TITLE XIII—HEALTH INFORMATION TECHNOLOGY

SEC. 13001. SHORT TITLE; TABLE OF CONTENTS OF TITLE.

(a) SHORT TITLE.—This title (and title IV of division B) may be cited as the ''Health Information Technology for Economic and Clinical Health Act'' or the ''HITECH Act''.

(b) TABLE OF CONTENTS OF TITLE.—The table of contents of this title is as follows:

Sec. 13001. Short title; table of contents of title.

Subtitle A—Promotion of Health Information Technology

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

Sec. 13101. ONCHIT; standards development and adoption.

''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; adoption of initial set of standards, implementation specifications, and certification criteria.

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

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

''Sec. 3007. Federal health information technology.

''Sec. 3008. Transitions.

''Sec. 3009. Miscellaneous provisions.

Sec. 13102. Technical amendment.

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

Sec. 13111. Coordination of Federal activities with adopted standards and implementation specifications.

Sec. 13112. Application to private entities.

Sec. 13113. Study and reports.

Subtitle B—Testing of Health Information Technology

Sec. 13201. National Institute for Standards and Technology testing.

Sec. 13202. Research and development programs.

Subtitle C—Grants and Loans Funding

Sec. 13301. Grant, loan, and demonstration programs.

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

''Sec. 3011. Immediate funding to strengthen the health information technology infrastructure.

''Sec. 3012. Health information technology implementation assistance.

''Sec. 3013. State grants to promote health information technology.

''Sec. 3014. Competitive grants to States and Indian tribes for the development of loan programs to facilitate the widespread adoption of certified EHR technology.

''Sec. 3015. Demonstration program to integrate information technology into clinical education.

''Sec. 3016. Information technology professionals in health care.

''Sec. 3017. General grant and loan provisions.

''Sec. 3018. Authorization for appropriations.

Subtitle D—Privacy

Sec. 13400. Definitions.

PART 1—IMPROVED PRIVACY PROVISIONS AND SECURITY PROVISIONS

Sec. 13401. Application of security provisions and penalties to business associates of covered entities; annual guidance on security provisions.

Sec. 13402. Notification in the case of breach.

Sec. 13403. Education on health information privacy.

Sec. 13404. Application of privacy provisions and penalties to business associates of covered entities.

Sec. 13405. Restrictions on certain disclosures and sales of health information; accounting of certain protected health information disclosures; access to certain information in electronic format.

Sec. 13406. Conditions on certain contacts as part of health care operations.

Sec. 13407. Temporary breach notification requirement for vendors of personal health records and other non-HIPAA covered entities.

Sec. 13408. Business associate contracts required for certain entities.

Sec. 13409. Clarification of application of wrongful disclosures criminal penalties.

Sec. 13410. Improved enforcement.

Sec. 13411. Audits.

PART 2—RELATIONSHIP TO OTHER LAWS; REGULATORY REFERENCES; EFFECTIVE DATE; REPORTS

Sec. 13421. Relationship to other laws.

Sec. 13422. Regulatory references.

Sec. 13423. Effective date.

Sec. 13424. Studies, reports, guidance.

Subtitle A—Promotion of Health Information Technology

PART 1—IMPROVING HEALTH CARE QUALITY, SAFETY, AND EFFICIENCY

SEC. 13101. ONCHIT; STANDARDS DEVELOPMENT AND ADOPTION.

The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

''TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

''SEC. 3000. DEFINITIONS.

''In this title:

''(1) CERTIFIED EHR TECHNOLOGY.—The term 'certified EHR technology' means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

''(2) ENTERPRISE INTEGRATION.—The term 'enterprise integration' means the electronic linkage of health care providers, health plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

''(4) HEALTH INFORMATION.—The term 'health information' has the meaning given such term in section 1171(4) of the Social Security Act.

''(5) HEALTH INFORMATION TECHNOLOGY.—The term 'health information technology' means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information

''(6) HEALTH PLAN.—The term 'health plan' has the meaning given such term in section 1171(5) of the Social Security Act.

''(7) HIT POLICY COMMITTEE.—The term 'HIT Policy Committee' means such Committee established under section 3002(a).

''(8) HIT STANDARDS COMMITTEE.—The term 'HIT Standards Committee' means such Committee established under section 3003(a).

''(9) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term 'individually identifiable health information' has the meaning given such term in section 1171(6) of the Social Security Act.

''(10) LABORATORY.—The term 'laboratory' has the meaning given such term in section 353(a).

''(11) NATIONAL COORDINATOR.—The term 'National Coordinator' means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a).

''(12) PHARMACIST.—The term 'pharmacist' has the meaning given such term in section 804(2) of the Federal Food, Drug, and Cosmetic Act.

''(13) QUALIFIED ELECTRONIC HEALTH RECORD.—The term 'qualified electronic health record' means an electronic record of health-related information on an individual that—

''(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

''(B) has the capacity—

''(i) to provide clinical decision support;

''(ii) to support physician order entry;

''(iii) to capture and query information relevant to health care quality; and

''(iv) to exchange electronic health information with, and integrate such information from other sources.

''(14) STATE.—The term 'State' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

''Subtitle A—Promotion of Health Information Technology

''SEC. 3001. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

''(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator

for Health Information Technology (referred to in this section as the 'Office'). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

''(b) PURPOSE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

''(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

''(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

''(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

''(4) provides appropriate information to help guide medical decisions at the time and place of care;

''(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

''(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

''(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

''(8) facilitates health and clinical research and health care quality;

''(9) promotes early detection, prevention, and management of chronic diseases;

''(10) promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and

''(11) improves efforts to reduce health disparities.

''(c) DUTIES OF THE NATIONAL COORDINATOR.—

''(1) STANDARDS.—The National Coordinator shall—

''(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Standards Committee under section 3003 for purposes of adoption under section 3004;

''(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

''(C) review Federal health information technology investments to ensure that Federal health information technology programs are meeting the objectives of the strategic plan published under paragraph (3).

''(2) HIT POLICY COORDINATION.—

''(A) IN GENERAL.—The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

''(B) HIT POLICY AND STANDARDS COMMITTEES.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.

''(3) STRATEGIC PLAN.—

''(A) IN GENERAL.—The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

''(i) The electronic exchange and use of health information and the enterprise integration of such information.

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

''(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

''(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

''(v) Specifying a framework for coordination and flow of recommendations and policies under this subtitle among the Secretary, the National Coordinator, the HIT Policy Committee, the HIT Standards Committee, and other health information exchanges and other relevant entities.

''(vi) Methods to foster the public understanding of health information technology.

''(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

''(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

''(B) COLLABORATION.—The strategic plan shall be updated through collaboration of public and private entities.

''(C) MEASURABLE OUTCOME GOALS.—The strategic plan update shall include measurable outcome goals.

''(D) PUBLICATION.—The National Coordinator shall republish the strategic plan, including all updates.

''(4) WEBSITE.—The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

''(5) CERTIFICATION.—

''(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include, as appropriate, testing of the technology in accordance with section 13201(b) of the Health Information Technology for Economic and Clinical Health Act.

''(B) CERTIFICATION CRITERIA DESCRIBED.—In this title, the term 'certification criteria' means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

''(6) REPORTS AND PUBLICATIONS.—

''(A) REPORT ON ADDITIONAL FUNDING OR AUTHORITY NEEDED.—Not later than 12 months after the date of the enactment of this title, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

''(B) IMPLEMENTATION REPORT.—The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

''(C) ASSESSMENT OF IMPACT OF HIT ON COMMUNITIES WITH HEALTH DISPARITIES AND UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED AREAS.—The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

''(D) EVALUATION OF BENEFITS AND COSTS OF THE ELECTRONIC USE AND EXCHANGE OF HEALTH INFORMATION.—The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

''(E) RESOURCE REQUIREMENTS.—The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

''(i) the required level of Federal funding;

''(ii) expectations for regional, State, and private investment;

''(iii) the expected contributions by volunteers to activities for the utilization of such records; and

''(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

''(7) ASSISTANCE.—The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).

''(8) GOVERNANCE FOR NATIONWIDE HEALTH INFORMATION NETWORK.—The National Coordinator shall establish a governance mechanism for the nationwide health information network.

''(d) DETAIL OF FEDERAL EMPLOYEES.—

''(1) IN GENERAL.—Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

''(2) EFFECT OF DETAIL.—Any detail of personnel under paragraph (1) shall—

''(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

''(B) be in addition to any other staff of the Department employed by the National Coordinator.

''(3) ACCEPTANCE OF DETAILEES.—Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

''(e) CHIEF PRIVACY OFFICER OF THE OFFICE OF THE NATIONAL COORDINATOR.—Not later

than 12 months after the date of the enactment of this title, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

"SEC. 3002. HIT POLICY COMMITTEE.

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

''(b) DUTIES.—

''(1) RECOMMENDATIONS ON HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The HIT Policy Committee shall recommend a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the strategic plan under section 3001(c)(3) and that includes the recommendations under paragraph (2). The Committee shall update such recommendations and make new recommendations as appropriate.

''(2) SPECIFIC AREAS OF STANDARD DEVELOPMENT.—

''(A) IN GENERAL.—The HIT Policy Committee shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such standards and implementation specifications shall include named standards, architectures, and software schemes for the authentication and security of individually identifiable health information and other information as needed to ensure the reproducible development of common solutions across disparate entities.

''(B) AREAS REQUIRED FOR CONSIDERATION.—For purposes of subparagraph (A), the HIT Policy Committee shall make recommendations for at least the following areas:

''(i) Technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law, and for the use and disclosure of limited data sets of such information.

''(ii) A nationwide health information technology infrastructure that allows for the electronic use and accurate exchange of health information.

''(iii) The utilization of a certified electronic health record for each person in the United States by 2014.

''(iv) Technologies that as a part of a qualified electronic health record allow for an accounting of disclosures made by a covered entity (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of such regulations).

''(v) The use of certified electronic health records to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing chronic disease, and by advancing research and education.

''(vi) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in the nationwide health information network or physically transported outside of the secured, physical perimeter of a health care provider, health plan, or health care clearinghouse.

''(vii) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum, race, ethnicity, primary language, and gender information.

''(viii) Technologies that address the needs of children and other vulnerable populations.

''(C) OTHER AREAS FOR CONSIDERATION.—In making recommendations under subparagraph (A), the HIT Policy Committee may consider the following additional areas:

''(i) The appropriate uses of a nationwide health information infrastructure, including for purposes of—

''(I) the collection of quality data and public reporting;

''(II) biosurveillance and public health;

''(III) medical and clinical research; and

''(IV) drug safety.

''(ii) Self-service technologies that facilitate the use and exchange of patient information and reduce wait times.

''(iii) Telemedicine technologies, in order to reduce travel requirements for patients in remote areas.

''(iv) Technologies that facilitate home health care and the monitoring of patients recuperating at home.

''(v) Technologies that help reduce medical errors.

''(vi) Technologies that facilitate the continuity of care among health settings.

''(vii) Technologies that meet the needs of diverse populations.

''(viii) Methods to facilitate secure access by an individual to such individual's protected health information.

''(ix) Methods, guidelines, and safeguards to facilitate secure access to patient information by a family member, caregiver, or guardian acting on behalf of a patient due to age-related and other disability, cognitive impairment, or dementia.

''(x) Any other technology that the HIT Policy Committee finds to be among the technologies with the greatest potential to improve the quality and efficiency of health care.

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

''(4) CONSISTENCY WITH EVALUATION CONDUCTED UNDER MIPPA.—

''(A) REQUIREMENT FOR CONSISTENCY.—The HIT Policy Committee shall ensure that recommendations made under paragraph (2)(B)(vi) are consistent with the evaluation conducted under section 1809(a) of the Social Security Act.

''(B) SCOPE.—Nothing in subparagraph (A) shall be construed to limit the recommendations under paragraph (2)(B)(vi) to the elements described in section 1809(a)(3) of the Social Security Act.

''(C) TIMING.—The requirement under subparagraph (A) shall be applicable to the extent that evaluations have been conducted under section 1809(a) of the Social Security Act, regardless of whether the report described in subsection (b) of such section has been submitted.

''(c) MEMBERSHIP AND OPERATIONS.—

''(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Policy Committee.

''(2) MEMBERSHIP.—The HIT Policy Committee shall be composed of members to be appointed as follows:

''(A) 3 members shall be appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official.

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

''(C) 1 member shall be appointed by the minority leader of the Senate.

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

''(E) 1 member shall be appointed by the minority leader of the House of Representatives.

''(F) Such other members as shall be appointed by the President as representatives of other relevant Federal agencies.

''(G) 13 members shall be appointed by the Comptroller General of the United States of whom—

''(i) 3 members shall advocates for patients or consumers;

''(ii) 2 members shall represent health care providers, one of which shall be a physician;

''(iii) 1 member shall be from a labor organization representing health care workers;

''(iv) 1 member shall have expertise in health information privacy and security;

''(v) 1 member shall have expertise in improving the health of vulnerable populations;

''(vi) 1 member shall be from the research community;

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

''(viii) 1 member shall represent information technology vendors;

''(ix) 1 member shall represent purchasers or employers; and

''(x) 1 member shall have expertise in health care quality measurement and reporting.

''(3) PARTICIPATION.—The members of the HIT Policy Committee appointed under paragraph (2) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Policy Committee.

''(4) TERMS.—

''(A) IN GENERAL.—The terms of the members of the HIT Policy Committee shall be for 3 years, except that the Comptroller General shall designate staggered terms for the members first appointed.

''(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Policy Committee that occurs prior to the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Policy Committee shall be filled in the manner in which the original appointment was made.

''(5) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies for the electronic exchange and use of health information, including in the areas of health information privacy and security.

''(6) QUORUM.—A majority of the member of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

''(7) FAILURE OF INITIAL APPOINTMENT.—If, on the date that is 45 days after the date of enactment of this title, an official authorized under paragraph (2) to appoint one or more members of the HIT Policy Committee has not appointed the full number of members that such paragraph authorizes such official to appoint, the Secretary is authorized to appoint such members.

''(8) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the

National Committee on Vital and Health Statistics are considered in the development of policies.

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

''(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Policy Committee under this section.

"SEC. 3003. HIT STANDARDS COMMITTEE.

''(a) ESTABLISHMENT.—There is established a committee to be known as the HIT Standards Committee to recommend to the National Coordinator standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption under section 3004, consistent with the implementation of the strategic plan described in section 3001(c)(3) and beginning with the areas listed in section 3002(b)(2)(B) in accordance with policies developed by the HIT Policy Committee.

''(b) DUTIES.—

''(1) STANDARDS DEVELOPMENT.—

''(A) IN GENERAL.—The HIT Standards Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Standards Committee. The HIT Standards Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the HIT Policy Committee.

''(B) HARMONIZATION.—The HIT Standards Committee recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specifications.

''(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.

''(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under this subsection shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.

''(2) FORUM.—The HIT Standards Committee shall serve as a forum for the participation of a broad range of stakeholders to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

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

''(4) PUBLIC INPUT.—The HIT Standards Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (3) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.

''(5) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of standards.

''(c) MEMBERSHIP AND OPERATIONS.—

''(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Standards Committee.

''(2) MEMBERSHIP.—The membership of the HIT Standards Committee shall at least reflect providers, ancillary healthcare workers, consumers, purchasers, health plans, technology vendors, researchers, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy and security, and on the electronic exchange and use of health information.

''(3) PARTICIPATION.—The members of the HIT Standards Committee appointed under this subsection shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

''(4) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.

''(5) BALANCE AMONG SECTORS.—In developing the procedures for conducting the activities of the HIT Standards Committee, the HIT Standards Committee shall act to ensure a balance among various sectors of the health care system so that no single sector unduly influences the actions of the HIT Standards Committee.

''(6) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Standards Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not for profit entities that work in the public interest as a part of their mission.

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

''(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all recommendations made by the HIT Standards Committee under this section.

"SEC. 3004. PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS; ADOPTION OF INITIAL SET OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.

''(a) PROCESS FOR ADOPTION OF ENDORSED RECOMMENDATIONS.—

''(1) REVIEW OF ENDORSED STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 3001(c), the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

''(2) DETERMINATION TO ADOPT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—If the Secretary determines—

''(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, United States Code, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria; or

''(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator and the HIT Standards Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation.

''(3) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

''(b) ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—

''(1) IN GENERAL.—Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 3002(b)(2)(B). The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

''(2) APPLICATION OF CURRENT STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—The standards, implementation specifications, and certification criteria adopted before the date of the enactment of this title through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

''(3) SUBSEQUENT STANDARDS ACTIVITY.—The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 3003(b)(2).

"SEC. 3005. APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY FEDERAL AGENCIES.

''For requirements relating to the application and use by Federal agencies of the standards and implementation specifications adopted under section 3004, see section 13111 of the Health Information Technology for Economic and Clinical Health Act.

"SEC. 3006. VOLUNTARY APPLICATION AND USE OF ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS BY PRIVATE ENTITIES.

''(a) IN GENERAL.—Except as provided under section 13112 of the HITECH Act, nothing in such Act or in the amendments made by such Act shall be construed—

''(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 3004; or

''(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

''(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 3004 with respect to activities not related to the contract.

"SEC. 3007. FEDERAL HEALTH INFORMATION TECHNOLOGY.

''(a) IN GENERAL.—The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 3000) consistent with subsections (b) and (c) and make available

such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

''(b) CERTIFICATION.—In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed under section 3001(c)(3) to be in compliance with applicable standards adopted under section 3003(a).

''(c) AUTHORIZATION TO CHARGE A NOMINAL FEE.—The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

''(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

''SEC. 3008. TRANSITIONS.

''(a) ONCHIT.—To the extent consistent with section 3001, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order No. 13335 or the Office of such National Coordinator on the date before the date of the enactment of this title shall be transferred to the National Coordinator appointed under section 3001(a) and the Office of such National Coordinator as of the date of the enactment of this title.

''(b) NATIONAL EHEALTH COLLABORATIVE.—Nothing in sections 3002 or 3003 or this subsection shall be construed as prohibiting the AHIC Successor, Inc. doing business as the National eHealth Collaborative from modifying its charter, duties, membership, and any other structure or function required to be consistent with section 3002 and 3003 so as to allow the Secretary to recognize such AHIC Successor, Inc. as the HIT Policy Committee or the HIT Standards Committee.

''(c) CONSISTENCY OF RECOMMENDATIONS.—In carrying out section 3003(b)(1)(A), until recommendations are made by the HIT Policy Committee, recommendations of the HIT Standards Committee shall be consistent with the most recent recommendations made by such AHIC Successor, Inc.

''SEC. 3009. MISCELLANEOUS PROVISIONS.

''(a) RELATION TO HIPAA PRIVACY AND SECURITY LAW.—

''(1) IN GENERAL.—With respect to the relation of this title to HIPAA privacy and security law:

''(A) This title may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

''(B) The purposes of this title include ensuring that the health information technology standards and implementation specifications adopted under section 3004 take into account the requirements of HIPAA privacy and security law.

''(2) DEFINITION.—For purposes of this section, the term 'HIPAA privacy and security law' means—

''(A) the provisions of part C of title XI of the Social Security Act, section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of title IV of the Health Information Technology for Economic and Clinical Health Act; and

''(B) regulations under such provisions.

''(b) FLEXIBILITY.—In administering the provisions of this title, the Secretary shall have flexibility in applying the definition of health care provider under section 3000(3), including the authority to omit certain entities listed in such definition when applying such definition under this title, where appropriate.''.

SEC. 13102. TECHNICAL AMENDMENT.

Section 1171(5) of the Social Security Act (42 U.S.C. 1320d) is amended by striking ''or C'' and inserting ''C, or D''.

PART 2—APPLICATION AND USE OF ADOPTED HEALTH INFORMATION TECHNOLOGY STANDARDS; REPORTS

SEC. 13111. COORDINATION OF FEDERAL ACTIVITIES WITH ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS.

(a) SPENDING ON HEALTH INFORMATION TECHNOLOGY SYSTEMS.—As each agency (as defined by the Director of the Office of Management and Budget, in consultation with the Secretary of Health and Human Services) implements, acquires, or upgrades health information technology systems used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101.

(b) FEDERAL INFORMATION COLLECTION ACTIVITIES.—With respect to a standard or implementation specification adopted under section 3004 of the Public Health Service Act, as added by section 13101, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such standard or implementation specification, respectively, within three years after the date of such adoption.

(c) APPLICATION OF DEFINITIONS.—The definitions contained in section 3000 of the Public Health Service Act, as added by section 13101, shall apply for purposes of this part.

SEC. 13112. APPLICATION TO PRIVATE ENTITIES.

Each agency (as defined in such Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet standards and implementation specifications adopted under section 3004 of the Public Health Service Act, as added by section 13101.

SEC. 13113. STUDY AND REPORTS.

(a) REPORT ON ADOPTION OF NATIONWIDE SYSTEM.—Not later than 2 years after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report that—

(1) describes the specific actions that have been taken by the Federal Government and private entities to facilitate the adoption of a nationwide system for the electronic use and exchange of health information;

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

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

(b) REIMBURSEMENT INCENTIVE STUDY AND REPORT.—

(1) STUDY.—The Secretary of Health and Human Services shall carry out, or contract with a private entity to carry out, a study that examines methods to create efficient reimbursement incentives for improving health care quality in Federally qualified health centers, rural health clinics, and free clinics.

(2) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on the study carried out under paragraph (1).

(c) AGING SERVICES TECHNOLOGY STUDY AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall carry out, or contract with a private entity to carry out, a study of matters relating to the potential use of new aging services technology to assist seniors, individuals with disabilities, and their caregivers throughout the aging process.

(2) MATTERS TO BE STUDIED.—The study under paragraph (1) shall include—

(A) an evaluation of—

(i) methods for identifying current, emerging, and future health technology that can be used to meet the needs of seniors and individuals with disabilities and their caregivers across all aging services settings, as specified by the Secretary;

(ii) methods for fostering scientific innovation with respect to aging services technology within the business and academic communities; and

(iii) developments in aging services technology in other countries that may be applied in the United States; and

(B) identification of—

(i) barriers to innovation in aging services technology and devising strategies for removing such barriers; and

(ii) barriers to the adoption of aging services technology by health care providers and consumers and devising strategies to removing such barriers.

(3) REPORT.—Not later than 24 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of jurisdiction of the House of Representatives and of the Senate a report on the study carried out under paragraph (1).

(4) DEFINITIONS.—For purposes of this subsection:

(A) AGING SERVICES TECHNOLOGY.—The term ''aging services technology'' means health technology that meets the health care needs of seniors, individuals with disabilities, and the caregivers of such seniors and individuals.

(B) SENIOR.—The term ''senior'' has such meaning as specified by the Secretary.

Subtitle B—Testing of Health Information Technology

SEC. 13201. NATIONAL INSTITUTE FOR STANDARDS AND TECHNOLOGY TESTING.

(a) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In coordination with the HIT Standards Committee established under section 3003 of the Public Health Service Act, as added by section 13101, with respect to the development of standards and implementation specifications under such section, the Director of the National Institute for Standards and Technology shall test such standards and implementation specifications, as appropriate, in order to assure the efficient implementation and use of such standards and implementation specifications.

(b) VOLUNTARY TESTING PROGRAM.—In coordination with the HIT Standards Committee established under section 3003 of the Public Health Service Act, as added by section 13101, with respect to the development of standards and implementation specifications under such section, the Director of the National Institute of Standards and Technology shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. The development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.

SEC. 13202. RESEARCH AND DEVELOPMENT PROGRAMS.

(a) HEALTH CARE INFORMATION ENTERPRISE INTEGRATION RESEARCH CENTERS.—

(1) IN GENERAL.—The Director of the National Institute of Standards and Technology, in consultation with the Director of the National Science Foundation and other appropriate Federal agencies, shall establish a program of assistance to institutions of higher education (or

consortia thereof which may include nonprofit entities and Federal Government laboratories) to establish multidisciplinary Centers for Health Care Information Enterprise Integration.

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

(3) PURPOSE.—The purposes of the Centers described in paragraph (1) shall be—

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

(B) the development and use of health information technologies and other complementary fields.

(4) RESEARCH AREAS.—Research areas may include—

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

(B) voice-recognition systems;

(C) software that improves interoperability and connectivity among health information systems;

(D) software dependability in systems critical to health care delivery;

(E) measurement of the impact of information technologies on the quality and productivity of health care;

(F) health information enterprise management;

(G) health information technology security and integrity; and

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

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

(A) the research projects that will be undertaken by the Center established pursuant to assistance under paragraph (1) and the respective contributions of the participating entities;

(B) how the Center will promote active collaboration among scientists and engineers from different disciplines, such as information technology, biologic sciences, management, social sciences, and other appropriate disciplines;

(C) technology transfer activities to demonstrate and diffuse the research results, technologies, and knowledge; and

(D) how the Center will contribute to the education and training of researchers and other professionals in fields relevant to health information enterprise integration.

(b) NATIONAL INFORMATION TECHNOLOGY RESEARCH AND DEVELOPMENT PROGRAM.—The National High-Performance Computing Program established by section 101 of the High-Performance Computing Act of 1991 (15 U.S.C. 5511) shall include Federal research and development programs related to health information technology.

Subtitle C—Grants and Loans Funding

SEC. 13301. GRANT, LOAN, AND DEMONSTRATION PROGRAMS.

Title XXX of the Public Health Service Act, as added by section 13101, is amended by adding at the end the following new subtitle:

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

"SEC. 3011. IMMEDIATE FUNDING TO STRENGTHEN THE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.

''(a) IN GENERAL.—The Secretary shall, using amounts appropriated under section 3018, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 3001. The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

''(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

''(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act for the adoption of such records.

''(3) Training on and dissemination of information on best practices to integrate health information technology, including electronic health records, into a provider's delivery of care, consistent with best practices learned from the Health Information Technology Research Center developed under section 3012(b), including community health centers receiving assistance under section 330, covered entities under section 340B, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act (relating to Medicare, Medicaid, and the State Children's Health Insurance Program).

''(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

''(5) Promotion of the interoperability of clinical data repositories or registries.

''(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

''(7) Improvement and expansion of the use of health information technology by public health departments.

''(b) COORDINATION.—The Secretary shall ensure funds under this section are used in a coordinated manner with other health information promotion activities.

''(c) ADDITIONAL USE OF FUNDS.—In addition to using funds as provided in subsection (a), the Secretary may use amounts appropriated under section 3018 to carry out health information technology activities that are provided for under laws in effect on the date of the enactment of this title.

''(d) STANDARDS FOR ACQUISITION OF HEALTH INFORMATION TECHNOLOGY.—To the greatest extent practicable, the Secretary shall ensure that where funds are expended under this section for the acquisition of health information technology, such funds shall be used to acquire health information technology that meets applicable standards adopted under section 3004. Where it is not practicable to expend funds on health information technology that meets such applicable standards, the Secretary shall ensure that such health information technology meets applicable standards otherwise adopted by the Secretary.

"SEC. 3012. HEALTH INFORMATION TECHNOLOGY IMPLEMENTATION ASSISTANCE.

''(a) HEALTH INFORMATION TECHNOLOGY EXTENSION PROGRAM.—To assist health care providers to adopt, implement, and effectively use certified EHR technology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program.

''(b) HEALTH INFORMATION TECHNOLOGY RESEARCH CENTER.—

''(1) IN GENERAL.—The Secretary shall create a Health Information Technology Research Center (in this section referred to as the 'Center') to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004.

''(2) INPUT.—The Center shall incorporate input from—

''(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;

''(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and

''(C) others as appropriate.

''(3) PURPOSES.—The purposes of the Center are to—

''(A) provide a forum for the exchange of knowledge and experience;

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

''(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);

''(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

''(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and

''(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

''(c) HEALTH INFORMATION TECHNOLOGY REGIONAL EXTENSION CENTERS.—

''(1) IN GENERAL.—The Secretary shall provide assistance for the creation and support of regional centers (in this subsection referred to as 'regional centers') to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 3004. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001.

''(2) AFFILIATION.—Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.

''(3) OBJECTIVE.—The objective of the regional centers is to enhance and promote the adoption of health information technology through—

''(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;

''(B) broad participation of individuals from industry, universities, and State governments;

''(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

''(D) participation, to the extent practicable, in health information exchanges;

''(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

''(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.

''(4) REGIONAL ASSISTANCE.—Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:

''(A) Public or not-for-profit hospitals or critical access hospitals.

''(B) Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).

''(C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

''(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

''(5) FINANCIAL SUPPORT.—The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

''(6) NOTICE OF PROGRAM DESCRIPTION AND AVAILABILITY OF FUNDS.—The Secretary shall publish in the Federal Register, not later than 90 days after the date of the enactment of this title, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:

''(A) A detailed explanation of the program and the programs goals.

''(B) Procedures to be followed by the applicants.

''(C) Criteria for determining qualified applicants.

''(D) Maximum support levels expected to be available to centers under the program.

''(7) APPLICATION REVIEW.—The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

''(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;

''(B) the types of service to be provided to health care providers;

''(C) geographical diversity and extent of service area; and

''(D) the percentage of funding and amount of in-kind commitment from other sources.

''(8) BIENNIAL EVALUATION.—Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.

''(9) CONTINUING SUPPORT.—After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services.

"SEC. 3013. STATE GRANTS TO PROMOTE HEALTH INFORMATION TECHNOLOGY.

''(a) IN GENERAL.—The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

''(b) PLANNING GRANTS.—The Secretary may award a grant to a State or qualified State-designated entity (as described in subsection (f)) that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described in subsection (d).

''(c) IMPLEMENTATION GRANTS.—The Secretary may award a grant to a State or qualified State designated entity that—

''(1) has submitted, and the Secretary has approved, a plan described in subsection (e) (regardless of whether such plan was prepared using amounts awarded under subsection (b); and

''(2) submits an application at such time, in such manner, and containing such information as the Secretary may specify.

''(d) USE OF FUNDS.—Amounts received under a grant under subsection (c) shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

''(1) enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;

''(2) identifying State or local resources available towards a nationwide effort to promote health information technology;

''(3) complementing other Federal grants, programs, and efforts towards the promotion of health information technology;

''(4) providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

''(5) promoting effective strategies to adopt and utilize health information technology in medically underserved communities;

''(6) assisting patients in utilizing health information technology;

''(7) encouraging clinicians to work with Health Information Technology Regional Extension Centers as described in section 3012, to the extent they are available and valuable;

''(8) supporting public health agencies' authorized use of and access to electronic health information;

''(9) promoting the use of electronic health records for quality improvement including through quality measures reporting; and

''(10) such other activities as the Secretary may specify.

''(e) PLAN.—

''(1) IN GENERAL.—A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.

''(2) REQUIRED ELEMENTS.—A plan described in paragraph (1) shall—

''(A) be pursued in the public interest;

''(B) be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 3001;

''(C) include a description of the ways the State or qualified State-designated entity will carry out the activities described in subsection (b); and

''(D) contain such elements as the Secretary may require.

''(f) QUALIFIED STATE-DESIGNATED ENTITY.—For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

''(1) be designated by the State as eligible to receive awards under this section;

''(2) be a not-for-profit entity with broad stakeholder representation on its governing board;

''(3) demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information;

''(4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and

''(5) conform to such other requirements as the Secretary may establish.

''(g) REQUIRED CONSULTATION.—In carrying out activities described in subsections (b) and (c), a State or qualified State-designated entity shall consult with and consider the recommendations of—

''(1) health care providers (including providers that provide services to low income and underserved populations);

''(2) health plans;

''(3) patient or consumer organizations that represent the population to be served;

''(4) health information technology vendors;

''(5) health care purchasers and employers;

''(6) public health agencies;

''(7) health professions schools, universities and colleges;

''(8) clinical researchers;

''(9) other users of health information technology such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and

''(10) such other entities, as may be determined appropriate by the Secretary.

''(h) CONTINUOUS IMPROVEMENT.—The Secretary shall annually evaluate the activities conducted under this section and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

''(i) REQUIRED MATCH.—

''(1) IN GENERAL.—For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant

awarded under subsection (c) in an amount equal to—

''(A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant;

''(B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and

''(C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant.

''(2) AUTHORITY TO REQUIRE STATE MATCH FOR FISCAL YEARS BEFORE FISCAL YEAR 2011.—For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

''SEC. 3014. COMPETITIVE GRANTS TO STATES AND INDIAN TRIBES FOR THE DEVELOPMENT OF LOAN PROGRAMS TO FACILITATE THE WIDESPREAD ADOPTION OF CERTIFIED EHR TECHNOLOGY.

''(a) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to conduct the activities described in subsection (e).

''(b) ELIGIBLE ENTITY DEFINED.—For purposes of this subsection, the term 'eligible entity' means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act) that—

''(1) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

''(2) submits to the National Coordinator a strategic plan in accordance with subsection (d) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such subsection;

''(3) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with subsection (c);

''(4) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider agrees to—

''(A) submit reports on quality measures adopted by the Federal Government (by not later than 90 days after the date on which such measures are adopted), to—

''(i) the Administrator of the Centers for Medicare & Medicaid Services (or his or her designee), in the case of an entity participating in the Medicare program under title XVIII of the Social Security Act or the Medicaid program under title XIX of such Act; or

''(ii) the Secretary in the case of other entities;

''(B) demonstrate to the satisfaction of the Secretary (through criteria established by the Secretary) that any certified EHR technology purchased, improved, or otherwise financially supported under a loan under this section is used to exchange health information in a manner that, in accordance with law and standards (as adopted under section 3004) applicable to the exchange of information, improves the quality of health care, such as promoting care coordination; and

''(C) comply with such other requirements as the entity or the Secretary may require;

''(D) include a plan on how health care providers involved intend to maintain and support the certified EHR technology over time;

''(E) include a plan on how the health care providers involved intend to maintain and support the certified EHR technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as the State or Indian Tribe, respectively, may require; and

''(5) agrees to provide matching funds in accordance with subsection (h).

''(c) ESTABLISHMENT OF FUND.—For purposes of subsection (b)(3), an eligible entity shall establish a certified EHR technology loan fund (referred to in this subsection as a 'Loan Fund') and comply with the other requirements contained in this section. A grant to an eligible entity under this section shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this title to be used for other purposes specified in this title shall be deposited in any Loan Fund.

''(d) STRATEGIC PLAN.—

''(1) IN GENERAL.—For purposes of subsection (b)(2), a strategic plan of an eligible entity under this subsection shall identify the intended uses of amounts available to the Loan Fund of such entity.

''(2) CONTENTS.—A strategic plan under paragraph (1), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

''(A) A list of the projects to be assisted through the Loan Fund during such year.

''(B) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

''(C) A description of the financial status of the Loan Fund as of the date of submission of the plan.

''(D) The short-term and long-term goals of the Loan Fund.

''(e) USE OF FUNDS.—Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in subsection (g)(4)(A), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under subsection (c). Loans under this section may be used by a health care provider to—

''(1) facilitate the purchase of certified EHR technology;

''(2) enhance the utilization of certified EHR technology (which may include costs associated with upgrading health information technology so that it meets criteria necessary to be a certified EHR technology);

''(3) train personnel in the use of such technology; or

''(4) improve the secure electronic exchange of health information.

''(f) TYPES OF ASSISTANCE.—Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this section may only be used for the following:

''(1) To award loans that comply with the following:

''(A) The interest rate for each loan shall not exceed the market interest rate.

''(B) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

''(C) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

''(2) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

''(3) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

''(4) To earn interest on the amounts deposited into the Loan Fund.

''(5) To make reimbursements described in subsection (g)(4)(A).

''(g) ADMINISTRATION OF LOAN FUNDS.—

''(1) COMBINED FINANCIAL ADMINISTRATION.—An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

''(2) COST OF ADMINISTERING FUND.—Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this section to pay the reasonable costs of the administration of the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after the date of the enactment of this title.

''(3) GUIDANCE AND REGULATIONS.—The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including—

''(A) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this section as efficiently as possible in accordance with this title and applicable State laws; and

''(B) guidance to prevent waste, fraud, and abuse.

''(4) PRIVATE SECTOR CONTRIBUTIONS.—

''(A) IN GENERAL.—A Loan Fund established under this section may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

''(B) AVAILABILITY OF INFORMATION.—An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under subparagraph (A) and may issue letters of commendation or make other awards (that have no financial value) to any such entity.

''(h) MATCHING REQUIREMENTS.—

''(1) IN GENERAL.—The National Coordinator may not make a grant under subsection (a) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to not less than $1 for each $5 of Federal funds provided under the grant.

''(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to subparagraph (A), the National Coordinator may not include any amounts provided to the entity by the Federal Government.

''(i) EFFECTIVE DATE.—The Secretary may not make an award under this section prior to January 1, 2010.

''SEC. 3015. DEMONSTRATION PROGRAM TO INTEGRATE INFORMATION TECHNOLOGY INTO CLINICAL EDUCATION.

''(a) IN GENERAL.—The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

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

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

''(2) submit to the Secretary a strategic plan for integrating certified EHR technology in the clinical education of health professionals to reduce medical errors, increase access to prevention, reduce chronic diseases, and enhance health care quality;

''(3) be—

''(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program in behavioral or mental health, or any other graduate health professions school;

''(B) a graduate school of nursing or physician assistant studies;

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

''(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

''(4) provide for the collection of data regarding the effectiveness of the demonstration project to be funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate certified EHR technology, in the delivery of health care services; and

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

''(c) USE OF FUNDS.—

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

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

''(B) use grant funds to integrate certified EHR technology into community-based clinical education.

''(2) LIMITATION.—An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

''(d) FINANCIAL SUPPORT.—The Secretary may not provide more than 50 percent of the costs of any activity for which assistance is provided under subsection (a), except in an instance of national economic conditions which would render the cost-share requirement under this subsection detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

''(e) EVALUATION.—The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable.

''(f) REPORTS.—Not later than 1 year after the date of enactment of this title, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

''(1) describes the specific projects established under this section; and

''(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

''SEC. 3016. INFORMATION TECHNOLOGY PROFESSIONALS IN HEALTH CARE.

''(a) IN GENERAL.—The Secretary, in consultation with the Director of the National Science Foundation, shall provide assistance to institutions of higher education (or consortia thereof) to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs, for both health care and information technology students to ensure the rapid and effective utilization and development of health information technologies (in the United States health care infrastructure).

''(b) ACTIVITIES.—Activities for which assistance may be provided under subsection (a) may include the following:

''(1) Developing and revising curricula in medical health informatics and related disciplines.

''(2) Recruiting and retaining students to the program involved.

''(3) Acquiring equipment necessary for student instruction in these programs, including the installation of testbed networks for student use.

''(4) Establishing or enhancing bridge programs in the health informatics fields between community colleges and universities.

''(c) PRIORITY.—In providing assistance under subsection (a), the Secretary shall give preference to the following:

''(1) Existing education and training programs.

''(2) Programs designed to be completed in less than six months.

''SEC. 3017. GENERAL GRANT AND LOAN PROVISIONS.

''(a) REPORTS.—The Secretary may require that an entity receiving assistance under this subtitle shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

''(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

''(2) an analysis of the impact of the project on health care quality and safety.

''(b) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this subtitle and shall, in awarding grants, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

''SEC. 3018. AUTHORIZATION FOR APPROPRIATIONS.

''For the purposes of carrying out this subtitle, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013.''.

Subtitle D—Privacy

SEC. 13400. DEFINITIONS.

In this subtitle, except as specified otherwise:

(1) BREACH.—

(A) IN GENERAL.—The term ''breach'' means the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information.

(B) EXCEPTIONS.—The term ''breach'' does not include—

(i) any unintentional acquisition, access, or use of protected health information by an employee or individual acting under the authority of a covered entity or business associate if—

(I) such acquisition, access, or use was made in good faith and within the course and scope of the employment or other professional relationship of such employee or individual, respectively, with the covered entity or business associate; and

(II) such information is not further acquired, accessed, used, or disclosed by any person; or

(ii) any inadvertent disclosure from an individual who is otherwise authorized to access protected health information at a facility operated by a covered entity or business associate to another similarly situated individual at same facility; and

(iii) any such information received as a result of such disclosure is not further acquired, accessed, used, or disclosed without authorization by any person.

(2) BUSINESS ASSOCIATE.—The term ''business associate'' has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(3) COVERED ENTITY.—The term ''covered entity'' has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(4) DISCLOSE.—The terms ''disclose'' and ''disclosure'' have the meaning given the term ''disclosure'' in section 160.103 of title 45, Code of Federal Regulations.

(5) ELECTRONIC HEALTH RECORD.—The term ''electronic health record'' means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.

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

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

(8) HEALTH PLAN.—The term ''health plan'' has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(9) NATIONAL COORDINATOR.—The term ''National Coordinator'' means the head of the Office of the National Coordinator for Health Information Technology established under section 3001(a) of the Public Health Service Act, as added by section 13101.

(10) PAYMENT.—The term ''payment'' has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(11) PERSONAL HEALTH RECORD.—The term ''personal health record'' means an electronic record of PHR identifiable health information (as defined in section 13407(f)(2)) on an individual that can be drawn from multiple sources and that is managed, shared, and controlled by or primarily for the individual.

(12) PROTECTED HEALTH INFORMATION.—The term ''protected health information'' has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(13) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(14) SECURITY.—The term ''security'' has the meaning given such term in section 164.304 of title 45, Code of Federal Regulations.

(15) STATE.—The term ''State'' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(16) TREATMENT.—The term ''treatment'' has the meaning given such term in section 164.501 of title 45, Code of Federal Regulations.

(17) USE.—The term ''use'' has the meaning given such term in section 160.103 of title 45, Code of Federal Regulations.

(18) VENDOR OF PERSONAL HEALTH RECORDS.—The term ''vendor of personal health records'' means an entity, other than a covered entity (as defined in paragraph (3)), that offers or maintains a personal health record.

PART 1—IMPROVED PRIVACY PROVISIONS AND SECURITY PROVISIONS

SEC. 13401. APPLICATION OF SECURITY PROVISIONS AND PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES; ANNUAL GUIDANCE ON SECURITY PROVISIONS.

(a) APPLICATION OF SECURITY PROVISIONS.—Sections 164.308, 164.310, 164.312, and 164.316 of title 45, Code of Federal Regulations, shall apply to a business associate of a covered entity in the same manner that such sections apply to the covered entity. The additional requirements of this title that relate to security and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity.

(b) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—In the case of a business associate that violates any security provision specified in subsection (a), sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to the business associate with respect to such violation in the same manner such sections apply to a covered entity that violates such security provision.

(c) ANNUAL GUIDANCE.—For the first year beginning after the date of the enactment of this Act and annually thereafter, the Secretary of Health and Human Services shall, after consultation with stakeholders, annually issue guidance on the most effective and appropriate

technical safeguards for use in carrying out the sections referred to in subsection (a) and the security standards in subpart C of part 164 of title 45, Code of Federal Regulations, including the use of standards developed under section 3002(b)(2)(B)(vi) of the Public Health Service Act, as added by section 13101 of this Act, as such provisions are in effect as of the date before the enactment of this Act.

SEC. 13402. NOTIFICATION IN THE CASE OF BREACH.

(a) IN GENERAL.—A covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information (as defined in subsection (h)(1)) shall, in the case of a breach of such information that is discovered by the covered entity, notify each individual whose unsecured protected health information has been, or is reasonably believed by the covered entity to have been, accessed, acquired, or disclosed as a result of such breach.

(b) NOTIFICATION OF COVERED ENTITY BY BUSINESS ASSOCIATE.—A business associate of a covered entity that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured protected health information shall, following the discovery of a breach of such information, notify the covered entity of such breach. Such notice shall include the identification of each individual whose unsecured protected health information has been, or is reasonably believed by the business associate to have been, accessed, acquired, or disclosed during such breach.

(c) BREACHES TREATED AS DISCOVERED.—For purposes of this section, a breach shall be treated as discovered by a covered entity or by a business associate as of the first day on which such breach is known to such entity or associate, respectively, (including any person, other than the individual committing the breach, that is an employee, officer, or other agent of such entity or associate, respectively) or should reasonably have been known to such entity or associate (or person) to have occurred.

(d) TIMELINESS OF NOTIFICATION.—

(1) IN GENERAL.—Subject to subsection (g), all notifications required under this section shall be made without unreasonable delay and in no case later than 60 calendar days after the discovery of a breach by the covered entity involved (or business associate involved in the case of a notification required under subsection (b)).

(2) BURDEN OF PROOF.—The covered entity involved (or business associate involved in the case of a notification required under subsection (b)), shall have the burden of demonstrating that all notifications were made as required under this part, including evidence demonstrating the necessity of any delay.

(e) METHODS OF NOTICE.—

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

(A) Written notification by first-class mail to the individual (or the next of kin of the individual if the individual is deceased) at the last known address of the individual or the next of kin, respectively, or, if specified as a preference by the individual, by electronic mail. The notification may be provided in one or more mailings as information is available.

(B) In the case in which there is insufficient, or out-of-date contact information (including a phone number, email address, or any other form of appropriate communication) that precludes direct written (or, if specified by the individual under subparagraph (A), electronic) notification to the individual, a substitute form of notice shall be provided, including, in the case that there are 10 or more individuals for which there is insufficient or out-of-date contact information, a conspicuous posting for a period determined by the Secretary on the home page of the Web site of the covered entity involved or notice in major print or broadcast media, including major media in geographic areas where the individuals affected by the breach likely reside. Such a notice in media or web posting will include a toll-free phone number where an individual can learn whether or not the individual's unsecured protected health information is possibly included in the breach.

(C) In any case deemed by the covered entity involved to require urgency because of possible imminent misuse of unsecured protected health information, the covered entity, in addition to notice provided under subparagraph (A), may provide information to individuals by telephone or other means, as appropriate.

(2) MEDIA NOTICE.—Notice shall be provided to prominent media outlets serving a State or jurisdiction, following the discovery of a breach described in subsection (a), if the unsecured protected health information of more than 500 residents of such State or jurisdiction is, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(3) NOTICE TO SECRETARY.—Notice shall be provided to the Secretary by covered entities of unsecured protected health information that has been acquired or disclosed in a breach. If the breach was with respect to 500 or more individuals than such notice must be provided immediately. If the breach was with respect to less than 500 individuals, the covered entity may maintain a log of any such breach occurring and annually submit such a log to the Secretary documenting such breaches occurring during the year involved.

(4) POSTING ON HHS PUBLIC WEBSITE.—The Secretary shall make available to the public on the Internet website of the Department of Health and Human Services a list that identifies each covered entity involved in a breach described in subsection (a) in which the unsecured protected health information of more than 500 individuals is acquired or disclosed.

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

(1) A brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known.

(2) A description of the types of unsecured protected health information that were involved in the breach (such as full name, Social Security number, date of birth, home address, account number, or disability code).

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

(4) A brief description of what the covered entity involved is doing to investigate the breach, to mitigate losses, and to protect against any further breaches.

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

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

(h) UNSECURED PROTECTED HEALTH INFORMATION.—

(1) DEFINITION.—

(A) IN GENERAL.—Subject to subparagraph (B), for purposes of this section, the term ''unsecured protected health information'' means protected health information that is not secured through the use of a technology or methodology specified by the Secretary in the guidance issued under paragraph (2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under paragraph (2) by the date specified in such paragraph, for purposes of this section, the term ''unsecured protected health information'' shall mean protected health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(2) GUIDANCE.—For purposes of paragraph (1) and section 13407(f)(3), not later than the date that is 60 days after the date of the enactment of this Act, the Secretary shall, after consultation with stakeholders, issue (and annually update) guidance specifying the technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals, including the use of standards developed under section 3002(b)(2)(B)(vi) of the Public Health Service Act, as added by section 13101 of this Act.

(i) REPORT TO CONGRESS ON BREACHES.—

(1) IN GENERAL.—Not later than 12 months after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report containing the information described in paragraph (2) regarding breaches for which notice was provided to the Secretary under subsection (e)(3).

(2) INFORMATION.—The information described in this paragraph regarding breaches specified in paragraph (1) shall include—

(A) the number and nature of such breaches; and

(B) actions taken in response to such breaches.

(j) REGULATIONS; EFFECTIVE DATE.—To carry out this section, the Secretary of Health and Human Services shall promulgate interim final regulations by not later than the date that is 180 days after the date of the enactment of this title. The provisions of this section shall apply to breaches that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations.

SEC. 13403. EDUCATION ON HEALTH INFORMATION PRIVACY.

(a) REGIONAL OFFICE PRIVACY ADVISORS.—Not later than 6 months after the date of the enactment of this Act, the Secretary shall designate an individual in each regional office of the Department of Health and Human Services to offer guidance and education to covered entities, business associates, and individuals on their rights and responsibilities related to Federal privacy and security requirements for protected health information.

(b) EDUCATION INITIATIVE ON USES OF HEALTH INFORMATION.—Not later than 12 months after the date of the enactment of this Act, the Office for Civil Rights within the Department of Health and Human Services shall develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the uses of protected health information, including programs to educate individuals about the potential uses of their protected health information, the effects of such uses, and the rights of individuals with respect to such uses. Such programs shall be conducted in a variety of languages and present information in a clear and understandable manner.

SEC. 13404. APPLICATION OF PRIVACY PROVISIONS AND PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES.

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

in section 164.502(e)(2) of title 45, Code of Federal Regulations, with such covered entity, the business associate may use and disclose such protected health information only if such use or disclosure, respectively, is in compliance with each applicable requirement of section 164.504(e) of such title. The additional requirements of this subtitle that relate to privacy and that are made applicable with respect to covered entities shall also be applicable to such a business associate and shall be incorporated into the business associate agreement between the business associate and the covered entity.

(b) APPLICATION OF KNOWLEDGE ELEMENTS ASSOCIATED WITH CONTRACTS.—Section 164.504(e)(1)(ii) of title 45, Code of Federal Regulations, shall apply to a business associate described in subsection (a), with respect to compliance with such subsection, in the same manner that such section applies to a covered entity, with respect to compliance with the standards in sections 164.502(e) and 164.504(e) of such title, except that in applying such section 164.504(e)(1)(ii) each reference to the business associate, with respect to a contract, shall be treated as a reference to the covered entity involved in such contract.

(c) APPLICATION OF CIVIL AND CRIMINAL PENALTIES.—In the case of a business associate that violates any provision of subsection (a) or (b), the provisions of sections 1176 and 1177 of the Social Security Act (42 U.S.C. 1320d–5, 1320d–6) shall apply to the business associate with respect to such violation in the same manner as such provisions apply to a person who violates a provision of part C of title XI of such Act.

SEC. 13405. RESTRICTIONS ON CERTAIN DISCLOSURES AND SALES OF HEALTH INFORMATION; ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES; ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.

(a) REQUESTED RESTRICTIONS ON CERTAIN DISCLOSURES OF HEALTH INFORMATION.—In the case that an individual requests under paragraph (a)(1)(i)(A) of section 164.522 of title 45, Code of Federal Regulations, that a covered entity restrict the disclosure of the protected health information of the individual, notwithstanding paragraph (a)(1)(ii) of such section, the covered entity must comply with the requested restriction if—

(1) except as otherwise required by law, the disclosure is to a health plan for purposes of carrying out payment or health care operations (and is not for purposes of carrying out treatment); and

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

(b) DISCLOSURES REQUIRED TO BE LIMITED TO THE LIMITED DATA SET OR THE MINIMUM NECESSARY.—

(1) IN GENERAL.—

(A) IN GENERAL.—Subject to subparagraph (B), a covered entity shall be treated as being in compliance with section 164.502(b)(1) of title 45, Code of Federal Regulations, with respect to the use, disclosure, or request of protected health information described in such section, only if the covered entity limits such protected health information, to the extent practicable, to the limited data set (as defined in section 164.514(e)(2) of such title) or, if needed by such entity, to the minimum necessary to accomplish the intended purpose of such use, disclosure, or request, respectively.

(B) GUIDANCE.—Not later than 18 months after the date of the enactment of this section, the Secretary shall issue guidance on what constitutes ''minimum necessary'' for purposes of subpart E of part 164 of title 45, Code of Federal Regulation. In issuing such guidance the Secretary shall take into consideration the guidance under section 13424(c) and the information necessary to improve patient outcomes and to detect, prevent, and manage chronic disease.

(C) SUNSET.—Subparagraph (A) shall not apply on and after the effective date on which the Secretary issues the guidance under subparagraph (B).

(2) DETERMINATION OF MINIMUM NECESSARY.—For purposes of paragraph (1), in the case of the disclosure of protected health information, the covered entity or business associate disclosing such information shall determine what constitutes the minimum necessary to accomplish the intended purpose of such disclosure.

(3) APPLICATION OF EXCEPTIONS.—The exceptions described in section 164.502(b)(2) of title 45, Code of Federal Regulations, shall apply to the requirement under paragraph (1) as of the effective date described in section 13423 in the same manner that such exceptions apply to section 164.502(b)(1) of such title before such date.

(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as affecting the use, disclosure, or request of protected health information that has been de-identified.

(c) ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES REQUIRED IF COVERED ENTITY USES ELECTRONIC HEALTH RECORD.—

''(1) IN GENERAL.—In applying section 164.528 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information—

''(A) the exception under paragraph (a)(1)(i) of such section shall not apply to disclosures through an electronic health record made by such entity of such information; and

''(B) an individual shall have a right to receive an accounting of disclosures described in such paragraph of such information made by such covered entity during only the three years prior to the date on which the accounting is requested.

''(2) REGULATIONS.—The Secretary shall promulgate regulations on what information shall be collected about each disclosure referred to in paragraph (1), not later than 6 months after the date on which the Secretary adopts standards on accounting for disclosure described in the section 3002(b)(2)(B)(iv) of the Public Health Service Act, as added by section 13101. Such regulations shall only require such information to be collected through an electronic health record in a manner that takes into account the interests of the individuals in learning the circumstances under which their protected health information is being disclosed and takes into account the administrative burden of accounting for such disclosures.

''(3) PROCESS.—In response to an request from an individual for an accounting, a covered entity shall elect to provide either an—

''(A) accounting, as specified under paragraph (1), for disclosures of protected health information that are made by such covered entity and by a business associate acting on behalf of the covered entity; or

''(B) accounting, as specified under paragraph (1), for disclosures that are made by such covered entity and provide a list of all business associates acting on behalf of the covered entity, including contact information for such associates (such as mailing address, phone, and email address).

A business associate included on a list under subparagraph (B) shall provide an accounting of disclosures (as required under paragraph (1) for a covered entity) made by the business associate upon a request made by an individual directly to the business associate for such an accounting.

''(4) EFFECTIVE DATE.—

''(A) CURRENT USERS OF ELECTRONIC RECORDS.—In the case of a covered entity insofar as it acquired an electronic health record as of January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such a record on and after January 1, 2014.

''(B) OTHERS.—In the case of a covered entity insofar as it acquires an electronic health record after January 1, 2009, paragraph (1) shall apply to disclosures, with respect to protected health information, made by the covered entity from such record on and after the later of the following:

''(i) January 1, 2011; or

''(ii) the date that it acquires an electronic health record.

''(C) LATER DATE.—The Secretary may set an effective date that is later that the date specified under subparagraph (A) or (B) if the Secretary determines that such later date is necessary, but in no case may the date specified under—

''(i) subparagraph (A) be later than 2016; or

''(ii) subparagraph (B) be later than 2013.''

(d) PROHIBITION ON SALE OF ELECTRONIC HEALTH RECORDS OR PROTECTED HEALTH INFORMATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), a covered entity or business associate shall not directly or indirectly receive remuneration in exchange for any protected health information of an individual unless the covered entity obtained from the individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization that includes, in accordance with such section, a specification of whether the protected health information can be further exchanged for remuneration by the entity receiving protected health information of that individual.

(2) EXCEPTIONS.—Paragraph (1) shall not apply in the following cases:

(A) The purpose of the exchange is for public health activities (as described in section 164.512(b) of title 45, Code of Federal Regulations).

(B) The purpose of the exchange is for research (as described in sections 164.501 and 164.512(i) of title 45, Code of Federal Regulations) and the price charged reflects the costs of preparation and transmittal of the data for such purpose.

(C) The purpose of the exchange is for the treatment of the individual, subject to any regulation that the Secretary may promulgate to prevent protected health information from inappropriate access, use, or disclosure.

(D) The purpose of the exchange is the health care operation specifically described in subparagraph (iv) of paragraph (6) of the definition of healthcare operations in section 164.501 of title 45, Code of Federal Regulations.

(E) The purpose of the exchange is for remuneration that is provided by a covered entity to a business associate for activities involving the exchange of protected health information that the business associate undertakes on behalf of and at the specific request of the covered entity pursuant to a business associate agreement.

(F) The purpose of the exchange is to provide an individual with a copy of the individual's protected health information pursuant to section 164.524 of title 45, Code of Federal Regulations.

(G) The purpose of the exchange is otherwise determined by the Secretary in regulations to be similarly necessary and appropriate as the exceptions provided in subparagraphs (A) through (F).

(3) REGULATIONS.—Not later than 18 months after the date of enactment of this title, the Secretary shall promulgate regulations to carry out this subsection. In promulgating such regulations, the Secretary—

(A) shall evaluate the impact of restricting the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, on research or public health activities, including those conducted by or for the use of the Food and Drug Administration; and

(B) may further restrict the exception described in paragraph (2)(A) to require that the price charged for the purposes described in such paragraph reflects the costs of the preparation and transmittal of the data for such purpose, if

the Secretary finds that such further restriction will not impede such research or public health activities.

(4) EFFECTIVE DATE.—Paragraph (1) shall apply to exchanges occurring on or after the date that is 6 months after the date of the promulgation of final regulations implementing this subsection.

(e) ACCESS TO CERTAIN INFORMATION IN ELECTRONIC FORMAT.—In applying section 164.524 of title 45, Code of Federal Regulations, in the case that a covered entity uses or maintains an electronic health record with respect to protected health information of an individual—

(1) the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format and, if the individual chooses, to direct the covered entity to transmit such copy directly to an entity or person designated by the individual, provided that any such choice is clear, conspicuous, and specific; and

(2) notwithstanding paragraph (c)(4) of such section, any fee that the covered entity may impose for providing such individual with a copy of such information (or a summary or explanation of such information) if such copy (or summary or explanation) is in an electronic form shall not be greater than the entity's labor costs in responding to the request for the copy (or summary or explanation).

SEC. 13406. CONDITIONS ON CERTAIN CONTACTS AS PART OF HEALTH CARE OPERATIONS.

(a) MARKETING.—

(1) IN GENERAL.—A communication by a covered entity or business associate that is about a product or service and that encourages recipients of the communication to purchase or use the product or service shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations, unless the communication is made as described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of such title.

(2) PAYMENT FOR CERTAIN COMMUNICATIONS.—A communication by a covered entity or business associate that is described in subparagraph (i), (ii), or (iii) of paragraph (1) of the definition of marketing in section 164.501 of title 45, Code of Federal Regulations, shall not be considered a health care operation for purposes of subpart E of part 164 of title 45, Code of Federal Regulations if the covered entity receives or has received direct or indirect payment in exchange for making such communication, except where—

(A)(i) such communication describes only a drug or biologic that is currently being prescribed for the recipient of the communication; and

(ii) any payment received by such covered entity in exchange for making a communication described in clause (i) is reasonable in amount;

(B) each of the following conditions apply—

(i) the communication is made by the covered entity; and

(ii) the covered entity making such communication obtains from the recipient of the communication, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section) with respect to such communication; or

(C) each of the following conditions apply—

(i) the communication is made by a business associate on behalf of the covered entity; and

(ii) the communication is consistent with the written contract (or other written arrangement described in section 164.502(e)(2) of such title) between such business associate and covered entity.

(3) REASONABLE IN AMOUNT DEFINED.—For purposes of paragraph (2), the term ''reasonable in amount'' shall have the meaning given such term by the Secretary by regulation.

(4) DIRECT OR INDIRECT PAYMENT.—For purposes of paragraph (2), the term ''direct or indirect payment'' shall not include any payment for treatment (as defined in section 164.501 of title 45, Code of Federal Regulations) of an individual.

(b) OPPORTUNITY TO OPT OUT OF FUNDRAISING.—The Secretary shall by rule provide that any written fundraising communication that is a healthcare operation as defined under section 164.501 of title 45, Code of Federal Regulations, shall, in a clear and conspicuous manner, provide an opportunity for the recipient of the communications to elect not to receive any further such communication. When an individual elects not to receive any further such communication, such election shall be treated as a revocation of authorization under section 164.508 of title 45, Code of Federal Regulations.

(c) EFFECTIVE DATE.—This section shall apply to written communications occurring on or after the effective date specified under section 13423.

SEC. 13407. TEMPORARY BREACH NOTIFICATION REQUIREMENT FOR VENDORS OF PERSONAL HEALTH RECORDS AND OTHER NON-HIPAA COVERED ENTITIES.

(a) IN GENERAL.—In accordance with subsection (c), each vendor of personal health records, following the discovery of a breach of security of unsecured PHR identifiable health information that is in a personal health record maintained or offered by such vendor, and each entity described in clause (ii), (iii), or (iv) of section 13424(b)(1)(A), following the discovery of a breach of security of such information that is obtained through a product or service provided by such entity, shall—

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

(2) notify the Federal Trade Commission.

(b) NOTIFICATION BY THIRD PARTY SERVICE PROVIDERS.—A third party service provider that provides services to a vendor of personal health records or to an entity described in clause (ii), (iii). or (iv) of section 13424(b)(1)(A) in connection with the offering or maintenance of a personal health record or a related product or service and that accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses unsecured PHR identifiable health information in such a record as a result of such services shall, following the discovery of a breach of security of such information, notify such vendor or entity, respectively, of such breach. Such notice shall include the identification of each individual whose unsecured PHR identifiable health information has been, or is reasonably believed to have been, accessed, acquired, or disclosed during such breach.

(c) APPLICATION OF REQUIREMENTS FOR TIMELINESS, METHOD, AND CONTENT OF NOTIFICATIONS.—Subsections (c), (d), (e), and (f) of section 13402 shall apply to a notification required under subsection (a) and a vendor of personal health records, an entity described in subsection (a) and a third party service provider described in subsection (b), with respect to a breach of security under subsection (a) of unsecured PHR identifiable health information in such records maintained or offered by such vendor, in a manner specified by the Federal Trade Commission.

(d) NOTIFICATION OF THE SECRETARY.—Upon receipt of a notification of a breach of security under subsection (a)(2), the Federal Trade Commission shall notify the Secretary of such breach.

(e) ENFORCEMENT.—A violation of subsection (a) or (b) shall be treated as an unfair and deceptive act or practice in violation of a regulation under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)) regarding unfair or deceptive acts or practices.

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

(1) BREACH OF SECURITY.—The term ''breach of security'' means, with respect to unsecured PHR identifiable health information of an individual in a personal health record, acquisition of such information without the authorization of the individual.

(2) PHR IDENTIFIABLE HEALTH INFORMATION.—The term ''PHR identifiable health information'' means individually identifiable health information, as defined in section 1171(6) of the Social Security Act (42 U.S.C. 1320d(6)), and includes, with respect to an individual, information—

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

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

(3) UNSECURED PHR IDENTIFIABLE HEALTH INFORMATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the term ''unsecured PHR identifiable health information'' means PHR identifiable health information that is not protected through the use of a technology or methodology specified by the Secretary in the guidance issued under section 13402(h)(2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under section 13402(h)(2) by the date specified in such section, for purposes of this section, the term ''unsecured PHR identifiable health information'' shall mean PHR identifiable health information that is not secured by a technology standard that renders protected health information unusable, unreadable, or indecipherable to unauthorized individuals and that is developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(g) REGULATIONS; EFFECTIVE DATE; SUNSET.—

(1) REGULATIONS; EFFECTIVE DATE.—To carry out this section, the Federal Trade Commission shall promulgate interim final regulations by not later than the date that is 180 days after the date of the enactment of this section. The provisions of this section shall apply to breaches of security that are discovered on or after the date that is 30 days after the date of publication of such interim final regulations.

(2) SUNSET.—If Congress enacts new legislation establishing requirements for notification in the case of a breach of security, that apply to entities that are not covered entities or business associates, the provisions of this section shall not apply to breaches of security discovered on or after the effective date of regulations implementing such legislation.

SEC. 13408. BUSINESS ASSOCIATE CONTRACTS REQUIRED FOR CERTAIN ENTITIES.

Each organization, with respect to a covered entity, that provides data transmission of protected health information to such entity (or its business associate) and that requires access on a routine basis to such protected health information, such as a Health Information Exchange Organization, Regional Health Information Organization, E-prescribing Gateway, or each vendor that contracts with a covered entity to allow that covered entity to offer a personal health record to patients as part of its electronic health record, is required to enter into a written contract (or other written arrangement) described in section 164.502(e)(2) of title 45, Code of Federal Regulations and a written contract (or other arrangement) described in section 164.308(b) of such title, with such entity and shall be treated as a business associate of the covered entity for purposes of the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this title.

SEC. 13409. CLARIFICATION OF APPLICATION OF WRONGFUL DISCLOSURES CRIMINAL PENALTIES.

Section 1177(a) of the Social Security Act (42 U.S.C. 1320d–6(a)) is amended by adding at the end the following new sentence: ''For purposes of the previous sentence, a person (including an

employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1180(b)(3)) and the individual obtained or disclosed such information without authorization.''.

SEC. 13410. IMPROVED ENFORCEMENT.

(a) IN GENERAL.—

(1) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended—

(A) in subsection (b)(1), by striking ''the act constitutes an offense punishable under section 1177'' and inserting ''a penalty has been imposed under section 1177 with respect to such act''; and

(B) by adding at the end the following new subsection:

''(c) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—

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

''(2) REQUIRED INVESTIGATION.—For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.''.

(2) ENFORCEMENT UNDER SOCIAL SECURITY ACT.—Any violation by a covered entity under thus subtitle is subject to enforcement and penalties under section 1176 and 1177 of the Social Security Act.

(b) EFFECTIVE DATE; REGULATIONS.—

(1) The amendments made by subsection (a) shall apply to penalties imposed on or after the date that is 24 months after the date of the enactment of this title.

(2) Not later than 18 months after the date of the enactment of this title, the Secretary of Health and Human Services shall promulgate regulations to implement such amendments.

(c) DISTRIBUTION OF CERTAIN CIVIL MONETARY PENALTIES COLLECTED.—

(1) IN GENERAL.—Subject to the regulation promulgated pursuant to paragraph (3), any civil monetary penalty or monetary settlement collected with respect to an offense punishable under this subtitle or section 1176 of the Social Security Act (42 U.S.C. 1320d–5) insofar as such section relates to privacy or security shall be transferred to the Office for Civil Rights of the Department of Health and Human Services to be used for purposes of enforcing the provisions of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this Act.

(2) GAO REPORT.—Not later than 18 months after the date of the enactment of this title, the Comptroller General shall submit to the Secretary a report including recommendations for a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(3) ESTABLISHMENT OF METHODOLOGY TO DISTRIBUTE PERCENTAGE OF CMPS COLLECTED TO HARMED INDIVIDUALS.—Not later than 3 years after the date of the enactment of this title, the Secretary shall establish by regulation and based on the recommendations submitted under paragraph (2), a methodology under which an individual who is harmed by an act that constitutes an offense referred to in paragraph (1) may receive a percentage of any civil monetary penalty or monetary settlement collected with respect to such offense.

(4) APPLICATION OF METHODOLOGY.—The methodology under paragraph (3) shall be applied with respect to civil monetary penalties or monetary settlements imposed on or after the effective date of the regulation.

(d) TIERED INCREASE IN AMOUNT OF CIVIL MONETARY PENALTIES.—

(1) IN GENERAL.—Section 1176(a)(1) of the Social Security Act (42 U.S.C. 1320d–5(a)(1)) is amended by striking ''who violates a provision of this part a penalty of not more than'' and all that follows and inserting the following: ''who violates a provision of this part—

''(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

''(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

''(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect—

''(i) if the violation is corrected as described in subsection (b)(3)(A), a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

''(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.''.

(2) TIERS OF PENALTIES DESCRIBED.—Section 1176(a) of such Act (42 U.S.C. 1320d–5(a)) is further amended by adding at the end the following new paragraph:

''(3) TIERS OF PENALTIES DESCRIBED.—For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

''(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

''(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

''(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

''(D) the amount described in this subparagraph is $50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $1,500,000.''.

(3) CONFORMING AMENDMENTS.—Section 1176(b) of such Act (42 U.S.C. 1320d–5(b)) is amended—

(A) by striking paragraph (2) and redesignating paragraphs (3) and (4) as paragraphs (2) and (3), respectively; and

(B) in paragraph (2), as so redesignated—

(i) in subparagraph (A), by striking ''in subparagraph (B), a penalty may not be imposed under subsection (a) if'' and all that follows through ''the failure to comply is corrected'' and inserting ''in subparagraph (B) or subsection (a)(1)(C), a penalty may not be imposed under subsection (a) if the failure to comply is corrected''; and

(ii) in subparagraph (B), by striking ''(A)(ii)'' and inserting ''(A)'' each place it appears.

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to violations occurring after the date of the enactment of this title.

(e) ENFORCEMENT THROUGH STATE ATTORNEYS GENERAL.—

(1) IN GENERAL.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended by adding at the end the following new subsection:

''(d) ENFORCEMENT BY STATE ATTORNEYS GENERAL.—

''(1) CIVIL ACTION.—Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as parens patriae, may bring a civil action on behalf of such residents of the State in a district court of the United States of appropriate jurisdiction—

''(A) to enjoin further such violation by the defendant; or

''(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

''(2) STATUTORY DAMAGES.—

''(A) IN GENERAL.—For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to $100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in section 1180(b)(3)) for violations of subsection (a).

''(B) LIMITATION.—The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

''(C) REDUCTION OF DAMAGES.—In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

''(3) ATTORNEY FEES.—In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

''(4) NOTICE TO SECRETARY.—The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right—

''(A) to intervene in the action;

''(B) upon so intervening, to be heard on all matters arising therein; and

''(C) to file petitions for appeal.

''(5) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

''(6) VENUE; SERVICE OF PROCESS.—

''(A) VENUE.—Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

''(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

''(i) is an inhabitant; or

''(ii) maintains a physical place of business.

''(7) LIMITATION ON STATE ACTION WHILE FEDERAL ACTION IS PENDING.—If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

''(8) APPLICATION OF CMP STATUTE OF LIMITATION.—A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of section 1128A(c)(1).''.

(2) CONFORMING AMENDMENTS.—Subsection (b) of such section, as amended by subsection (d)(3), is amended—

(A) in paragraph (1), by striking ''A penalty may not be imposed under subsection (a)'' and inserting ''No penalty may be imposed under subsection (a) and no damages obtained under subsection (d)'';

(B) in paragraph (2)(A)—

(i) after ''subsection (a)(1)(C),'', by striking ''a penalty may not be imposed under subsection (a)'' and inserting ''no penalty may be imposed under subsection (a) and no damages obtained under subsection (d)''; and

(ii) in clause (ii), by inserting ''or damages'' after ''the penalty'';

(C) in paragraph (2)(B)(i), by striking ''The period'' and inserting ''With respect to the imposition of a penalty by the Secretary under subsection (a), the period''; and

(D) in paragraph (3), by inserting ''and any damages under subsection (d)'' after ''any penalty under subsection (a)''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to violations occurring after the date of the enactment of this Act.

(f) ALLOWING CONTINUED USE OF CORRECTIVE ACTION.—Such section is further amended by adding at the end the following new subsection:

''(e) ALLOWING CONTINUED USE OF CORRECTIVE ACTION.—Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.''.

SEC. 13411. AUDITS.

The Secretary shall provide for periodic audits to ensure that covered entities and business associates that are subject to the requirements of this subtitle and subparts C and E of part 164 of title 45, Code of Federal Regulations, as such provisions are in effect as of the date of enactment of this Act, comply with such requirements.

PART 2—RELATIONSHIP TO OTHER LAWS; REGULATORY REFERENCES; EFFECTIVE DATE; REPORTS

SEC. 13421. RELATIONSHIP TO OTHER LAWS.

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

(b) HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT.—The standards governing the privacy and security of individually identifiable health information promulgated by the Secretary under sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 shall remain in effect to the extent that they are consistent with this subtitle. The Secretary shall by rule amend such Federal regulations as required to make such regulations consistent with this subtitle.

(c) CONSTRUCTION.—Nothing in this subtitle shall constitute a waiver of any privilege otherwise applicable to an individual with respect to the protected health information of such individual.

SEC. 13422. REGULATORY REFERENCES.

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

SEC. 13423. EFFECTIVE DATE.

Except as otherwise specifically provided, the provisions of part I shall take effect on the date that is 12 months after the date of the enactment of this title.

SEC. 13424. STUDIES, REPORTS, GUIDANCE.

(a) REPORT ON COMPLIANCE.—

(1) IN GENERAL.—For the first year beginning after the date of the enactment of this Act and annually thereafter, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report concerning complaints of alleged violations of law, including the provisions of this subtitle as well as the provisions of subparts C and E of part 164 of title 45, Code of Federal Regulations, (as such provisions are in effect as of the date of enactment of this Act) relating to privacy and security of health information that are received by the Secretary during the year for which the report is being prepared. Each such report shall include, with respect to such complaints received during the year—

(A) the number of such complaints;

(B) the number of such complaints resolved informally, a summary of the types of such complaints so resolved, and the number of covered entities that received technical assistance from the Secretary during such year in order to achieve compliance with such provisions and the types of such technical assistance provided;

(C) the number of such complaints that have resulted in the imposition of civil monetary penalties or have been resolved through monetary settlements, including the nature of the complaints involved and the amount paid in each penalty or settlement;

(D) the number of compliance reviews conducted and the outcome of each such review;

(E) the number of subpoenas or inquiries issued;

(F) the Secretary's plan for improving compliance with and enforcement of such provisions for the following year; and

(G) the number of audits performed and a summary of audit findings pursuant to section 13411.

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

(b) STUDY AND REPORT ON APPLICATION OF PRIVACY AND SECURITY REQUIREMENTS TO NON-HIPAA COVERED ENTITIES.—

(1) STUDY.—Not later than one year after the date of the enactment of this title, the Secretary, in consultation with the Federal Trade Commission, shall conduct a study, and submit a report under paragraph (2), on privacy and security requirements for entities that are not covered entities or business associates as of the date of the enactment of this title, including—

(A) requirements relating to security, privacy, and notification in the case of a breach of security or privacy (including the applicability of an exemption to notification in the case of individually identifiable health information that has been rendered unusable, unreadable, or indecipherable through technologies or methodologies recognized by appropriate professional organization or standard setting bodies to provide effective security for the information) that should be applied to—

(i) vendors of personal health records;

(ii) entities that offer products or services through the website of a vendor of personal health records;

(iii) entities that are not covered entities and that offer products or services through the websites of covered entities that offer individuals personal health records;

(iv) entities that are not covered entities and that access information in a personal health record or send information to a personal health record; and

(v) third party service providers used by a vendor or entity described in clause (i), (ii), (iii), or (iv) to assist in providing personal health record products or services;

(B) a determination of which Federal government agency is best equipped to enforce such requirements recommended to be applied to such vendors, entities, and service providers under subparagraph (A); and

(C) a timeframe for implementing regulations based on such findings.

(2) REPORT.—The Secretary shall submit to the Committee on Finance, the Committee on Health, Education, Labor, and Pensions, and the Committee on Commerce of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on the findings of the study under paragraph (1) and shall include in such report recommendations on the privacy and security requirements described in such paragraph.

(c) GUIDANCE ON IMPLEMENTATION SPECIFICATION TO DE-IDENTIFY PROTECTED HEALTH INFORMATION.—Not later than 12 months after the date of the enactment of this title, the Secretary shall, in consultation with stakeholders, issue guidance on how best to implement the requirements for the de-identification of protected health information under section 164.514(b) of title 45, Code of Federal Regulations.

(d) GAO REPORT ON TREATMENT DISCLOSURES.—Not later than one year after the date of the enactment of this title, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report on the best practices related to the disclosure among health care providers of protected health information of an individual for purposes of treatment of such individual. Such report shall include an examination of the best practices implemented by States and by other entities, such as health information exchanges and regional health information organizations, an examination of the extent to which such best practices are successful with respect to the quality of the resulting health care provided to the individual and with respect to the ability of the health care provider to manage such best practices, and an examination of the use of electronic informed consent for disclosing protected health information for treatment, payment, and health care operations.

(e) REPORT REQUIRED.—Not later than 5 years after the date of enactment of this section, the Government Accountability Office shall submit to Congress and the Secretary of Health and Human Services a report on the impact of any of the provisions of this Act on health insurance premiums, overall health care costs, adoption of electronic health records by providers, and reduction in medical errors and other quality improvements.

(f) STUDY.—The Secretary shall study the definition of ''psychotherapy notes'' in section 164.501 of title 45, Code of Federal Regulations, with regard to including test data that is related to direct responses, scores, items, forms, protocols, manuals, or other materials that are part of a mental health evaluation, as determined by the mental health professional providing treatment or evaluation in such definitions and may, based on such study, issue regulations to revise such definition.