

110TH CONGRESS
2D SESSION

H. R. 6357

To amend the Public Health Service Act to promote the adoption of health information technology, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 2008

Mr. DINGELL (for himself, Mr. BARTON of Texas, Mr. PALLONE, Mr. DEAL of Georgia, Mr. GORDON of Tennessee, Mr. HALL of Texas, Mr. TOWNS, Mr. UPTON, Mr. ENGEL, Mrs. WILSON of New Mexico, Mr. GONZALEZ, Mr. GINGREY, and Mrs. BIGGERT) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Science and Technology and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To amend the Public Health Service Act to promote the adoption of health information technology, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Protecting Records, Optimizing Treatment, and Easing

1 Communication through Healthcare Technology Act of
2 2008” or the “PRO(TECH)T Act of 2008”.

3 (b) TABLE OF CONTENTS.—The table of contents of
4 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 im-
plementation 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 imple-
mentation specifications.

Sec. 112. Application to private entities.

Sec. 113. 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 of health information; accounting of certain protected health information disclosures.
- Sec. 313. Conditions on certain contacts as part of health care operations.
- Sec. 314. Study on application of privacy and security requirements to vendors of personal health records.
- Sec. 315. Temporary breach notification requirement for vendors of personal health records.
- 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.

Subtitle C—Relationship to Other Laws; Clarification; Effective Date

- Sec. 321. Relationship to other laws.
- Sec. 322. 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 ADOP-**
 8 **TION; 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
 23 among all the components in the health care infra-
 24 structure in accordance with applicable law, and

1 such term includes related application protocols and
2 other related standards.

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

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

24 “(4) HEALTH INFORMATION TECHNOLOGY.—
25 The term ‘health information technology’ means

1 hardware, software, license, right, intellectual prop-
2 erty, equipment, or other information technology (in-
3 cluding new versions, upgrades, and connectivity)
4 designed or provided primarily for the electronic cre-
5 ation, maintenance, or exchange of health informa-
6 tion to coordinate care or improve health care qual-
7 ity, efficiency, or research.

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

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

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

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

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

23 “(10) NATIONAL COORDINATOR.—The term
24 ‘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 interoperable
24 health information technology infrastructure 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, elec-
24 tronic authentication, and encryption of
25 health information.

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

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

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

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

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

23 “(D) PUBLICATION.—The National Coor-
24 dinator shall publish the strategic plan, includ-
25 ing all updates.

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

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

7 “(B) The recommendations of the HIT
8 Policy Committee under section 3002.

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

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

15 “(E) The report prepared by the National
16 Coordinator under paragraph (5).

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

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

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

23 “(5) IMPLEMENTATION REPORT.—The National
24 Coordinator shall prepare a report that identifies
25 lessons learned from major public and private health

1 care systems in their implementation of health infor-
2 mation technology systems, including information on
3 whether the systems and practices developed by such
4 systems may be applicable to and usable in whole or
5 in part by other health care providers.

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

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

24 “(8) RESOURCE REQUIREMENTS.—The Na-
25 tional Coordinator shall estimate and publish re-

1 sources required annually to reach the goal of utili-
2 zation of an electronic health record for each person
3 in the United States by 2014, including the required
4 level of Federal funding, expectations for regional,
5 State, and private investment, and the expected con-
6 tributions by volunteers to activities for the utiliza-
7 tion of such records.

8 “(9) CERTIFICATION.—

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

20 “(B) CERTIFICATION CRITERIA DE-
21 SCRIBED.—In this title, the term ‘certification
22 criteria’ means, with respect to standards and
23 implementation specifications for health infor-
24 mation technology, criteria to establish that the

1 technology meets such standards and implemen-
2 tation specifications.

3 “(d) DETAIL OF FEDERAL EMPLOYEES.—

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

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

12 “(A) not interrupt or otherwise affect the
13 civil service status or privileges of the Federal
14 employee; and

15 “(B) be in addition to any other staff of
16 the Department employed by the National Co-
17 ordinator.

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

23 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section
25 \$66,000,000 for fiscal year 2009.

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

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

8 “(b) DUTIES.—

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

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

24 “(A) IN GENERAL.—The HIT Policy Com-
25 mittee shall recommend the areas in which
26 standards, implementation specifications, and

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

15 “(B) AREAS REQUIRED FOR CONSIDER-
16 ATION.—In making recommendations under
17 subparagraph (A), the HIT Policy Committee
18 shall consider at least the following areas:

19 “(i) Technologies that protect the pri-
20 vacy of health information and promote se-
21 curity, including for the protection from
22 disclosure of specific individually identifi-
23 able health information, in accordance with
24 applicable law, and for the use and dislo-
25 sure of limited data sets (as defined for

1 purposes of regulations promulgated under
2 section 264(c) of the Health Insurance
3 Portability and Accountability Act of
4 1996) of such information.

5 “(ii) A nationwide interoperable
6 health information technology infrastruc-
7 ture that permits the electronic exchange
8 and use of health information.

9 “(iii) The utilization of an electronic
10 health record for each person in the United
11 States by 2014.

12 “(C) OTHER AREAS FOR CONSIDER-
13 ATION.—In making recommendations under
14 subparagraph (A), the HIT Policy Committee
15 may consider the following additional areas:

16 “(i) The appropriate uses of a nation-
17 wide health information infrastructure, in-
18 cluding for purposes of—

19 “(I) the collection of quality data
20 and public reporting;

21 “(II) biosurveillance and public
22 health;

23 “(III) medical and clinical re-
24 search; and

25 “(IV) drug safety.

1 “(ii) Self-service technologies that fa-
2 cilitate the use and exchange of patient in-
3 formation and reduce wait times.

4 “(iii) Telemedicine technologies, in
5 order to reduce travel requirements for pa-
6 tients in remote areas.

7 “(iv) Technologies that facilitate home
8 health care and the monitoring of patients
9 recuperating at home.

10 “(v) Technologies that help reduce
11 medical errors.

12 “(vi) Technologies that facilitate the
13 continuity of care among health settings.

14 “(vii) Technologies that meet the
15 needs of diverse populations.

16 “(viii) Any other technology that the
17 HIT Policy Committee finds to be among
18 the technologies with the greatest potential
19 to improve the quality and efficiency of
20 health care.

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

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

5 “(A) Established governance rules.

6 “(B) A business plan.

7 “(C) Meeting notices at least 14 days prior
8 to each meeting.

9 “(D) Meeting agendas at least 7 days prior
10 to each meeting.

11 “(E) Meeting materials at least 3 days
12 prior to each meeting.

13 “(c) MEMBERSHIP.—

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

17 “(A) 3 members shall be appointed by the
18 Secretary, 1 of whom shall be appointed to rep-
19 resent the Department of Health and Human
20 Services and 1 of whom shall be a public health
21 official.

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

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

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

3 “(E) 1 member shall be appointed by the
4 minority leader of the House of Representa-
5 tives.

6 “(F) Such other members as shall be ap-
7 pointed by the President as representatives of
8 other relevant Federal agencies.

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

12 “(i) 1 member shall be an advocate
13 for patients or consumers;

14 “(ii) 2 members shall represent health
15 care providers, one of which shall be a phy-
16 sician;

17 “(iii) 1 member shall be from a labor
18 organization representing health care
19 workers;

20 “(iv) 1 member shall have expertise in
21 privacy and security;

22 “(v) 1 member shall have expertise in
23 improving the health of vulnerable popu-
24 lations;

1 “(vi) 1 member shall be from the re-
2 search community;

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

5 “(viii) 1 member shall represent infor-
6 mation technology vendors;

7 “(ix) 1 member shall represent pur-
8 chasers or employers; and

9 “(x) 1 member shall have expertise in
10 health care quality measurement and re-
11 porting.

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

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

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

1 unduly influences the recommendations of such
2 Committee.

3 “(5) TERMS.—

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

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

22 “(6) OUTSIDE INVOLVEMENT.—The HIT Policy
23 Committee shall ensure an adequate opportunity for
24 the participation in activities of the Committee of
25 outside advisors, including individuals with expertise

1 in the development of policies for the electronic ex-
2 change and use of health information, including in
3 the areas of health information privacy and security.

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

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

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

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

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

1 “(b) DUTIES.—

2 “(1) STANDARD DEVELOPMENT.—

3 “(A) IN GENERAL.—Beginning not later
4 than 1 year after the date of the enactment of
5 this title, the HIT Standards Committee shall
6 recommend to the National Coordinator stand-
7 ards, implementation specifications, and certifi-
8 cation criteria described in subsection (a) that
9 have been developed, harmonized, or recognized
10 by the Committee. Annually thereafter the
11 Committee shall update such recommendations
12 and make new recommendations as appropriate,
13 including in response to a notification sent
14 under section 3004(b)(2). Such recommenda-
15 tions shall be consistent with the latest rec-
16 ommendations made by the HIT Policy Com-
17 mittee.

18 “(B) PILOT TESTING OF STANDARDS AND
19 IMPLEMENTATION SPECIFICATIONS.—In the de-
20 velopment, harmonization, or recognition of
21 standards and implementation specifications,
22 the HIT Standards Committee, as appropriate,
23 shall provide for the testing of such standards
24 and specifications by the National Institute for

1 Standards and Technology under section 201 of
2 the PRO(TECH)T Act of 2008.

3 “(C) CONSISTENCY.—The standards, im-
4 plementation specifications, and certification
5 criteria recommended under this subsection
6 shall be consistent with the standards for infor-
7 mation transactions and data elements adopted
8 pursuant to section 1173 of the Social Security
9 Act.

10 “(2) FORUM.—The HIT Standards Committee
11 shall serve as a forum for the participation of a
12 broad range of stakeholders to provide input on the
13 development, harmonization, and recognition of
14 standards, implementation specifications, and certifi-
15 cation criteria necessary for the development and
16 adoption of a nationwide interoperable health infor-
17 mation technology infrastructure.

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

1 “(4) PUBLIC INPUT.—The HIT Standards
2 Committee shall conduct open public meetings and
3 develop a process to allow for public comment on the
4 schedule described in paragraph (3) and rec-
5 ommendations described in this subsection. Under
6 such process comments shall be submitted in a time-
7 ly manner after the date of publication of a rec-
8 ommendation under this subsection.

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

13 “(A) Established governance rules.

14 “(B) A business plan.

15 “(C) Meeting notices at least 14 days prior
16 to each meeting.

17 “(D) Meeting agendas at least 7 days prior
18 to each meeting.

19 “(E) Meeting materials at least 3 days
20 prior to each meeting.

21 “(6) REQUIREMENT TO INTEGRATE REC-
22 OMMENDATIONS.—In carrying out the activities
23 under this section, the HIT Standards Committee
24 shall integrate the recommendations of the HIT Pol-
25 icy Committee.

1 “(c) MEMBERSHIP.—

2 “(1) APPOINTMENTS.—The HIT Standards
3 Committee shall be composed of members to be ap-
4 pointed as follows:

5 “(A) 2 members shall be appointed by the
6 Secretary.

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

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

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

13 “(E) 1 member shall be appointed by the
14 minority leader of the House of Representa-
15 tives.

16 “(F) 9 members shall be appointed by the
17 Comptroller General of the United States of
18 whom—

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

21 “(ii) 1 member shall be a representa-
22 tive of organizations with expertise in pri-
23 vacy;

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

4 “(iv) 2 members shall be a representa-
5 tive of health care providers, one of which
6 shall be a physician;

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

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

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

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

16 “(G) 1 member shall be appointed by the
17 Director of the National Institute for Standards
18 and Technology.

19 “(2) NATIONAL COORDINATOR.—The National
20 Coordinator shall be a member of the HIT Stand-
21 ards Committee and act as a liaison among the HIT
22 Standards Committee, the HIT Policy Committee,
23 and the Federal government.

24 “(3) CHAIRPERSON AND VICE CHAIRPERSON.—
25 The HIT Standards Committee shall designate 1

1 member to serve as the chairperson and 1 member
2 to serve as the vice chairperson of the Committee.

3 “(4) PARTICIPATION.—The members of the
4 HIT Standards Committee appointed under para-
5 graph (1) shall represent a balance among various
6 sectors of the health care system so that no single
7 sector unduly influences the recommendations of
8 such Committee.

9 “(5) TERMS.—

10 “(A) IN GENERAL.—The terms of mem-
11 bers of the HIT Standards Committee ap-
12 pointed under paragraph (1) shall be 3 years
13 except that the Comptroller General of the
14 United States shall designate staggered terms
15 for the members first appointed under para-
16 graph (1)(F).

17 “(B) VACANCIES.—Any member appointed
18 to fill a vacancy in the membership of the HIT
19 Standards Committee that occurs prior to the
20 expiration of the term for which the member’s
21 predecessor was appointed shall be appointed
22 only for the remainder of that term. A member
23 may serve after the expiration of that member’s
24 term until a successor has been appointed. A
25 vacancy in the HIT Standards Committee shall

1 be filled in the manner in which the original ap-
2 pointment was made.

3 “(6) OUTSIDE INVOLVEMENT.—The HIT
4 Standards Committee shall ensure an adequate op-
5 portunity for the participation in activities of the
6 Committee of outside advisors, including individuals
7 with expertise in the development of standards for
8 the electronic exchange and use of health informa-
9 tion, including in the areas of health information
10 privacy and security.

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

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

18 “(e) PUBLICATION.—The Secretary shall provide for
19 publication in the Federal Register and the posting on the
20 Internet website of the Office of the National Coordinator
21 for Health Information Technology of all recommenda-
22 tions made by the HIT Standards Committee under this
23 section.

1 **“SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED REC-**
2 **COMMENDATIONS.**

3 “(a) REVIEW OF ENDORSED STANDARDS, SPECI-
4 FICATIONS, AND CRITERIA.—Not later than 90 days after
5 the date of receipt of standards, implementation specifica-
6 tions, or certification criteria endorsed under section
7 3001(c), the Secretary, in consultation with representa-
8 tives of other relevant Federal agencies, shall jointly re-
9 view such standards, specifications, or criteria and shall
10 determine whether or not to propose adoption of such
11 standards, specifications, or criteria.

12 “(b) DETERMINATION TO ADOPT STANDARDS, SPEC-
13 IFICATIONS, AND CRITERIA.—If the Secretary deter-
14 mines—

15 “(1) to propose adoption of any grouping of
16 such standards, specifications, or criteria, the Sec-
17 retary shall, through a rulemaking process, deter-
18 mine whether or not to adopt such grouping of
19 standards, specifications, or criteria; or

20 “(2) not to propose adoption of any grouping of
21 standards, specifications, or criteria, the Secretary
22 shall notify the National Coordinator and the HIT
23 Standards Committee in writing of such determina-
24 tion and the reasons for not proposing the adoption
25 of such recommendation.

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

4 **“SEC. 3005. APPLICATION AND USE OF ADOPTED STAND-**
5 **ARDS AND IMPLEMENTATION SPECIFICA-**
6 **TIONS BY FEDERAL AGENCIES.**

7 “For requirements relating to the application and use
8 by Federal agencies of the standards and implementation
9 specifications adopted under section 3004(b), see section
10 111 of the PRO(TECH)T Act of 2008.

11 **“SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPT-**
12 **ED STANDARDS AND IMPLEMENTATION**
13 **SPECIFICATIONS BY PRIVATE ENTITIES.**

14 “(a) IN GENERAL.—Except as provided under section
15 112 of the PRO(TECH)T Act of 2008, any standard or
16 implementation specification adopted under section
17 3004(b) shall be voluntary with respect to private entities.

18 “(b) RULE OF CONSTRUCTION.—Nothing in this sub-
19 title shall be construed to require that a private entity that
20 enters into a contract with the Federal Government apply
21 or use the standards and implementation specifications
22 adopted under section 3004(b) with respect to activities
23 not related to the contract.

1 **“SEC. 3007. HEALTH INFORMATION TECHNOLOGY RE-**
2 **SOURCE CENTER.**

3 “(a) DEVELOPMENT.—

4 “(1) IN GENERAL.—The National Coordinator
5 shall develop a Health Information Technology Re-
6 source Center to provide technical assistance and de-
7 velop best practices to support and accelerate efforts
8 to adopt, implement, and effectively use health infor-
9 mation technology that allows for the electronic ex-
10 change and use of information in compliance with
11 standards, implementation specifications, and certifi-
12 cation criteria adopted under section 3004(b).

13 “(2) PURPOSES.—The purpose of the Center is
14 to—

15 “(A) provide a forum for the exchange of
16 knowledge and experience;

17 “(B) accelerate the transfer of lessons
18 learned from existing public and private sector
19 initiatives, including those currently receiving
20 Federal financial support;

21 “(C) assemble, analyze, and widely dis-
22 seminate evidence and experience related to the
23 adoption, implementation, and effective use of
24 health information technology that allows for
25 the electronic exchange and use of information;

1 “(D) provide technical assistance for the
2 establishment and evaluation of regional and
3 local health information networks to facilitate
4 the electronic exchange of information across
5 health care settings and improve the quality of
6 health care;

7 “(E) provide technical assistance for the
8 development and dissemination of solutions to
9 barriers to the exchange of electronic health in-
10 formation;

11 “(F) learn about effective strategies to
12 adopt and utilize health information technology
13 in medically underserved communities;

14 “(G) conduct other activities identified by
15 the States, local or regional health information
16 networks, or health care stakeholders as a focus
17 for developing and sharing best practices; and

18 “(H) provide technical assistance to pro-
19 mote adoption and utilization of health informa-
20 tion technology by health care providers, includ-
21 ing in medically underserved communities.

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

1 “(1) learn about Federal grants and technical
2 assistance services related to interoperable health in-
3 formation technology;

4 “(2) learn about standards, implementation
5 specifications, and certification criteria adopted
6 under section 3004(b);

7 “(3) learn about regional and local health infor-
8 mation networks for assistance with health informa-
9 tion technology; and

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

12 **SEC. 102. TRANSITIONS.**

13 (a) ONCHIT.—To the extent consistent with section
14 3001 of the Public Health Service Act, as added by section
15 101, all functions, personnel, assets, liabilities, and admin-
16 istrative actions applicable to the National Coordinator for
17 Health Information Technology appointed under Execu-
18 tive Order 13335 or the Office of such National Coordi-
19 nator on the date before the date of the enactment of this
20 Act shall be transferred to the National Coordinator ap-
21 pointed under section 3001(a) of such Act and the Office
22 of such National Coordinator as of the date of the enact-
23 ment of this Act.

24 (b) AHIC.—

1 (1) To the extent consistent with sections 3002
2 and 3003 of the Public Health Service Act, as added
3 by section 101, all functions, personnel, assets, and
4 liabilities applicable to the American Health Infor-
5 mation Community created in response to Executive
6 Order 13335 as of the day before the date of the en-
7 actment of this Act shall be transferred to the HIT
8 Policy Committee or the HIT Standards Committee,
9 established under section 3002(a) or 3003(a) of such
10 Act, as appropriate, as of the date of the enactment
11 of this Act.

12 (2) In carrying out section 3003(b)(1)(A) of the
13 Public Health Service Act, as so added, until rec-
14 ommendations are made by the HIT Policy Com-
15 mittee, recommendations of the HIT Standards
16 Committee shall be consistent with the most recent
17 recommendations made by the American Health In-
18 formation Community.

19 (c) RULES OF CONSTRUCTION.—

20 (1) ONCHIT.—Nothing in section 3001 of the
21 Public Health Service Act, as added by section 101,
22 or subsection (a) shall be construed as requiring the
23 creation of a new entity to the extent that the Office
24 of the National Coordinator for Health Information
25 Technology established pursuant to Executive Order

1 13335 is consistent with the provisions of such sec-
2 tion 3001.

3 (2) AHIC.—Nothing in sections 3002 or 3003
4 of the Public Health Service Act, as added by sec-
5 tion 101, or subsection (b) shall be construed as re-
6 quiring the creation of a new entity to the extent
7 that the American Health Information Community
8 created in response to Executive Order 13335 is
9 consistent with the provisions of such sections 3002
10 and 3003.

11 **PART II—APPLICATION AND USE OF ADOPTED**
12 **HEALTH INFORMATION TECHNOLOGY**
13 **STANDARDS; REPORTS**

14 **SEC. 111. COORDINATION OF FEDERAL ACTIVITIES WITH**
15 **ADOPTED STANDARDS AND IMPLEMENTA-**
16 **TION SPECIFICATIONS.**

17 (a) SPENDING ON HEALTH INFORMATION TECH-
18 NOLOGY SYSTEMS.—As each agency (as defined in the Ex-
19 ecutive Order issued on August 22, 2006, relating to pro-
20 moting quality and efficient health care in Federal govern-
21 ment administered or sponsored health care programs) im-
22 plements, acquires, or upgrades health information tech-
23 nology systems used for the direct exchange of individually
24 identifiable health information between agencies and with
25 non-Federal entities, it shall utilize, where available,

1 health information technology systems and products that
2 meet standards and implementation specifications adopted
3 under section 3004(b) of the Public Health Service Act,
4 as added by section 101.

5 (b) FEDERAL INFORMATION COLLECTION ACTIVI-
6 TIES.—With respect to a standard or implementation
7 specification adopted under section 3004(b) of the Public
8 Health Service Act, as added by section 101, the President
9 shall take measures to ensure that Federal activities in-
10 volving the broad collection and submission of health in-
11 formation are consistent with such standard or specifica-
12 tion, respectively, within three years after the date of such
13 adoption.

14 (c) APPLICATION OF DEFINITIONS.—The definitions
15 contained in section 3000 of the Public Health Service
16 Act, as added by section 101, shall apply for purposes of
17 this part.

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

19 Each agency (as defined in such Executive Order
20 issued on August 22, 2006, relating to promoting quality
21 and efficient health care in Federal government adminis-
22 tered or sponsored health care programs) shall require in
23 contracts or agreements with health care providers, health
24 plans, or health insurance issuers that as each provider,
25 plan, or issuer implements, acquires, or upgrades health

1 information technology systems, it shall utilize, where
2 available, health information technology systems and prod-
3 ucts that meet standards and implementation specifica-
4 tions adopted under section 3004(b) of the Public Health
5 Service Act, as added by section 101.

6 **SEC. 113. REPORTS.**

7 (a) IN GENERAL.—The Secretary of Health and
8 Human Services shall submit to the Committee on Health,
9 Education, Labor, and Pensions and the Committee on
10 Commerce, Science, and Transportation of the Senate and
11 the Committee on Energy and Commerce and the Com-
12 mittee on Science and Technology of the House of Rep-
13 resentatives, on an annual basis, a report that—

14 (1) describes the specific actions that have been
15 taken by the Federal Government and private enti-
16 ties to facilitate the adoption of an interoperable na-
17 tionwide system for the electronic exchange of health
18 information;

19 (2) describes barriers to the adoption of such a
20 nationwide system; and

21 (3) contains recommendations to achieve full
22 implementation of such a nationwide system.

23 (b) REIMBURSEMENT INCENTIVE STUDY.—The Sec-
24 retary of Health and Human Services shall carry out, or
25 contract with a private entity to carry out, a study that

1 examines methods to create efficient reimbursement incen-
 2 tives for improving health care quality in Federally quali-
 3 fied health centers, rural health clinics, and free clinics.

4 **Subtitle B—Incentives for the Use**
 5 **of Health Information Technology**

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

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

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

12 **“SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDE-**
 13 **SPREAD ADOPTION OF QUALIFIED HEALTH**
 14 **INFORMATION TECHNOLOGY.**

15 **“(a) COMPETITIVE GRANTS TO FACILITATE THE**
 16 **WIDESPREAD ADOPTION OF HEALTH INFORMATION**
 17 **TECHNOLOGY.—**

18 **“(1) IN GENERAL.—**The National Coordinator
 19 may award competitive grants to eligible entities to
 20 purchase qualified health information technology.

21 **“(2) QUALIFIED HEALTH INFORMATION TECH-**
 22 **NOLOGY.—**For purposes of this section, the term
 23 ‘qualified health information technology’ means
 24 health information technology that consists of hard-

1 ware, software, or the provision of support services
2 and that—

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

5 “(B) is (or is necessary for the operation
6 of) an electronic health records system, includ-
7 ing the provision of decision support and physi-
8 cian order entry for medications;

9 “(C) has the ability to allow timely and
10 permissible access to patient information and to
11 transmit and exchange health information
12 among providers, patients, or insurers; and

13 “(D) is certified under the program devel-
14 oped under section 3001(c)(9) to be in compli-
15 ance with any applicable standards and imple-
16 mentation specifications adopted under section
17 3004(b).

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

20 “(A) submit to the National Coordinator
21 an application at such time and in such manner
22 as the National Coordinator may require, and
23 containing—

24 “(i) a plan on how the entity intends
25 to maintain and support the qualified

1 health information technology that would
2 be purchased with amounts under such
3 grant, including the type of resources ex-
4 pected to be involved; and

5 “(ii) such other information as the
6 National Coordinator may require;

7 “(B) submit to the National Coordinator a
8 strategic plan for the electronic exchange and
9 use of health information;

10 “(C) be—

11 “(i) a not for profit hospital or a Fed-
12 erally qualified health center (as defined in
13 section 1861(aa)(4) of the Social Security
14 Act);

15 “(ii) an individual or group practice;
16 or

17 “(iii) another health care provider not
18 described in clause (i) or (ii);

19 “(D) demonstrate significant financial
20 need;

21 “(E) agree to notify individuals in accord-
22 ance with section 302 of the PRO(TECH)T Act
23 of 2008 if their individually identifiable health
24 information is accessed or acquired as a result
25 of a breach; and

1 “(F) provide matching funds in accordance
2 with paragraph (5).

3 “(4) USE OF FUNDS.—Amounts received under
4 a grant under this subsection shall be used to facili-
5 tate the purchase of qualified health information
6 technology.

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

13 “(6) PREFERENCE IN AWARDING GRANTS.—In
14 awarding grants under this subsection the National
15 Coordinator shall give preference to the following eli-
16 gible entities:

17 “(A) Small health care providers.

18 “(B) Entities that are located in rural,
19 frontier, and other areas that serve uninsured,
20 underinsured, and medically underserved indi-
21 viduals (regardless of whether such area is
22 urban, rural, or frontier).

23 “(C) Entities that will link, to the extent
24 practicable, to local or regional health informa-
25 tion plan or plans.

1 “(D) Nonprofit health care providers.

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

8 “(A) Medicaid transformation grants
9 under section 1903(z) of the Social Security
10 Act.

11 “(B) Grants or funding available through
12 the Agency for Healthcare Research and Qual-
13 ity.

14 “(C) Grants or funding that may be avail-
15 able through the Health Resources and Services
16 Administration for investment in health infor-
17 mation technologies or telehealth.

18 “(D) Grants or funding that may be avail-
19 able through the Department of Agriculture’s
20 Rural Development Telecommunications Pro-
21 gram for investment in telemedicine.

22 “(b) COMPETITIVE GRANTS TO STATES AND INDIAN
23 TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO
24 FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED
25 HEALTH INFORMATION TECHNOLOGY.—

1 “(1) IN GENERAL.—The National Coordinator
2 may award competitive grants to eligible entities for
3 the establishment of programs for loans to health
4 care providers to purchase qualified health informa-
5 tion technology.

6 “(2) ELIGIBLE ENTITY DEFINED.—For pur-
7 poses of this subsection, the term ‘eligible entity’
8 means a State or Indian tribe (as defined in the In-
9 dian Self-Determination and Education Assistance
10 Act) that—

11 “(A) submits to the National Coordinator
12 an application at such time, in such manner,
13 and containing such information as the Na-
14 tional Coordinator may require;

15 “(B) submits to the National Coordinator
16 a strategic plan in accordance with paragraph
17 (4) and provides to the National Coordinator
18 assurances that the entity will update such plan
19 annually in accordance with such paragraph;

20 “(C) provides assurances to the National
21 Coordinator that the entity will establish a
22 Loan Fund in accordance with paragraph (3);

23 “(D) provides assurances to the National
24 Coordinator that the entity will not provide a
25 loan from the Loan Fund to a health care pro-

1 vider unless the provider meets each of the con-
2 ditions described in paragraph (5); and

3 “(E) agrees to provide matching funds in
4 accordance with paragraph (9).

5 “(3) ESTABLISHMENT OF FUND.—For purposes
6 of paragraph (3)(C), an eligible entity shall establish
7 a qualified health information technology loan fund
8 (referred to in this subsection as a ‘Loan Fund’)
9 and comply with the other requirements contained in
10 this section. A grant to an eligible entity under this
11 subsection shall be deposited in the Loan Fund es-
12 tablished by the eligible entity. No funds authorized
13 by other provisions of this subtitle to be used for
14 other purposes specified in this subtitle shall be de-
15 posited in any Loan Fund.

16 “(4) STRATEGIC PLAN.—

17 “(A) IN GENERAL.—For purposes of para-
18 graph (3)(B), a strategic plan of an eligible en-
19 tity under this paragraph shall identify the in-
20 tended uses of amounts available to the Loan
21 Fund of such entity.

22 “(B) CONTENTS.—A strategic plan under
23 subparagraph (A), with respect to a Loan Fund
24 of an eligible entity, shall include for a year the
25 following:

1 “(i) A list of the projects to be as-
2 sisted through the Loan Fund during such
3 year.

4 “(ii) A description of the criteria and
5 methods established for the distribution of
6 funds from the Loan Fund during the
7 year.

8 “(iii) A description of the financial
9 status of the Loan Fund as of the date of
10 submission of the plan.

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

13 “(5) HEALTH CARE PROVIDER CONDITIONS FOR
14 RECEIPT OF LOANS.—For purposes of paragraph
15 (2)(D), the conditions described in this paragraph,
16 with respect to a health care provider that seeks a
17 loan from a Loan Fund established under this sub-
18 section, are the following:

19 “(A) The health care provider links, to the
20 extent practicable, to a local or regional health
21 information network.

22 “(B) The health care provider consults
23 with the Health Information Technology Re-
24 source Center established under section 3007 to
25 access the knowledge and experience of existing

1 initiatives regarding the successful implementa-
2 tion and effective use of health information
3 technology.

4 “(C) The health care provider agrees to
5 notify individuals in accordance with section
6 302 of the PRO(TECH)T Act of 2008 if their
7 individually identifiable health information is
8 accessed or acquired as a result of a breach.

9 “(D) The health care provider submits to
10 the State or Indian tribe involved a plan on how
11 the health care provider intends to maintain
12 and support the qualified health information
13 technology that would be purchased with such
14 loan, including the type of resources expected to
15 be involved and any such other information as
16 the State or Indian Tribe, respectively, may re-
17 quire.

18 “(6) USE OF FUNDS.—

19 “(A) IN GENERAL.—Amounts deposited in
20 a Loan Fund, including loan repayments and
21 interest earned on such amounts, shall be used
22 only for awarding loans or loan guarantees, or
23 as a source of reserve and security for leveraged
24 loans, the proceeds of which are deposited in
25 the Loan Fund established under paragraph

1 (1). Loans under this section may be used by
2 a health care provider to purchase qualified
3 health information technology.

4 “(B) LIMITATION.—Amounts received by
5 an eligible entity under this subsection may not
6 be used—

7 “(i) for the purchase or other acquisi-
8 tion of any health information technology
9 system that is not a qualified health infor-
10 mation technology;

11 “(ii) to conduct activities for which
12 Federal funds are expended under this
13 title; or

14 “(iii) for any purpose other than mak-
15 ing loans to health care providers in ac-
16 cordance with this section.

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

21 “(A) To award loans that comply with the
22 following:

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

1 “(ii) The principal and interest pay-
2 ments on each loan shall commence not
3 later than 1 year after the date the loan
4 was awarded, and each loan shall be fully
5 amortized not later than 10 years after the
6 date of the loan.

7 “(iii) The Loan Fund shall be cred-
8 ited with all payments of principal and in-
9 terest on each loan awarded from the Loan
10 Fund.

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

18 “(C) As a source of revenue or security for
19 the payment of principal and interest on rev-
20 enue or general obligation bonds issued by the
21 eligible entity if the proceeds of the sale of the
22 bonds will be deposited into the Loan Fund.

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

25 “(8) ADMINISTRATION OF LOAN FUNDS.—

1 “(A) COMBINED FINANCIAL ADMINISTRA-
2 TION.—An eligible entity may (as a convenience
3 and to avoid unnecessary administrative costs)
4 combine, in accordance with applicable State
5 law, the financial administration of a Loan
6 Fund established under this subsection with the
7 financial administration of any other revolving
8 fund established by the entity if otherwise not
9 prohibited by the law under which the Loan
10 Fund was established.

11 “(B) COST OF ADMINISTERING FUND.—
12 Each eligible entity may annually use not to ex-
13 ceed 4 percent of the funds provided to the en-
14 tity under a grant under this subsection to pay
15 the reasonable costs of the administration of
16 the programs under this section, including the
17 recovery of reasonable costs expended to estab-
18 lish a Loan Fund which are incurred after the
19 date of the enactment of this title.

20 “(C) GUIDANCE AND REGULATIONS.—The
21 National Coordinator shall publish guidance
22 and promulgate regulations as may be nec-
23 essary to carry out the provisions of this sub-
24 section, including—

1 “(i) provisions to ensure that each eli-
2 gible entity commits and expends funds al-
3 lotted to the entity under this subsection
4 as efficiently as possible in accordance with
5 this title and applicable State laws; and

6 “(ii) guidance to prevent waste, fraud,
7 and abuse.

8 “(D) PRIVATE SECTOR CONTRIBUTIONS.—

9 “(i) IN GENERAL.—A Loan Fund es-
10 tablished under this subsection may accept
11 contributions from private sector entities,
12 except that such entities may not specify
13 the recipient or recipients of any loan
14 issued under this subsection. An eligible
15 entity may agree to reimburse a private
16 sector entity for any contribution made
17 under this subparagraph, except that the
18 amount of such reimbursement may not be
19 greater than the principal amount of the
20 contribution made.

21 “(ii) AVAILABILITY OF INFORMA-
22 TION.—An eligible entity shall make pub-
23 licly available the identity of, and amount
24 contributed by, any private sector entity
25 under clause (i) and may issue letters of

1 commendation or make other awards (that
2 have no financial value) to any such entity.

3 “(9) MATCHING REQUIREMENTS.—

4 “(A) IN GENERAL.—The National Coordi-
5 nator may not make a grant under paragraph
6 (1) to an eligible entity unless the entity agrees
7 to make available (directly or through donations
8 from public or private entities) non-Federal
9 contributions in cash to the costs of carrying
10 out the activities for which the grant is awarded
11 in an amount equal to not less than \$1 for each
12 \$1 of Federal funds provided under the grant.

13 “(B) DETERMINATION OF AMOUNT OF
14 NON-FEDERAL CONTRIBUTION.—In determining
15 the amount of non-Federal contributions that
16 an eligible entity has provided pursuant to sub-
17 paragraph (A), the National Coordinator may
18 not include any amounts provided to the entity
19 by the Federal Government.

20 “(10) REPORTS.—The National Coordinator
21 shall annually submit to the Committee on Health,
22 Education, Labor, and Pensions and the Committee
23 on Finance of the Senate, and the Committee on
24 Energy and Commerce of the House of Representa-
25 tives, a report summarizing the reports received by

1 the National Coordinator from each eligible entity
2 that receives a grant under this subsection.

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

6 “(1) IN GENERAL.—The National Coordinator
7 may award competitive grants to eligible entities to
8 implement regional or local health information plans
9 to improve health care quality and efficiency through
10 the electronic exchange and use of health informa-
11 tion.

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

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

17 “(B) demonstrate financial need to the Na-
18 tional Coordinator;

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

23 “(D) adopt bylaws, memoranda of under-
24 standing, or other charter documents that dem-
25 onstrate that the governance structure and de-

1 decisionmaking processes of such entity allow for
2 participation on an ongoing basis by multiple
3 stakeholders within a community, including—

4 “(i) physicians (as defined in section
5 1861(r) of the Social Security Act), includ-
6 ing physicians that provide services to low
7 income populations and populations that
8 are uninsured, underinsured, and medically
9 underserved (including such populations in
10 urban and rural areas);

11 “(ii) hospitals (including hospitals
12 that provide services to low income and un-
13 derserved populations);

14 “(iii) pharmacists and pharmacies;

15 “(iv) health plans;

16 “(v) health centers (as defined in sec-
17 tion 330(b)) and Federally qualified health
18 centers (as defined in section 1861(aa)(4)
19 of the Social Security Act);

20 “(vi) rural health clinics (as defined in
21 section 1861(aa) of the Social Security
22 Act);

23 “(vii) patient or consumer organiza-
24 tions that reflect the population to be
25 served;

- 1 “(viii) employers;
- 2 “(ix) public health agencies; and
- 3 “(x) such other health care providers
- 4 or other entities, as determined appro-
- 5 priate by the National Coordinator;
- 6 “(E) demonstrate the participation, to the
- 7 extent practicable, of stakeholders in the elec-
- 8 tronic exchange and use of health information
- 9 within the local or regional health information
- 10 plan pursuant to subparagraph (D);
- 11 “(F) adopt nondiscrimination and conflict
- 12 of interest policies that demonstrate a commit-
- 13 ment to open, fair, and nondiscriminatory par-
- 14 ticipation in the regional or local health infor-
- 15 mation plan by all stakeholders;
- 16 “(G) comply with applicable standards and
- 17 implementation specifications adopted under
- 18 subtitle A of this title;
- 19 “(H) prepare and submit to the National
- 20 Coordinator an application in accordance with
- 21 paragraph (3); and
- 22 “(I) agree to provide matching funds in ac-
- 23 cordance with paragraph (6).
- 24 “(3) APPLICATION.—

1 “(A) IN GENERAL.—To be eligible to re-
2 ceive a grant under paragraph (1), an entity
3 shall submit to the National Coordinator an ap-
4 plication at such time, in such manner, and
5 containing such information (in addition to in-
6 formation required under subparagraph (B), as
7 the National Coordinator may require.

8 “(B) REQUIRED INFORMATION.—At a
9 minimum, an application submitted under this
10 paragraph shall include—

11 “(i) clearly identified short-term and
12 long-term objectives of the regional or local
13 health information plan;

14 “(ii) an estimate of costs of the hard-
15 ware, software, training, and other services
16 necessary to implement the regional or
17 local health information plan;

18 “(iii) a strategy that includes initia-
19 tives to improve health care quality and ef-
20 ficiency;

21 “(iv) a plan that describes provisions
22 to encourage the electronic exchange and
23 use of health information by all physicians,
24 including single physician practices and

1 small physician groups, participating in the
2 health information plan;

3 “(v) a plan to ensure the privacy and
4 security of individually identifiable health
5 information that is consistent with applica-
6 ble Federal and State law;

7 “(vi) a governance plan that defines
8 the manner in which the stakeholders shall
9 jointly make policy and operational deci-
10 sions on an ongoing basis;

11 “(vii) a financial or business plan that
12 describes—

13 “(I) the sustainability of the
14 plan;

15 “(II) the financial costs and ben-
16 efits of the plan; and

17 “(III) the entities to which such
18 costs and benefits will accrue;

19 “(viii) a plan on how the entity in-
20 volved intends to maintain and support the
21 regional or local health information plan,
22 including the type of resources expected to
23 be involved; and

24 “(ix) in the case of an applicant that
25 is unable to demonstrate the participation

1 of all stakeholders pursuant to paragraph
2 (2)(D), the justification from the entity for
3 any such nonparticipation.

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

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

16 “(6) MATCHING REQUIREMENT.—

17 “(A) IN GENERAL.—The National Coordi-
18 nator may not make a grant under this sub-
19 section to an entity unless the entity agrees
20 that, with respect to the costs of carrying out
21 the activities for which the grant is awarded,
22 the entity will make available (directly or
23 through donations from public or private enti-
24 ties) non-Federal contributions toward such
25 costs in an amount equal to not less than 50

1 percent of such costs (\$1 for each \$2 of Federal
2 funds provided under the grant).

3 “(B) DETERMINATION OF AMOUNT CON-
4 TRIBUTED.—Non-Federal contributions re-
5 quired under subparagraph (A) may be in cash
6 or in kind, fairly evaluated, including equip-
7 ment, technology, or services. Amounts provided
8 by the Federal Government, or services assisted
9 or subsidized to any significant extent by the
10 Federal Government, may not be included in
11 determining the amount of such non-Federal
12 contributions.

13 “(d) REPORTS.—Not later than 1 year after the date
14 on which the first grant is awarded under this section,
15 and annually thereafter during the grant period, an entity
16 that receives a grant under this section shall submit to
17 the National Coordinator a report on the activities carried
18 out under the grant involved. Each such report shall in-
19 clude—

20 “(1) a description of the financial costs and
21 benefits of the project involved and of the entities to
22 which such costs and benefits accrue;

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

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

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

7 “(5) an analysis of the effectiveness of the
8 project involved on ensuring the privacy and security
9 of individually identifiable health information in ac-
10 cordance with applicable Federal and State law; and

11 “(6) other information as required by the Na-
12 tional Coordinator.

13 “(e) REQUIREMENT TO IMPROVE QUALITY OF CARE
14 AND DECREASE IN COSTS.—The National Coordinator
15 shall annually evaluate the activities conducted under this
16 section and shall, in awarding grants, implement the les-
17 sons learned from such evaluation in a manner so that
18 awards made subsequent to each such evaluation are made
19 in a manner that, in the determination of the National
20 Coordinator, will result in the greatest improvement in
21 quality of care and decrease in costs.

22 “(f) LIMITATION.—An eligible entity may only receive
23 one non-renewable grant under subsection (a), one non-
24 renewable grant under subsection (b), and one non-renew-
25 able grant under subsection (c).

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

6 “(h) AUTHORIZATION OF APPROPRIATIONS.—

7 “(1) IN GENERAL.—For the purpose of car-
8 rying out subsections (a) through (d), there is au-
9 thorized to be appropriated \$115,000,000 for each
10 of the fiscal years 2009 through 2013.

11 “(2) AVAILABILITY.—Amounts appropriated
12 under paragraph (1) shall remain available through
13 fiscal year 2013.

14 **“SEC. 3012. DEMONSTRATION PROGRAM TO INTEGRATE IN-**
15 **FORMATION TECHNOLOGY INTO CLINICAL**
16 **EDUCATION.**

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

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

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

4 “(2) submit to the Secretary a strategic plan
5 for integrating qualified health information tech-
6 nology in the clinical education of health profes-
7 sionals to reduce medical errors and enhance health
8 care quality;

9 “(3) be—

10 “(A) a school of medicine, osteopathic
11 medicine, dentistry, or pharmacy, or a graduate
12 program in behavioral or mental health;

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

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

17 “(D) an institution with a graduate med-
18 ical education program in medicine, osteopathic
19 medicine, dentistry, pharmacy, nursing, or phy-
20 sician assistance studies.

21 “(4) provide for the collection of data regarding
22 the effectiveness of the demonstration project to be
23 funded under the grant in improving the safety of
24 patients, the efficiency of health care delivery, and
25 in increasing the likelihood that graduates of the

1 grantee will adopt and incorporate qualified health
2 information technology, in the delivery of health care
3 services; and

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

6 “(c) USE OF FUNDS.—

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

9 “(A) use grant funds in collaboration with
10 2 or more disciplines; and

11 “(B) use grant funds to integrate qualified
12 health information technology into community-
13 based clinical education.

14 “(2) LIMITATION.—An eligible entity shall not
15 use amounts received under a grant under sub-
16 section (a) to purchase hardware, software, or serv-
17 ices.

18 “(d) MATCHING FUNDS.—

19 “(1) IN GENERAL.—The Secretary may award
20 a grant to an entity under this section only if the
21 entity agrees to make available non-Federal con-
22 tributions toward the costs of the program to be
23 funded under the grant in an amount that is not
24 less than \$1 for each \$2 of Federal funds provided
25 under the grant.

1 “(2) DETERMINATION OF AMOUNT CONTRIB-
2 UTED.—Non-Federal contributions under paragraph
3 (1) may be in cash or in kind, fairly evaluated, in-
4 cluding equipment or services. Amounts provided by
5 the Federal Government, or services assisted or sub-
6 sidized to any significant extent by the Federal Gov-
7 ernment, may not be included in determining the
8 amount of such contributions.

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

14 “(f) REPORTS.—Not later than 1 year after the date
15 of enactment of this title, and annually thereafter, the Sec-
16 retary shall submit to the Committee on Health, Edu-
17 cation, Labor, and Pensions and the Committee on Fi-
18 nance of the Senate, and the Committee on Energy and
19 Commerce of the House of Representatives a report
20 that—

21 “(1) describes the specific projects established
22 under this section; and

23 “(2) contains recommendations for Congress
24 based on the evaluation conducted under subsection
25 (e).

1 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
2 is authorized to be appropriated to carry out this section,
3 \$10,000,000 for each of fiscal years 2009 through 2011.

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

6 **TITLE II—TESTING OF HEALTH**
7 **INFORMATION TECHNOLOGY**

8 **SEC. 201. NATIONAL INSTITUTE FOR STANDARDS AND**
9 **TECHNOLOGY TESTING.**

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

20 (b) VOLUNTARY TESTING PROGRAM.—In coordina-
21 tion with the HIT Standards Committee established under
22 section 3003 of the Public Health Service Act, as added
23 by section 101, with respect to the development of stand-
24 ards and implementation specifications under such sec-
25 tion, the Director of the National Institute of Standards

1 and Technology shall support the establishment of a con-
2 formance testing infrastructure, including the develop-
3 ment of technical test beds. The development of this con-
4 formance testing infrastructure may include a program to
5 accredit independent, non-Federal laboratories to perform
6 testing.

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

8 (a) HEALTH CARE INFORMATION ENTERPRISE INTE-
9 GRATION RESEARCH CENTERS.—

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

19 (2) REVIEW; COMPETITION.—Grants shall be
20 awarded under this subsection on a merit-reviewed,
21 competitive basis.

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

24 (A) to generate innovative approaches to
25 health care information enterprise integration

1 by conducting cutting-edge, multidisciplinary
2 research on the systems challenges to health
3 care delivery; and

4 (B) the development and use of health in-
5 formation technologies and other complemen-
6 tary fields.

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

9 (A) interfaces between human information
10 and communications technology systems;

11 (B) voice-recognition systems;

12 (C) software that improves interoperability
13 and connectivity among health information sys-
14 tems;

15 (D) software dependability in systems crit-
16 ical to health care delivery;

17 (E) measurement of the impact of informa-
18 tion technologies on the quality and productivity
19 of health care;

20 (F) health information enterprise manage-
21 ment;

22 (G) health information technology security
23 and integrity; and

24 (H) relevant health information technology
25 to reduce medical errors.

1 (5) APPLICATIONS.—An institution of higher
2 education (or a consortium thereof) seeking funding
3 under this subsection shall submit an application to
4 the Director of the National Institute of Standards
5 and Technology at such time, in such manner, and
6 containing such information as the Director may re-
7 quire. The application shall include, at a minimum,
8 a description of—

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

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

18 (C) technology transfer activities to dem-
19 onstrate and diffuse the research results, tech-
20 nologies, and knowledge; and

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

1 (b) NATIONAL INFORMATION TECHNOLOGY RE-
2 SEARCH AND DEVELOPMENT PROGRAM.—The National
3 High-Performance Computing Program established by
4 section 101 of the High-Performance Computing Act of
5 1991 (15 U.S.C. 5511) shall coordinate Federal research
6 and development programs related to the development and
7 deployment of health information technology, including ac-
8 tivities related to—

9 (1) computer infrastructure;

10 (2) data security;

11 (3) development of large-scale, distributed, reli-
12 able computing systems;

13 (4) wired, wireless, and hybrid high-speed net-
14 working;

15 (5) development of software and software-inten-
16 sive systems;

17 (6) human-computer interaction and informa-
18 tion management technologies; and

19 (7) the social and economic implications of in-
20 formation technology.

21 **TITLE III—PRIVACY AND**
22 **SECURITY PROVISIONS**

23 **SEC. 300. DEFINITIONS.**

24 In this title, except as specified otherwise:

1 (1) BREACH.—The term “breach” means the
2 unauthorized acquisition or disclosure of protected
3 health information which compromises the security,
4 privacy, or integrity of protected health information
5 maintained by or on behalf of a person. Such term
6 does not include any unintentional acquisition of
7 such information by an employee or agent of the
8 covered entity or business associate involved if such
9 acquisition was made in good faith and within the
10 course and scope of the employment or other con-
11 tractual relationship of such employee or agent, re-
12 spectively, with the covered entity or business asso-
13 ciate and if such information is not further acquired,
14 used, or disclosed by such employee or agent.

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

19 (3) COVERED ENTITY.—The term “covered en-
20 tity” has the meaning given such term in section
21 160.103 of title 45, Code of Federal Regulations.

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

1 (5) ENCRYPTION.—The term “encryption” has
2 the meaning given such term in section 164.304 of
3 title 45, Code of Federal Regulations.

4 (6) HEALTH CARE OPERATIONS.—The term
5 “health care operation” has the meaning given such
6 term in section 164.501 of title 45, Code of Federal
7 Regulations.

8 (7) HEALTH CARE PROVIDER.—The term
9 “health care provider” has the meaning given such
10 term in section 160.103 of title 45, Code of Federal
11 Regulations.

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

18 (9) PROTECTED HEALTH INFORMATION.—The
19 term “protected health information” has the mean-
20 ing given such term under section 160.103 of title
21 45, Code of Federal Regulations.

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

1 (11) SECURITY.—The term “security” has the
2 meaning given such term in section 164.304 of title
3 45, Code of Federal Regulations.

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

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

11 (14) VENDOR OF PERSONAL HEALTH
12 RECORDS.—The term “vendor” means an entity that
13 offers or maintains a personal health record and
14 that is not a covered entity.

15 **Subtitle A—Security Provisions**

16 **SEC. 301. APPLICATION OF SECURITY PROVISIONS AND** 17 **PENALTIES TO BUSINESS ASSOCIATES OF** 18 **COVERED ENTITIES; ANNUAL GUIDANCE ON** 19 **SECURITY PROVISIONS.**

20 (a) APPLICATION OF SECURITY PROVISIONS.—Sec-
21 tions 164.308, 164.310, and 164.312 of title 45, Code of
22 Federal Regulations, shall apply to a business associate
23 of a covered entity in the same manner that such sections
24 apply to the covered entity.

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

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

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

16 (a) IN GENERAL.—A covered entity that accesses,
17 maintains, retains, modifies, records, stores, destroys, or
18 otherwise holds, uses, or discloses unencrypted protected
19 health information (as defined in subsection (h)) shall, in
20 the case of a breach of such information that is discovered
21 by the covered entity, notify each individual whose
22 unencrypted protected health information has been, or is
23 reasonably believed by the covered entity to have been,
24 accessed or acquired as a result of such breach.

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

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

20 (d) TIMELINESS OF NOTIFICATION.—

21 (1) IN GENERAL.—All notifications required
22 under this section shall be made without unreason-
23 able delay and in no case later than 60 calendar
24 days after the discovery of a breach by the covered

1 entity involved (or business associate involved in the
2 case of a notification required under subsection (b)).

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

10 (e) METHODS OF NOTICE.—

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

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

23 (B) In the case where there is insufficient,
24 or out-of-date contact information that pre-
25 cludes direct written (or, if specified by the in-

1 dividual under subparagraph (A), electronic)
2 notification to the individual, a substitute form
3 of notice shall be provided, including a con-
4 spicuous posting on the home page of the Web
5 site of the covered entity involved or notice in
6 major print or broadcast media, including
7 major media in geographic areas where the in-
8 dividuals affected by the breach likely reside.
9 Such a notice in media will include a toll-free
10 phone number where an individual can learn
11 whether or not the individual's unencrypted
12 protected health information is possibly in-
13 cluded in the breach.

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

21 (2) MEDIA NOTICE.—Notice shall be provided
22 to prominent media outlets serving a State or juris-
23 diction, following the discovery of a breach described
24 in subsection (a), if the unencrypted protected
25 health information of more than 500 residents of

1 such State or jurisdiction is, or is reasonably be-
2 lieved to have been, accessed or acquired during
3 such breach.

4 (3) NOTICE TO SECRETARY.—Notice shall be
5 provided to the Secretary by covered entities of
6 unencrypted protected health information that has
7 been acquired or disclosed in a breach.

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

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

20 (1) A brief description of what happened, in-
21 cluding the date of the breach and the date of the
22 discovery of the breach, if known.

23 (2) A description of the types of unencrypted
24 protected health information that were involved in
25 the breach (such as full name, Social Security num-

1 ber, date of birth, home address, account number, or
2 disability code).

3 (3) The steps individuals should take to protect
4 themselves from potential harm resulting from the
5 breach.

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

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

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

23 (h) UNENCRYPTED PROTECTED HEALTH INFORMA-
24 TION DEFINED.—For purposes of this section, the term

1 “unencrypted protected health information” means pro-
2 tected health information that is not protected—

3 (1) through the use of encryption; or

4 (2) through the use of a technology specified by
5 the Secretary as being at least as effective as
6 encryption for purposes of rendering protected
7 health information indecipherable without authoriza-
8 tion.

9 **SEC. 303. EDUCATION ON HEALTH INFORMATION PRIVACY**

10 **AND REPORT ON COMPLIANCE.**

11 (a) REGIONAL OFFICE PRIVACY ADVISORS.—Not
12 later than 6 months after the date of the enactment of
13 this Act, the Secretary shall designate an individual in
14 each regional office of the Department of Health and
15 Human Services to offer guidance and education to cov-
16 ered entities, business associates, and individuals on their
17 rights and responsibilities related to Federal privacy re-
18 quirements for protected health information.

19 (b) REPORT ON COMPLIANCE.—

20 (1) IN GENERAL.—For the first year beginning
21 after the date of the enactment of this Act and an-
22 nually thereafter, the Secretary shall prepare and
23 submit to Congress a report concerning complaints
24 of alleged violations of the provisions of sections 301
25 and 302, the provisions of subtitle B, and the provi-

1 sions of subparts C and E of title 45, Code of Fed-
2 eral Regulations that are received by the Secretary
3 during the year for which the report is being pre-
4 pared. Each such report shall include, with respect
5 to such complaints received during the year—

6 (A) the number of such complaints;

7 (B) the resolution or disposition of such
8 complaints;

9 (C) the amount of civil money penalties
10 imposed with respect to such complaints, as ap-
11 plicable;

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

14 (E) the number of subpoenas or inquiries
15 issued; and

16 (F) the Secretary's plan for improving
17 compliance with and enforcement of such provi-
18 sions for the following year.

19 (2) AVAILABILITY TO PUBLIC.—Each report
20 under paragraph (1) shall be made available to the
21 public on the Internet website of the Department of
22 Health and Human Services.

23 (c) EDUCATION INITIATIVE ON USES OF HEALTH IN-
24 FORMATION.—

1 (1) IN GENERAL.—The Office for Civil Rights
2 within the Department of Health and Human Serv-
3 ices shall develop and maintain a multi-faceted na-
4 tional education initiative to enhance public trans-
5 parency regarding the uses of protected health infor-
6 mation, including programs to educate individuals
7 about the potential uses of their health information
8 and effects of such uses. Such programs shall be
9 conducted in a variety of languages and present in-
10 formation in a clear and understandable manner.

11 (2) AUTHORIZATION OF APPROPRIATIONS.—
12 There is authorized to be appropriated to carry out
13 paragraph (1), \$10,000,000 for the period of fiscal
14 years 2009 through 2013.

15 **Subtitle B—Improved Privacy Pro-**
16 **visions and Additional Security**
17 **Provisions**

18 **SEC. 311. APPLICATION OF PENALTIES TO BUSINESS ASSO-**
19 **CIATES OF COVERED ENTITIES FOR VIOLA-**
20 **TIONS OF PRIVACY CONTRACT REQUIRE-**
21 **MENTS.**

22 (a) APPLICATION OF CONTRACT REQUIREMENTS.—
23 In the case of a business associate of a covered entity that
24 obtains or creates protected health information pursuant
25 to a written contract (or other written arrangement) de-

1 scribed in section 164.502(e)(2) of title 45, Code of Fed-
2 eral Regulations, with such covered entity, the business
3 associate may use and disclose such protected health infor-
4 mation only if such use or disclosure, respectively, is in
5 compliance with each applicable requirement of section
6 164.504(e) of such title.

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

18 (c) APPLICATION OF CIVIL AND CRIMINAL PEN-
19 ALTIES.—In the case of a business associate that violates
20 any provision of subsection (a) or (b), the provisions of
21 sections 1176 and 1177 of the Social Security Act shall
22 apply to the business associate with respect to such viola-
23 tion in the same manner as such provisions apply to a
24 person who violates a provision of part C of title XI of
25 such Act.

1 **SEC. 312. RESTRICTIONS ON CERTAIN DISCLOSURES OF**
2 **HEALTH INFORMATION; ACCOUNTING OF**
3 **CERTAIN PROTECTED HEALTH INFORMATION**
4 **DISCLOSURES.**

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

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

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

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

24 (1) IN GENERAL.—A covered entity shall be
25 treated as being in compliance with section
26 164.502(b)(1) of title 45, Code of Federal Regula-

1 tions, with respect to the use, disclosure, or request
2 of protected health information described in such
3 section, only if the covered entity makes reasonable
4 efforts to limit such protected health information to
5 the limited data set (as defined in section
6 164.514(e)(2) of such title) or, if needed by such en-
7 tity, to the minimum necessary to accomplish the in-
8 tended purpose of such use, disclosure, or request,
9 respectively.

10 (2) APPLICATION OF EXCEPTIONS.—The excep-
11 tions described in section 164.502(b)(2) of title 45,
12 Code of Federal Regulations, shall apply to the re-
13 quirement under paragraph (1) as of the effective
14 date described in section 322 in the same manner
15 that such exceptions apply to section 164.502(b)(1)
16 of such title before such date.

17 (c) ACCOUNTING OF CERTAIN PROTECTED HEALTH
18 INFORMATION DISCLOSURES REQUIRED IF COVERED EN-
19 TITY USES ELECTRONIC MEDICAL RECORD.—

20 (1) IN GENERAL.—In the case that a covered
21 entity uses or maintains an electronic medical record
22 with respect to protected health information, the ex-
23 ception under section 164.528(a)(1)(i) of title 45,
24 Code of Federal Regulations, shall not apply to dis-

1 closures (other than oral disclosures) made by such
2 entity of such information.

3 (2) ELECTRONIC MEDICAL RECORD DEFINED.—

4 For purposes of paragraph (1), the term “electronic
5 medical record” means an electronic record of indi-
6 vidually identifiable health information on an indi-
7 vidual that is created, gathered, managed, and con-
8 sulted by authorized clinicians and staff within a
9 single organization.

10 (3) EFFECTIVE DATE.—The provisions of this
11 subsection shall apply to disclosures made by a cov-
12 ered entity on or after the date specified under sec-
13 tion 322.

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

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

1 entity obtains the consent of the individual to dis-
2 close such information for such purposes and any
3 such consent shall be revocable by the individual at
4 any time.

5 (2) EFFECTIVE DATE.—The provisions of this
6 subsection shall apply to disclosures made by a cov-
7 ered entity on or after the date specified under sec-
8 tion 322.

9 **SEC. 313. CONDITIONS ON CERTAIN CONTACTS AS PART OF**
10 **HEALTH CARE OPERATIONS.**

11 (a) IN GENERAL.—A communication by a covered en-
12 tity or business associate that is about a product or service
13 and that encourages recipients of the communication to
14 purchase or use the product or service shall not be consid-
15 ered a health care operation for purposes of subpart E
16 of part 164 of title 45, Code of Federal Regulations, un-
17 less the communication is made as described in subpara-
18 graph (i), (ii), or (iii) of paragraph (1) of the definition
19 of marketing in section 164.501 of such title. A covered
20 entity or business associate may not receive direct pay-
21 ment for any such communication made as described in
22 such subparagraph (i), (ii), or (iii).

23 (b) EFFECTIVE DATE.—Subsection (a) shall apply to
24 contracting occurring on or after the effective date speci-
25 fied under section 322.

1 **SEC. 314. STUDY ON APPLICATION OF PRIVACY AND SECU-**
2 **RITY REQUIREMENTS TO VENDORS OF PER-**
3 **SONAL HEALTH RECORDS.**

4 Not later than one year after the date of the enact-
5 ment of this Act, the Secretary , in consultation with the
6 Federal Trade Commission, shall submit to Congress rec-
7 ommendations—

8 (1) to identify requirements relating to security,
9 privacy, and notification in the case of a breach of
10 security or privacy (including the applicability of an
11 exemption to notification in the case of protected
12 health information which has been rendered indeci-
13 pherable through the use of encryption or alternative
14 technologies) that should be applied to vendors of
15 personal health records and to third party service
16 providers that such vendors make available to indi-
17 viduals with personal health records offered or main-
18 tained by such vendor, with respect to information
19 in such a record so offered or maintained; and

20 (2) to determine which Federal government
21 agency is best equipped to enforce such requirements
22 recommended to be applied to such vendors of per-
23 sonal health records and such third party service
24 providers.

1 **SEC. 315. TEMPORARY BREACH NOTIFICATION REQUIRE-**
2 **MENT FOR VENDORS OF PERSONAL HEALTH**
3 **RECORDS.**

4 (a) IN GENERAL.—In accordance with subsection (c),
5 each vendor of personal health records shall, following the
6 discovery of a breach of security of unencrypted individ-
7 ually identifiable health information in such records main-
8 tained or offered by such vendor—

9 (1) notify each individual who is a citizen or
10 resident of the United States whose unencrypted in-
11 dividually identifiable health information was ac-
12 quired by an unauthorized person as a result of such
13 a breach of security; and

14 (2) notify the Federal Trade Commission.

15 (b) NOTIFICATION OF VENDORS OF PERSONAL
16 HEALTH RECORDS BY THIRD PARTY SERVICE PRO-
17 VIDERS.—A third party service provider that is made
18 available by a vendor of personal health records to individ-
19 uals with such records maintained or offered by such ven-
20 dor and that accesses, maintains, retains, modifies,
21 records, stores, destroys, or otherwise holds, uses, or dis-
22 closes unencrypted individually identifiable health infor-
23 mation in such records shall, following the discovery of
24 a breach of security of such information, notify such ven-
25 dor of such breach. Such notice shall include the identi-
26 fication of each individual whose unencrypted individually

1 identifiable health information has been, or is reasonably
2 believed to have been, accessed or acquired during such
3 breach.

4 (c) APPLICATION OF REQUIREMENTS FOR TIMELI-
5 NESS, METHOD, AND CONTENT OF NOTIFICATIONS.—
6 Subsections (c), (d), (e), and (f) of section 302 shall apply
7 to a notification required under subsection (a) and a ven-
8 dor of personal health records and a third party service
9 provider described in subsection (b), with respect to a
10 breach of security under subsection (a) of unencrypted in-
11 dividually identifiable health information in such records
12 maintained or offered by such vendor, in the same manner
13 that such subsections apply to a notification required
14 under such section and a covered entity and a business
15 associate of such covered entity, with respect to a breach
16 under such section of unencrypted protected health infor-
17 mation held, used, or disclosed by such covered entity.

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

22 (e) ENFORCEMENT.—A violation of subsection (a) or
23 (b) shall be treated as an unfair and deceptive act or prac-
24 tice in violation of a regulation under section 18(a)(1)(B)
25 of the Federal Trade Commission Act (15 U.S.C.

1 57a(a)(1)(B)) regarding unfair or deceptive acts or prac-
2 tices.

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

4 (1) BREACH OF SECURITY.—The term “breach
5 of security” means, with respect to unencrypted in-
6 dividually identifiable health information of an indi-
7 vidual in a personal health record, acquisition of
8 such information without the authorization of the in-
9 dividual.

10 (2) INDIVIDUALLY IDENTIFIABLE HEALTH IN-
11 FORMATION.—The term “individually identifiable
12 health information” has the meaning given such
13 term in section 1171(6) of the Social Security Act
14 (42 U.S.C. 1320d(6)).

15 (3) UNENCRYPTED INDIVIDUALLY IDENTIFI-
16 ABLE HEALTH INFORMATION.—The term
17 “unencrypted individually identifiable health infor-
18 mation” means individually identifiable health infor-
19 mation that is not protected—

20 (A) through the use of encryption; or

21 (B) through the use of a technology speci-
22 fied by the Secretary as being at least as effec-
23 tive as encryption for purposes of rendering in-
24 dividually identifiable health information indeci-
25 pherable without authorization.

1 (g) EFFECTIVE DATE.—The provisions of this sec-
2 tion shall apply to breaches of security occurring during
3 the 2-year period beginning on the date of the enactment
4 of this Act.

5 **SEC. 316. BUSINESS ASSOCIATE CONTRACTS REQUIRED**
6 **FOR CERTAIN ENTITIES.**

7 Each organization, with respect to a covered entity,
8 that provides data transmission of protected health infor-
9 mation to such entity and that requires access on a routine
10 basis to such protected health information, such as a
11 Health Information Exchange, Regional Health Informa-
12 tion Organization, or E-prescribing Gateway, is required
13 to enter into a written contract (or other written arrange-
14 ment) described in section 164.502(e)(2) of title 45, Code
15 of Federal Regulations, with such entity and shall be
16 treated as a business associate of the covered entity for
17 purposes of section 311.

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 **Subtitle C—Relationship to Other** 6 **Laws; Clarification; Effective Date**

7 **SEC. 321. RELATIONSHIP TO OTHER LAWS.**

8 (a) APPLICATION OF HIPAA STATE PREEMPTION.—
9 Section 1178 of the Social Security Act (42 U.S.C.
10 1320d–7) shall apply to a provision or requirement under
11 this title in the same manner that such section applies
12 to a provision or requirement under part C of title XI of
13 such Act or a standard or implementation specification
14 adopted or established under sections 1172 through 1174
15 of such Act.

16 (b) HEALTH INSURANCE PORTABILITY AND AC-
17 COUNTABILITY ACT.—The standards governing the pri-
18 vacy and security of individually identifiable health infor-
19 mation promulgated by the Secretary under sections
20 262(a) and 264 of the Health Insurance Portability and
21 Accountability Act of 1996 shall remain in effect to the
22 extent that they are consistent with this title. The Sec-
23 retary shall by rule amend such Federal regulations as re-
24 quired to make such regulations consistent with this title.

1 **SEC. 322. EFFECTIVE DATE.**

2 The provisions of this title (other than sections
3 301(c), 303, 314, 315, 317, 318, and 319) shall take ef-
4 fect on the date that is 12 months after the date of the
5 enactment of this Act.

○