phy-
11 sician assistance studies.

12 “(4) provide for the collection of data regarding
13 the effectiveness of the demonstration project to be
14 funded under the grant in improving the safety of
15 patients, the efficiency of health care delivery, and
16 in increasing the likelihood that graduates of the
17 grantee will adopt and incorporate qualified health
18 information technology, in the delivery of health care
19 services; and

20 “(5) provide matching funds in accordance with
21 subsection (d).

22 “(c) USE OF FUNDS.—

23 “(1) IN GENERAL.—With respect to a grant
24 under subsection (a), an eligible entity shall—

1 “(A) use grant funds in collaboration with
2 2 or more disciplines; and

3 “(B) use grant funds to integrate qualified
4 health information technology into community-
5 based clinical education.

6 “(2) LIMITATION.—An eligible entity shall not
7 use amounts received under a grant under sub-
8 section (a) to purchase hardware, software, or serv-
9 ices.

10 “(d) MATCHING FUNDS.—

11 “(1) IN GENERAL.—The Secretary may award
12 a grant to an entity under this section only if the
13 entity agrees to make available non-Federal con-
14 tributions toward the costs of the program to be
15 funded under the grant in an amount that is not
16 less than \$1 for each \$2 of Federal funds provided
17 under the grant.

18 “(2) DETERMINATION OF AMOUNT CONTRIB-
19 UTED.—Non-Federal contributions under paragraph
20 (1) may be in cash or in kind, fairly evaluated, in-
21 cluding equipment or services. Amounts provided by
22 the Federal Government, or services assisted or sub-
23 sidized to any significant extent by the Federal Gov-
24 ernment, may not be included in determining the
25 amount of such contributions.

1 “(e) EVALUATION.—The Secretary shall take such
2 action as may be necessary to evaluate the projects funded
3 under this section and publish, make available, and dis-
4 seminate the results of such evaluations on as wide a basis
5 as is practicable.

6 “(f) REPORTS.—Not later than 1 year after the date
7 of enactment of this title, and annually thereafter, the Sec-
8 retary shall submit to the Committee on Health, Edu-
9 cation, Labor, and Pensions and the Committee on Fi-
10 nance of the Senate, and the Committee on Energy and
11 Commerce of the House of Representatives a report
12 that—

13 “(1) describes the specific projects established
14 under this section; and

15 “(2) contains recommendations for Congress
16 based on the evaluation conducted under subsection
17 (e).

18 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
19 is authorized to be appropriated to carry out this section,
20 \$10,000,000 for each of fiscal years 2009 through 2011.

21 “(h) SUNSET.—This section shall not apply after
22 September 30, 2011.”.

1 **TITLE II—TESTING OF HEALTH**
2 **INFORMATION TECHNOLOGY**

3 **SEC. 201. NATIONAL INSTITUTE FOR STANDARDS AND**
4 **TECHNOLOGY TESTING.**

5 (a) PILOT TESTING OF STANDARDS AND IMPLEMEN-
6 TATION SPECIFICATIONS.—In coordination with the HIT
7 Standards Committee established under section 3003 of
8 the Public Health Service Act, as added by section 101,
9 with respect to the development of standards and imple-
10 mentations specifications under such section, the Director
11 of the National Institute for Standards and Technology
12 shall test such standards and specifications in order to as-
13 sure the efficient implementation and use of such stand-
14 ards and specifications.

15 (b) VOLUNTARY TESTING PROGRAM.—In coordina-
16 tion with the HIT Standards Committee established under
17 section 3003 of the Public Health Service Act, as added
18 by section 101, with respect to the development of stand-
19 ards and implementation specifications under such sec-
20 tion, the Director of the National Institute of Standards
21 and Technology shall support the establishment of a con-
22 formance testing infrastructure, including the develop-
23 ment of technical test beds. The development of this con-
24 formance testing infrastructure may include a program to

1 accredit independent, non-Federal laboratories to perform
2 testing.

3 **SEC. 202. RESEARCH AND DEVELOPMENT PROGRAMS.**

4 (a) HEALTH CARE INFORMATION ENTERPRISE INTE-
5 GRATION RESEARCH CENTERS.—

6 (1) IN GENERAL.—The Director of the National
7 Institute of Standards and Technology, in consulta-
8 tion the Director of the National Science Foundation
9 and other appropriate Federal agencies, shall estab-
10 lish a program of assistance to institutions of higher
11 education (or consortia thereof which may include
12 nonprofit entities and Federal Government labora-
13 tories) to establish multidisciplinary Centers for
14 Health Care Information Enterprise Integration.

15 (2) REVIEW; COMPETITION.—Grants shall be
16 awarded under this subsection on a merit-reviewed,
17 competitive basis.

18 (3) PURPOSE.—The purposes of the Centers de-
19 scribed in paragraph (1) shall be—

20 (A) to generate innovative approaches to
21 health care information enterprise integration
22 by conducting cutting-edge, multidisciplinary
23 research on the systems challenges to health
24 care delivery; and

1 (B) the development and use of health in-
2 formation technologies and other complemen-
3 tary fields.

4 (4) RESEARCH AREAS.—Research areas may in-
5 clude—

6 (A) interfaces between human information
7 and communications technology systems;

8 (B) voice-recognition systems;

9 (C) software that improves interoperability
10 and connectivity among health information sys-
11 tems;

12 (D) software dependability in systems crit-
13 ical to health care delivery;

14 (E) measurement of the impact of informa-
15 tion technologies on the quality and productivity
16 of health care;

17 (F) health information enterprise manage-
18 ment;

19 (G) health information technology security
20 and integrity; and

21 (H) relevant health information technology
22 to reduce medical errors.

23 (5) APPLICATIONS.—An institution of higher
24 education (or a consortium thereof) seeking funding
25 under this subsection shall submit an application to

1 the Director of the National Institute of Standards
2 and Technology at such time, in such manner, and
3 containing such information as the Director may re-
4 quire. The application shall include, at a minimum,
5 a description of—

6 (A) the research projects that will be un-
7 dertaken by the Center established pursuant to
8 assistance under paragraph (1) and the respec-
9 tive contributions of the participating entities;

10 (B) how the Center will promote active col-
11 laboration among scientists and engineers from
12 different disciplines, such as information tech-
13 nology, biologic sciences, management, social
14 sciences, and other appropriate disciplines;

15 (C) technology transfer activities to dem-
16 onstrate and diffuse the research results, tech-
17 nologies, and knowledge; and

18 (D) how the Center will contribute to the
19 education and training of researchers and other
20 professionals in fields relevant to health infor-
21 mation enterprise integration.

22 (b) NATIONAL INFORMATION TECHNOLOGY RE-
23 SEARCH AND DEVELOPMENT PROGRAM.—The National
24 High-Performance Computing Program established by
25 section 101 of the High-Performance Computing Act of

1 1991 (15 U.S.C. 5511) shall coordinate Federal research
2 and development programs related to the development and
3 deployment of health information technology, including ac-
4 tivities related to—

5 (1) computer infrastructure;

6 (2) data security;

7 (3) development of large-scale, distributed, reli-
8 able computing systems;

9 (4) wired, wireless, and hybrid high-speed net-
10 working;

11 (5) development of software and software-inten-
12 sive systems;

13 (6) human-computer interaction and informa-
14 tion management technologies; and

15 (7) the social and economic implications of in-
16 formation technology.

17 **TITLE III—PRIVACY AND**
18 **SECURITY PROVISIONS**

19 **SEC. 300. DEFINITIONS.**

20 In this title, except as specified otherwise:

21 (1) **BREACH.**—The term “breach” means the
22 unauthorized acquisition, access, or disclosure of
23 protected health information which compromises the
24 security, privacy, or integrity of protected health in-
25 formation maintained by or on behalf of a person.

1 Such term does not include any unintentional acqui-
2 sition, access, or disclosure of such information by
3 an employee or agent of the covered entity or busi-
4 ness associate involved if such acquisition, access, or
5 disclosure, respectively, was made in good faith and
6 within the course and scope of the employment or
7 other contractual relationship of such employee or
8 agent, respectively, with the covered entity or busi-
9 ness associate and if such information is not further
10 acquired, accessed, or disclosed by such employee or
11 agent.

12 (2) BUSINESS ASSOCIATE.—The term “business
13 associate” has the meaning given such term in sec-
14 tion 160.103 of title 45, Code of Federal Regula-
15 tions.

16 (3) COVERED ENTITY.—The term “covered en-
17 tity” has the meaning given such term in section
18 160.103 of title 45, Code of Federal Regulations.

19 (4) DISCLOSE.—The terms “disclose” and “dis-
20 closure” have the meaning given the term “disclo-
21 sure” in section 160.103 of title 45, Code of Federal
22 Regulations.

23 (5) HEALTH CARE OPERATIONS.—The term
24 “health care operation” has the meaning given such

1 term in section 164.501 of title 45, Code of Federal
2 Regulations.

3 (6) HEALTH CARE PROVIDER.—The term
4 “health care provider” has the meaning given such
5 term in section 160.103 of title 45, Code of Federal
6 Regulations.

7 (7) PAYMENT.—The term “payment” has the
8 meaning given such term in section 164.501 of title
9 45, Code of Federal Regulations.

10 (8) PERSONAL HEALTH RECORD.—The term
11 “personal health record” means an electronic record
12 of individually identifiable health information on an
13 individual that can be drawn from multiple sources
14 and that is managed, shared, and controlled by or
15 for the individual.

16 (9) PROTECTED HEALTH INFORMATION.—The
17 term “protected health information” has the mean-
18 ing given such term in section 160.103 of title 45,
19 Code of Federal Regulations.

20 (10) SECRETARY.—The term “Secretary”
21 means the Secretary of Health and Human Services.

22 (11) SECURITY.—The term “security” has the
23 meaning given such term in section 164.304 of title
24 45, Code of Federal Regulations.

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

5 (13) TREATMENT.—The term “treatment” has
6 the meaning given such term in section 164.501 of
7 title 45, Code of Federal Regulations.

8 (14) USE.—The term “use” has the meaning
9 given such term in section 160.103 of title 45, Code
10 of Federal Regulations.

11 (15) VENDOR OF PERSONAL HEALTH
12 RECORDS.—The term “vendor of personal health
13 records” means an entity that offers or maintains a
14 personal health record. Such term does not include
15 an entity that is a covered entity for purposes of of-
16 fering or maintaining such personal health record.

17 **Subtitle A—Security Provisions**

18 **SEC. 301. APPLICATION OF SECURITY PROVISIONS AND** 19 **PENALTIES TO BUSINESS ASSOCIATES OF** 20 **COVERED ENTITIES; ANNUAL GUIDANCE ON** 21 **SECURITY PROVISIONS.**

22 (a) APPLICATION OF SECURITY PROVISIONS.—Sec-
23 tions 164.308, 164.310, and 164.312 of title 45, Code of
24 Federal Regulations, shall apply to a business associate

1 of a covered entity in the same manner that such sections
2 apply to the covered entity.

3 (b) APPLICATION OF CIVIL AND CRIMINAL PEN-
4 ALTIES.—Sections 1176 and 1177 of the Social Security
5 Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to a busi-
6 ness associate of a covered entity with respect to a section
7 applied under subsection (a) to such business associate in
8 the same manner that such sections apply to a covered
9 entity with respect to such section.

10 (c) ANNUAL GUIDANCE.—For the first year begin-
11 ning after the date of the enactment of this Act and annu-
12 ally thereafter, the Secretary of Health and Human Serv-
13 ices shall, in consultation with industry stakeholders, an-
14 nually issue guidance on the latest safeguard technologies
15 for use in carrying out the sections described in subsection
16 (a).

17 **SEC. 302. NOTIFICATION IN THE CASE OF BREACH.**

18 (a) IN GENERAL.—A covered entity that accesses,
19 maintains, retains, modifies, records, stores, destroys, or
20 otherwise holds, uses, or discloses unsecured protected
21 health information (as defined in subsection (h)(1)) shall,
22 in the case of a breach of such information that is discov-
23 ered by the covered entity, notify each individual whose
24 unsecured protected health information has been, or is

1 reasonably believed by the covered entity to have been,
2 accessed, acquired, or disclosed as a result of such breach.

3 (b) NOTIFICATION OF COVERED ENTITY BY BUSI-
4 NESS ASSOCIATE.—A business associate of a covered enti-
5 ty that accesses, maintains, retains, modifies, records,
6 stores, destroys, or otherwise holds, uses, or discloses un-
7 secured protected health information shall, following the
8 discovery of a breach of such information, notify the cov-
9 ered entity of such breach. Such notice shall include the
10 identification of each individual whose unsecured protected
11 health information has been, or is reasonably believed by
12 the business associate to have been, accessed, acquired,
13 or disclosed during such breach.

14 (c) BREACHES TREATED AS DISCOVERED.—For pur-
15 poses of this section, a breach shall be treated as discov-
16 ered by a covered entity or by a business associate as of
17 the first day on which such breach is known to such entity
18 or associate, respectively, (including any person that is an
19 employee, officer, or other agent of such entity or asso-
20 ciate, respectively) or should reasonably have been known
21 to such entity or associate (or person) to have occurred.

22 (d) TIMELINESS OF NOTIFICATION.—

23 (1) IN GENERAL.—Subject to subsection (g), all
24 notifications required under this section shall be
25 made without unreasonable delay and in no case

1 later than 60 calendar days after the discovery of a
2 breach by the covered entity involved (or business
3 associate involved in the case of a notification re-
4 quired under subsection (b)).

5 (2) BURDEN OF PROOF.—The covered entity in-
6 volved (or business associate involved in the case of
7 a notification required under subsection (b)), shall
8 have the burden of demonstrating that all notifica-
9 tions were made as required under this subtitle, in-
10 cluding evidence demonstrating the necessity of any
11 delay.

12 (e) METHODS OF NOTICE.—

13 (1) INDIVIDUAL NOTICE.—Notice required
14 under this section to be provided to an individual,
15 with respect to a breach, shall be provided promptly
16 and in the following form:

17 (A) Written notification by first-class mail
18 to the individual (or the next of kin of the indi-
19 vidual if the individual is deceased) at the last
20 known address of the individual or the next of
21 kin, respectively, or, if specified as a preference
22 by the individual, by electronic mail. The notifi-
23 cation may be provided in one or more mailings
24 as information is available.

1 (B) In the case in which there is insuffi-
2 cient, or out-of-date contact information that
3 precludes direct written (or, if specified by the
4 individual under subparagraph (A), electronic)
5 notification to the individual, a substitute form
6 of notice shall be provided, including a con-
7 spicuous posting on the home page of the Web
8 site of the covered entity involved or notice in
9 major print or broadcast media, including
10 major media in geographic areas where the in-
11 dividuals affected by the breach likely reside.
12 Such a notice in media will include a toll-free
13 phone number where an individual can learn
14 whether or not the individual's unsecured pro-
15 tected health information is possibly included in
16 the breach.

17 (C) In any case deemed by the covered en-
18 tity involved to require urgency because of pos-
19 sible imminent misuse of unsecured protected
20 health information, the covered entity, in addi-
21 tion to notice provided under subparagraph (A),
22 may provide information to individuals by tele-
23 phone or other means, as appropriate.

24 (2) MEDIA NOTICE.—Notice shall be provided
25 to prominent media outlets serving a State or juris-

1 diction, following the discovery of a breach described
2 in subsection (a), if the unsecured protected health
3 information of more than 500 residents of such
4 State or jurisdiction is, or is reasonably believed to
5 have been, accessed, acquired, or disclosed during
6 such breach.

7 (3) NOTICE TO SECRETARY.—Notice shall be
8 provided to the Secretary by covered entities of un-
9 secured protected health information that has been
10 acquired or disclosed in a breach.

11 (4) POSTING ON HHS PUBLIC WEBSITE.—The
12 Secretary shall make available to the public on the
13 Internet website of the Department of Health and
14 Human Services a list that identifies each covered
15 entity involved in a breach described in subsection
16 (a) in which the unsecured protected health informa-
17 tion of more than 1,000 individuals is acquired or
18 disclosed.

19 (f) CONTENT OF NOTIFICATION.—Regardless of the
20 method by which notice is provided to individuals under
21 this section, notice of a breach shall include, to the extent
22 possible, the following:

23 (1) A brief description of what happened, in-
24 cluding the date of the breach and the date of the
25 discovery of the breach, if known.

1 (2) A description of the types of unsecured pro-
2 tected health information that were involved in the
3 breach (such as full name, Social Security number,
4 date of birth, home address, account number, or dis-
5 ability code).

6 (3) The steps individuals should take to protect
7 themselves from potential harm resulting from the
8 breach.

9 (4) A brief description of what the covered enti-
10 ty involved is doing to investigate the breach, to
11 mitigate losses, and to protect against any further
12 breaches.

13 (5) Contact procedures for individuals to ask
14 questions or learn additional information, which
15 shall include a toll-free telephone number, an e-mail
16 address, Web site, or postal address.

17 (g) DELAY OF NOTIFICATION AUTHORIZED FOR LAW
18 ENFORCEMENT PURPOSES.—If a law enforcement official
19 determines that a notification, notice, or posting required
20 under this section would impede a criminal investigation
21 or cause damage to national security, such notification,
22 notice, or posting shall be delayed in the same manner
23 as provided under section 164.528(a)(2) of title 45, Code
24 of Federal Regulations, in the case of a disclosure covered
25 under such section.

1 (h) UNSECURED PROTECTED HEALTH INFORMA-
2 TION.—

3 (1) DEFINITION.—

4 (A) IN GENERAL.—Subject to subpara-
5 graph (B), for purposes of this section, the
6 term “unsecured protected health information”
7 means protected health information that is not
8 protected through the use of a technology or
9 methodology specified by the Secretary in the
10 guidance issued under paragraph (2).

11 (B) EXCEPTION IN CASE TIMELY GUID-
12 ANCE NOT ISSUED.—In the case that the Sec-
13 retary does not issue guidance under paragraph
14 (2) by the date specified in such paragraph, for
15 purposes of this section, the term “unsecured
16 protected health information” shall mean infor-
17 mation that is not protected by encryption
18 standards in a Federal Information Standard
19 (FIPS) Publication issued by the National In-
20 stitute of Standards and Technology or an
21 equivalent standard developed by a standards
22 developing organization that is accredited by
23 the American National Standards Institute.

24 (2) GUIDANCE.—For purposes of paragraph (1)
25 and section 315(f), not later than the date that is

1 60 days after the date of the enactment of this Act,
2 the Secretary shall, after consultation with stake-
3 holders, issue (and annually update) guidance speci-
4 fying the technologies and methodologies that render
5 protected health information unusable, unreadable,
6 or indecipherable to unauthorized individuals, taking
7 into account for such purpose the use of the
8 encryption standards in a Federal Information
9 Standard (FIPS) Publication issued by the National
10 Institute of Standards and Technology or an equiva-
11 lent standard developed by a standards developing
12 organization that is accredited by the American Na-
13 tional Standards Institute.

14 (i) **EFFECTIVE DATE.**—The provisions of this section
15 shall apply to breaches that are discovered on or after the
16 date that is 90 days after the date of the enactment of
17 this Act.

18 **SEC. 303. EDUCATION ON HEALTH INFORMATION PRIVACY**
19 **AND REPORT ON COMPLIANCE.**

20 (a) **REGIONAL OFFICE PRIVACY ADVISORS.**—Not
21 later than 6 months after the date of the enactment of
22 this Act, the Secretary shall designate an individual in
23 each regional office of the Department of Health and
24 Human Services to offer guidance and education to cov-
25 ered entities, business associates, and individuals on their

1 rights and responsibilities related to Federal privacy and
2 security requirements for protected health information.

3 (b) REPORT ON COMPLIANCE.—

4 (1) IN GENERAL.—For the first year beginning
5 after the date of the enactment of this Act and an-
6 nually thereafter, the Secretary shall prepare and
7 submit to Congress a report concerning complaints
8 of alleged violations of the provisions of sections 301
9 and 302, the provisions of subtitle B, and the provi-
10 sions of subparts C and E of title 45, Code of Fed-
11 eral Regulations that are received by the Secretary
12 during the year for which the report is being pre-
13 pared. Each such report shall include, with respect
14 to such complaints received during the year—

15 (A) the number of such complaints;

16 (B) the number of such complaints re-
17 solved informally, a summary of the types of
18 such complaints so resolved, and the number of
19 covered entities that received technical assist-
20 ance from the Secretary during such year in
21 order to achieve compliance with such provi-
22 sions and the types of such technical assistance
23 provided;

24 (C) the number of such complaints that re-
25 sulted in the imposition of civil money penalties,

1 the amount of the civil money penalty imposed
2 in each such case, and a summary of the basis
3 for each such civil money penalty;

4 (D) the number of compliance reviews con-
5 ducted and the outcome of each such review;

6 (E) the number of subpoenas or inquiries
7 issued; and

8 (F) the Secretary's plan for improving
9 compliance with and enforcement of such provi-
10 sions for the following year.

11 (2) AVAILABILITY TO PUBLIC.—Each report
12 under paragraph (1) shall be made available to the
13 public on the Internet website of the Department of
14 Health and Human Services.

15 (c) EDUCATION INITIATIVE ON USES OF HEALTH IN-
16 FORMATION.—

17 (1) IN GENERAL.—The Office for Civil Rights
18 within the Department of Health and Human Serv-
19 ices shall develop and maintain a multi-faceted na-
20 tional education initiative to enhance public trans-
21 parency regarding the uses of protected health infor-
22 mation, including programs to educate individuals
23 about the potential uses of their protected health in-
24 formation, the effects of such uses, and the rights of
25 individuals with respect to such uses. Such programs

1 shall be conducted in a variety of languages and
2 present information in a clear and understandable
3 manner.

4 (2) AUTHORIZATION OF APPROPRIATIONS.—

5 There is authorized to be appropriated to carry out
6 paragraph (1), \$10,000,000 for the period of fiscal
7 years 2009 through 2013.

8 **Subtitle B—Improved Privacy Pro-**
9 **visions and Additional Security**
10 **Provisions**

11 **SEC. 311. APPLICATION OF PENALTIES TO BUSINESS ASSO-**
12 **CIATES OF COVERED ENTITIES FOR VIOLA-**
13 **TIONS OF PRIVACY CONTRACT REQUIRE-**
14 **MENTS.**

15 (a) APPLICATION OF CONTRACT REQUIREMENTS.—

16 In the case of a business associate of a covered entity that
17 obtains or creates protected health information pursuant
18 to a written contract (or other written arrangement) de-
19 scribed in section 164.502(e)(2) of title 45, Code of Fed-
20 eral Regulations, with such covered entity, the business
21 associate may use and disclose such protected health infor-
22 mation only if such use or disclosure, respectively, is in
23 compliance with each applicable requirement of section
24 164.504(e) of such title.

1 (b) APPLICATION OF KNOWLEDGE ELEMENTS ASSO-
2 CIATED WITH CONTRACTS.—Section 164.504(e)(1)(ii) of
3 title 45, Code of Federal Regulations, shall apply to a
4 business associate described in subsection (a), with respect
5 to compliance with such subsection, in the same manner
6 that such section applies to a covered entity, with respect
7 to compliance with the standards in sections 164.502(e)
8 and 164.504(e) of such title, except that in applying such
9 section 164.504(e)(1)(ii) each reference to the business as-
10 sociate, with respect to a contract, shall be treated as a
11 reference to the covered entity involved in such contract.

12 (c) APPLICATION OF CIVIL AND CRIMINAL PEN-
13 ALTIES.—In the case of a business associate that violates
14 any provision of subsection (a) or (b), the provisions of
15 sections 1176 and 1177 of the Social Security Act (42
16 U.S.C. 1320d-5, 1320d-6) shall apply to the business as-
17 sociate with respect to such violation in the same manner
18 as such provisions apply to a person who violates a provi-
19 sion of part C of title XI of such Act.

1 **SEC. 312. RESTRICTIONS ON CERTAIN DISCLOSURES AND**
2 **SALES OF HEALTH INFORMATION; ACCOUNT-**
3 **ING OF CERTAIN PROTECTED HEALTH IN-**
4 **FORMATION DISCLOSURES; ACCESS TO CER-**
5 **TAIN INFORMATION IN ELECTRONIC FOR-**
6 **MAT.**

7 (a) REQUESTED RESTRICTIONS ON CERTAIN DIS-
8 CLOSURES OF HEALTH INFORMATION.—In the case that
9 an individual requests under paragraph (a)(1)(i)(A) of
10 section 164.522 of title 45, Code of Federal Regulations,
11 that a covered entity restrict the disclosure of the pro-
12 tected health information of the individual, notwith-
13 standing paragraph (a)(1)(ii) of such section, the covered
14 entity must comply with the requested restriction if—

15 (1) except as otherwise required by law, the dis-
16 closure is to a health plan for purposes of carrying
17 out payment or health care operations (and is not
18 for purposes of carrying out treatment); and

19 (2) the protected health information pertains
20 solely to a health care item or service for which the
21 health care provider involved has been paid out of
22 pocket in full.

23 (b) DISCLOSURES REQUIRED TO BE LIMITED TO
24 THE LIMITED DATA SET OR THE MINIMUM NEC-
25 ESSARY.—

1 (1) IN GENERAL.—A covered entity shall be
2 treated as being in compliance with section
3 164.502(b)(1) of title 45, Code of Federal Regula-
4 tions, with respect to the use, disclosure, or request
5 of protected health information described in such
6 section, only if the covered entity limits such pro-
7 tected health information, to the extent practicable,
8 to the limited data set (as defined in section
9 164.514(e)(2) of such title) or, if needed by such en-
10 tity, to the minimum necessary to accomplish the in-
11 tended purpose of such use, disclosure, or request,
12 respectively.

13 (2) APPLICATION OF EXCEPTIONS.—The excep-
14 tions described in section 164.502(b)(2) of title 45,
15 Code of Federal Regulations, shall apply to the re-
16 quirement under paragraph (1) as of the effective
17 date described in section 323 in the same manner
18 that such exceptions apply to section 164.502(b)(1)
19 of such title before such date.

20 (c) ACCOUNTING OF CERTAIN PROTECTED HEALTH
21 INFORMATION DISCLOSURES REQUIRED IF COVERED EN-
22 TITY USES ELECTRONIC MEDICAL RECORD.—

23 (1) IN GENERAL.—In applying section 164.528
24 of title 45, Code of Federal Regulations, in the case
25 that a covered entity uses or maintains an electronic

1 medical record with respect to protected health in-
2 formation—

3 (A) the exception under section paragraph
4 (a)(1)(i) of such section shall not apply to dis-
5 closures (other than oral disclosures) made by
6 such entity of such information; and

7 (B) an individual shall have a right to re-
8 ceive an accounting of disclosures described in
9 such paragraph of such information made by
10 such covered entity during only the three years
11 prior to the date on which the accounting is re-
12 quested.

13 (2) ELECTRONIC MEDICAL RECORD DEFINED.—
14 For purposes of paragraph (1), the term “electronic
15 medical record” means an electronic record of indi-
16 vidually identifiable health information on an indi-
17 vidual that is created, gathered, managed, and con-
18 sulted by authorized health care clinicians and staff
19 within a single organization.

20 (3) EFFECTIVE DATE.—The provisions of this
21 subsection shall apply to disclosures, with respect to
22 protected health information, made by a covered en-
23 tity on or after the sooner of the following dates:

24 (A) In the case of an entity that does not
25 use or maintain an electronic medical record be-

1 fore the date of the enactment of this Act with
2 respect to such information, the date on which
3 the covered entity first uses or maintains an
4 electronic medical record, with respect to such
5 information, and in the case of an entity that
6 uses or maintains an electronic medical record
7 with respect to such information before such
8 date of enactment, the date on which the cov-
9 ered entity upgrades such electronic medical
10 record.

11 (B) The date that is 6 months after the
12 date on which a standard described in section
13 3002(b)(2)(B) of the Public Health Service Act,
14 as added by section 101, is adopted under sec-
15 tion 3004 of such Act, as so added.

16 (d) APPLICATION OF CONSENT REQUIREMENTS FOR
17 CERTAIN USES AND DISCLOSURES BY HEALTH CARE
18 PROVIDERS WITH ELECTRONIC MEDICAL RECORDS.—

19 (1) IN GENERAL.—In applying section 164.506
20 of title 45, Code of Federal Regulations, in the case
21 of a covered entity that is a health care provider,
22 with respect to protected health information of an
23 individual that is used or maintained by such entity
24 in an electronic medical record (as defined in sub-
25 section (c)(2)), such covered entity may not use or

1 disclose such protected health information for pur-
2 poses of health care operations unless the covered
3 entity obtains the consent of the individual to use or
4 disclose such information for such purposes.

5 (2) TREATMENT OF CONSENT AND
6 REVOCABILITY OF CONSENT.—For purposes of para-
7 graph (1), in the case that an individual provides
8 consent to a covered entity described in such para-
9 graph to use or disclose protected health information
10 described in such paragraph for purposes of health
11 care operations—

12 (A) such consent may be valid and applica-
13 ble to future uses or disclosures by such covered
14 entity of such information for such purposes
15 unless and until the individual revokes such
16 consent;

17 (B) such consent shall be revocable by the
18 individual at any time; and

19 (C) in the case that an individual revokes
20 such consent, such revocation shall only apply
21 to any information acquired by the covered enti-
22 ty after the date of such revocation.

23 (3) APPLICATION OF MINIMUM NECESSARY AND
24 LIMITED DATA SET RULES.—The provision of con-
25 sent under paragraph (1) shall not affect the appli-

1 cation of the requirements under section
2 164.502(b)(1) of title 45, Code of Federal Regula-
3 tions, and subsection (b) of this section to such enti-
4 ty for purposes of the use or disclosure of protected
5 health information described in such paragraph.

6 (4) CLARIFICATION.—Nothing in this sub-
7 section shall be construed as preventing a covered
8 entity described in paragraph (1) from maintaining
9 protected health information of an individual in an
10 electronic medical record solely on the basis that the
11 covered entity seeks consent of the individual as re-
12 quired under paragraph (1) and the individual does
13 not provide such consent (or revokes any such con-
14 sent provided).

15 (5) REGULATIONS.—Not later than 18 months
16 after the date of the enactment of this Act, the Sec-
17 retary shall promulgate regulations to implement
18 this subsection to ensure the integrity of protected
19 health information in a reasonable and workable
20 manner. In such regulations, the Secretary may ex-
21 empt certain health care operations specified by the
22 Secretary from the requirements under paragraphs
23 (1) and (7).

24 (6) RULE OF CONSTRUCTION.—The provision of
25 consent under paragraph (1) by an individual, with

1 respect to protected health information, does not
2 constitute a waiver of any privilege otherwise appli-
3 cable to such individual with respect to such infor-
4 mation.

5 (7) DISCLOSURES BY HEALTH PLANS.—In the
6 case that a covered entity seeks consent, with re-
7 spect to protected health information of an indi-
8 vidual, as required under paragraph (1) and the in-
9 dividual does not provide such consent (or revokes
10 any such consent provided) and such information is
11 disclosed to a health plan for a purpose, such plan
12 may only use such information for such purpose.

13 (8) EFFECTIVE DATE.—The provisions of this
14 subsection shall apply to disclosures made by a cov-
15 ered entity on or after the date that is 24 months
16 after the date of the enactment of this Act.

17 (e) PROHIBITION ON SALE OF ELECTRONIC MEDICAL
18 RECORDS OR PROTECTED HEALTH INFORMATION OB-
19 TAINED FROM ELECTRONIC MEDICAL RECORDS.—A cov-
20 ered entity or business associate may not sell an electronic
21 medical record (as defined in subsection (c)(2)) of an indi-
22 vidual or any protected health information obtained from
23 such electronic medical record unless—

1 (1) such sale is necessary for treatment of the
2 individual or payment for treatment of the indi-
3 vidual; or

4 (2) the covered entity obtains from the indi-
5 vidual, in accordance with section 164.508 of title
6 45, Code of Federal Regulations, a valid authoriza-
7 tion (as described in paragraph (b) of such section)
8 to sell such record or information, respectively.

9 (f) ACCESS TO CERTAIN INFORMATION IN ELEC-
10 TRONIC FORMAT.—In applying section 164.524 of title
11 45, Code of Federal Regulations, in the case that a cov-
12 ered entity uses or maintains an electronic medical record
13 (as defined in subsection (c)(2)) with respect to protected
14 health information of an individual—

15 (1) the individual shall have a right to obtain
16 from such covered entity a copy of such information
17 in an electronic format; and

18 (2) notwithstanding paragraph (c)(4) of such
19 section, the covered entity may not impose any fee
20 for providing such individual with a copy of such in-
21 formation (or a summary or explanation of such in-
22 formation) if such copy (or summary or explanation)
23 is in an electronic form.

1 **SEC. 313. CONDITIONS ON CERTAIN CONTACTS AS PART OF**
2 **HEALTH CARE OPERATIONS.**

3 (a) IN GENERAL.—A communication by a covered en-
4 tity or business associate that is about a product or service
5 and that encourages recipients of the communication to
6 purchase or use the product or service shall not be consid-
7 ered a health care operation for purposes of subpart E
8 of part 164 of title 45, Code of Federal Regulations, un-
9 less the communication is made as described in subpara-
10 graph (i), (ii), or (iii) of paragraph (1) of the definition
11 of marketing in section 164.501 of such title.

12 (b) PAYMENT FOR CERTAIN COMMUNICATIONS.—
13 Subject to paragraph (2), a covered entity or business as-
14 sociate may not receive direct or indirect payment in ex-
15 change for making any communication described in sub-
16 paragraph (i), (ii), or (iii) of paragraph (1) of the defini-
17 tion of marketing in section 164.501 of title 45, Code of
18 Federal Regulations, except—

19 (1) a business associate of a covered entity may
20 receive payment from the covered entity for making
21 any such communication on behalf of the covered en-
22 tity that is consistent with the written contract (or
23 other written arrangement) described in section
24 164.502(e)(2) of such title between such business
25 associate and covered entity; and

1 (2) a covered entity may receive payment in ex-
2 change for making any such communication if the
3 entity obtains from the recipient of the communica-
4 tion, in accordance with section 164.508 of title 45,
5 Code of Federal Regulations, a valid authorization
6 (as described in paragraph (b) of such section) with
7 respect to such communication.

8 (c) EFFECTIVE DATE.—Subsections (a) and (b) shall
9 apply to contracting occurring on or after the effective
10 date specified under section 323.

11 **SEC. 314. STUDY ON APPLICATION OF PRIVACY AND SECU-**
12 **RITY REQUIREMENTS TO NON-HIPAA COV-**
13 **ERED ENTITIES.**

14 Not later than one year after the date of the enact-
15 ment of this Act, the Secretary, in consultation with the
16 Federal Trade Commission, shall submit to Congress rec-
17 ommendations—

18 (1) to identify requirements relating to security,
19 privacy, and notification in the case of a breach of
20 security or privacy (including the applicability of an
21 exemption to notification in the case of individually
22 identifiable health information that has been ren-
23 dered unusable, unreadable, or indecipherable
24 through technologies or methodologies recognized by
25 appropriate professional organization or standard

1 setting bodies to provide effective security for the in-
2 formation) that should be applied to—

3 (A) vendors of personal health records;

4 (B) entities that offer products or services
5 through the website of a vendor of personal
6 health records;

7 (C) entities that are not covered entities
8 and that offer products or services through the
9 websites of covered entities that offer individ-
10 uals personal health records;

11 (D) entities that are not covered entities
12 and that access information in a personal
13 health record or send information to a personal
14 health record; and

15 (E) third party service providers used by a
16 vendor or entity described in subparagraph (A),
17 (B), (C), or (D) to assist in providing personal
18 health record products or services; and

19 (2) to determine which Federal government
20 agency is best equipped to enforce such requirements
21 recommended to be applied to such vendors, entities,
22 and service providers under paragraph (1).

1 **SEC. 315. TEMPORARY BREACH NOTIFICATION REQUIRE-**
2 **MENT FOR VENDORS OF PERSONAL HEALTH**
3 **RECORDS AND OTHER NON-HIPAA COVERED**
4 **ENTITIES.**

5 (a) IN GENERAL.—In accordance with subsection (c),
6 each vendor of personal health records, following the dis-
7 covery of a breach of security of unsecured PHR identifi-
8 able health information that is in a personal health record
9 maintained or offered by such vendor, and each entity de-
10 scribed in subparagraph (B), (C), or (D) of section
11 314(1), following the discovery of a breach of security of
12 such information that is obtained through a product or
13 service provided by such entity, shall—

14 (1) notify each individual who is a citizen or
15 resident of the United States whose unsecured PHR
16 identifiable health information was acquired by an
17 unauthorized person as a result of such a breach of
18 security; and

19 (2) notify the Federal Trade Commission.

20 (b) NOTIFICATION BY THIRD PARTY SERVICE PRO-
21 VIDERS.—A third party service provider that provides
22 services to a vendor of personal health records or to an
23 entity described in subparagraph (B), (C), or (D) of sec-
24 tion 314(1) in connection with the offering or maintenance
25 of a personal health record or a related product or service
26 and that accesses, maintains, retains, modifies, records,

1 stores, destroys, or otherwise holds, uses, or discloses un-
2 secured PHR identifiable health information in such a
3 record as a result of such services shall, following the dis-
4 covery of a breach of security of such information, notify
5 such vendor or entity, respectively, of such breach. Such
6 notice shall include the identification of each individual
7 whose unsecured PHR identifiable health information has
8 been, or is reasonably believed to have been, accessed, ac-
9 quired, or disclosed during such breach.

10 (c) APPLICATION OF REQUIREMENTS FOR TIMELI-
11 NESS, METHOD, AND CONTENT OF NOTIFICATIONS.—
12 Subsections (c), (d), (e), and (f) of section 302 shall apply
13 to a notification required under subsection (a) and a ven-
14 dor of personal health records, an entity described in sub-
15 section (a) and a third party service provider described
16 in subsection (b), with respect to a breach of security
17 under subsection (a) of unsecured PHR identifiable health
18 information in such records maintained or offered by such
19 vendor, in a manner specified by the Federal Trade Com-
20 mission.

21 (d) NOTIFICATION OF THE SECRETARY.—Upon re-
22 ceipt of a notification of a breach of security under sub-
23 section (a)(2), the Federal Trade Commission shall notify
24 the Secretary of such breach.

1 (e) ENFORCEMENT.—A violation of subsection (a) or
2 (b) shall be treated as an unfair and deceptive act or prac-
3 tice in violation of a regulation under section 18(a)(1)(B)
4 of the Federal Trade Commission Act (15 U.S.C.
5 57a(a)(1)(B)) regarding unfair or deceptive acts or prac-
6 tices.

7 (f) DEFINITIONS.—For purposes of this section:

8 (1) BREACH OF SECURITY.—The term “breach
9 of security” means, with respect to unsecured PHR
10 identifiable health information of an individual in a
11 personal health record, acquisition of such informa-
12 tion without the authorization of the individual.

13 (2) PHR IDENTIFIABLE HEALTH INFORMA-
14 TION.—The term “PHR identifiable health informa-
15 tion” means individually identifiable health informa-
16 tion, as defined in section 1171(6) of the Social Se-
17 curity Act (42 U.S.C. 1320d(6)), and includes, with
18 respect to an individual, information—

19 (A) that is provided by or on behalf of the
20 individual; and

21 (B) that identifies the individual or with
22 respect to which there is a reasonable basis to
23 believe that the information can be used to
24 identify the individual.

1 (3) UNSECURED PHR IDENTIFIABLE HEALTH
2 INFORMATION.—

3 (A) IN GENERAL.—Subject to subpara-
4 graph (B), the term “unsecured PHR identifi-
5 able health information” means PHR identifi-
6 able health information that is not protected
7 through the use of a technology or methodology
8 specified by the Secretary in the guidance
9 issued under section 302(h)(2).

10 (B) EXCEPTION IN CASE TIMELY GUID-
11 ANCE NOT ISSUED.—In the case that the Sec-
12 retary does not issue guidance under section
13 302(h)(2) by the date specified in such section,
14 for purposes of this section, the term “unse-
15 cured PHR identifiable health information”
16 shall mean information that is not protected by
17 encryption standards in a Federal Information
18 Standard (FIPS) Publication issued by the Na-
19 tional Institute of Standards and Technology or
20 an equivalent standard developed by a stand-
21 ards developing organization that is accredited
22 by the American National Standards Institute.

23 (g) EFFECTIVE DATE.—The provisions of this sec-
24 tion shall apply to breaches of security occurring during

1 the 2-year period beginning on the date that is 90 days
2 after the date of the enactment of this Act.

3 **SEC. 316. BUSINESS ASSOCIATE CONTRACTS REQUIRED**
4 **FOR CERTAIN ENTITIES.**

5 Each organization, with respect to a covered entity,
6 that provides data transmission of protected health infor-
7 mation to such entity and that requires access on a routine
8 basis to such protected health information, such as a
9 Health Information Exchange, Regional Health Informa-
10 tion Organization, or E-prescribing Gateway, is required
11 to enter into a written contract (or other written arrange-
12 ment) described in section 164.502(e)(2) of title 45, Code
13 of Federal Regulations and a written contract (or other
14 arrangement) described in section 164.308(b) of such
15 title, with such entity and shall be treated as a business
16 associate of the covered entity for purposes of the provi-
17 sions of this title.

18 **SEC. 317. GUIDANCE ON IMPLEMENTATION SPECIFICATION**
19 **TO DE-IDENTIFY PROTECTED HEALTH INFOR-**
20 **MATION.**

21 Not later than 12 months after the date of the enact-
22 ment of this Act, the Secretary shall, in consultation with
23 stakeholders, issue guidance on how best to implement the
24 requirements for the de-identification of protected health

1 information under section 164.514(b) of title 45, Code of
2 Federal Regulations.

3 **SEC. 318. GAO REPORT ON TREATMENT DISCLOSURES.**

4 Not later than one year after the date of the enact-
5 ment of this Act, the Comptroller General of the United
6 States shall submit to Congress a report on the best prac-
7 tices related to the disclosure among health care providers
8 of protected health information of an individual for pur-
9 poses of treatment of such individual. Such report shall
10 include an examination of the best practices implemented
11 by States and by other entities, such as health information
12 exchanges and regional health information organizations,
13 including an examination of the extent to which such best
14 practices are successful with respect to the quality of the
15 resulting health care provided to the individual and with
16 respect to the ability of the health care provider to manage
17 such best practices.

18 **SEC. 319. CLARIFICATION OF APPLICATION OF WRONGFUL**
19 **DISCLOSURES CRIMINAL PENALTIES.**

20 Section 1177(a) of the Social Security Act (42 U.S.C.
21 1320d-6(a)) is amended by adding at the end the fol-
22 lowing new sentence: “For purposes of the previous sen-
23 tence, a person (including an employee or other individual)
24 shall be considered to have obtained or disclosed individ-
25 ually identifiable health information in violation of this

1 part if the information is maintained by a covered entity
2 (as defined in the HIPAA privacy regulation described in
3 section 1180(b)(3)) and the individual obtained or dis-
4 closed such information without authorization.”.

5 **SEC. 320. IMPROVED ENFORCEMENT.**

6 (a) IN GENERAL.—Section 1176 of the Social Secu-
7 rity Act (42 U.S.C. 1320d-5) is amended—

8 (1) in subsection (b)(1), by striking “the act
9 constitutes an offense punishable under section
10 1177” and inserting “a penalty has been imposed
11 under section 1177 with respect to such act”; and

12 (2) by adding at the end the following new sub-
13 section:

14 “(c) NONCOMPLIANCE DUE TO WILLFUL NE-
15 GLECT.—

16 “(1) IN GENERAL.—A violation of a provision
17 of this part due to willful neglect is a violation for
18 which the Secretary is required to impose a penalty
19 under subsection (a)(1).

20 “(2) REQUIRED INVESTIGATION.—For purposes
21 of paragraph (1), the Secretary shall formally inves-
22 tigate any complaint of a violation of a provision of
23 this part if a preliminary investigation of the facts
24 of the complaint indicate such a possible violation
25 due to willful neglect.

1 “(3) REGULATIONS.—Not later than 180 days
2 after the date of the enactment of the
3 PRO(TECH)T Act of 2008, the Secretary shall pro-
4 mulgate regulations to implement this subsection.”.

5 (b) EFFECTIVE DATE.—The amendments made by
6 subsection (a) shall apply to penalties imposed on or after
7 the date specified in section 323.

8 **Subtitle A—Relationship to Other**
9 **Laws; Regulatory References;**
10 **Effective Date**

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

12 (a) APPLICATION OF HIPAA STATE PREEMPTION.—
13 Section 1178 of the Social Security Act (42 U.S.C.
14 1320d–7) shall apply to a provision or requirement under
15 this title in the same manner that such section applies
16 to a provision or requirement under part C of title XI of
17 such Act or a standard or implementation specification
18 adopted or established under sections 1172 through 1174
19 of such Act.

20 (b) HEALTH INSURANCE PORTABILITY AND AC-
21 COUNTABILITY ACT.—The standards governing the pri-
22 vacy and security of individually identifiable health infor-
23 mation promulgated by the Secretary under sections
24 262(a) and 264 of the Health Insurance Portability and
25 Accountability Act of 1996 shall remain in effect to the

1 extent that they are consistent with this title. The Sec-
2 retary shall by rule amend such Federal regulations as re-
3 quired to make such regulations consistent with this title.

4 **SEC. 2. REGULATORY REFERENCES.**

5 Each reference in this title to a provision of the Code
6 of Federal Regulations refers to such provision as in effect
7 on the date of the enactment of this Act (or to the most
8 recent update of such provision).

9 **SEC. 3. EFFECTIVE DATE.**

10 The provisions of subtitles A and B of this title (other
11 than sections 301(c), 302, 303, 312(c), 312(d), 314, 315,
12 317, 318, and 319) shall take effect on the date that is
13 12 months after the date of the enactment of this Act.

