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2d Session
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REPT. 110–837
Part 1

PRO(TECH)T ACT OF 2008

SEPTEMBER 11, 2008.—Ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 6357]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 6357) to amend the Public Health Service Act to promote the adoption of health information technology, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

69–006

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

TITLE I—HEALTH INFORMATION TECHNOLOGY

Subtitle A—Promotion of Health Information Technology

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

SEC. 101. ONCHIT; STANDARDS DEVELOPMENT AND ADOPTION; HEALTH INFORMATION TECHNOLOGY RESOURCE CENTER.

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) 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.

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means a hospital, skilled nursing facility, nursing facility, home health entity, health care clinic, Federally qualified health center, group practice (as defined in section 1877(h)(4) of the Social Security Act), 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, and any other category of facility or clinician determined appropriate by the Secretary.

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

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

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

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

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

"(8) 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.

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

"(10) 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).

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

"(12) 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, 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) ensures that appropriate information to help guide medical decisions is available 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 reporting 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 prevention 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 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). The Coordinator shall make such determination, and report to the Secretary such determination, not later than 90 days after the date the recommendation is received by the Coordinator.

"(2) HIT POLICY COORDINATION.—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.

"(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), maintain and update a strategic plan with specific objectives, milestones, and metrics for 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, and in improving the continuity of care among health care settings.

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

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

"(D) PUBLICATION.—The National Coordinator shall publish 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 that includes the following:

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

"(B) The recommendations of the HIT Policy Committee under section 3002.

"(C) Recommendations of the HIT Standards Committee under section 3003.

"(D) Sources of Federal grant funds and technical assistance that are available to facilitate the purchase of, or enhance the utilization of, health information technology systems.

"(E) The report prepared by the National Coordinator under paragraph (5).

"(F) The assessment by the National Coordinator under paragraph (6).

"(G) The evaluation by the National Coordinator under paragraph (7).

"(H) The annual estimate of resources required under paragraph (8).

"(5) 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 systems, including information on whether the systems and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

"(6) 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 that serve 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.

"(7) 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.

"(8) 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 the required level of Federal funding, expectations for regional, State, and private investment, and the expected contributions by volunteers to activities for the utilization of such records.

"(9) CERTIFICATION.—

"(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall develop a program (either directly or by contract) for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include testing of the technology in accordance with section 201(b) of the PRO(TECH)T Act of 2008.

"(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.

"(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) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $66,000,000 for fiscal year 2009.

"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.—Not later than 1 year after the date of the enactment of this title, 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). Annually thereafter 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(b) and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and 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, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information, in accordance with applicable law, and for the use and disclosure of limited data sets (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) of such information.

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

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

"(iv) Technologies that 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).

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

"(A) Established governance rules.

"(B) A business plan.

"(C) Meeting notices at least 14 days prior to each meeting.

"(D) Meeting agendas at least 7 days prior to each meeting.

"(E) Meeting materials at least 3 days prior to each meeting.

"(c) MEMBERSHIP.—

"(1) APPOINTMENTS.—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) 11 members shall be appointed by the Comptroller General of the United States of whom—

"(i) 1 member shall be an advocate 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 privacy and security;

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

"(vi) 1 member shall be from the health 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.

"(2) NATIONAL COORDINATOR.—The National Coordinator shall be a member of the HIT Policy Committee and act as a liaison among the HIT Policy Committee, the HIT Standards Committee, and the Federal Government.

"(3) CHAIRPERSON AND VICE CHAIRPERSON.—The HIT Policy Committee shall designate 1 member to serve as the chairperson and 1 member to serve as the vice chairperson of the HIT Policy Committee.

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

"(5) TERMS.—

"(A) IN GENERAL.—The terms of members of the HIT Policy Committee appointed under paragraph (1) shall be 3 years except that the Comptroller

General of the United States shall designate staggered terms for the members first appointed under paragraph (1)(G).

"(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.

"(6) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an adequate 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.

"(7) QUORUM.—Ten members of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

"(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(b), consistent with the implementation of the strategic plan described in section 3001(c)(3).

"(b) DUTIES.—

"(1) STANDARD DEVELOPMENT.—

"(A) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of this title, 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 Committee. Annually thereafter the Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(b)(2). Such recommendations shall be consistent with the latest recommendations made by the HIT Policy Committee.

"(B) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee, as appropriate, shall provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 201 of the PRO(TECH)T Act of 2008.

"(C) 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) WEBSITE.—The HIT Standards Committee shall develop and maintain an Internet website on which there is posted information that includes the following:

"(A) Established governance rules.

"(B) A business plan.

"(C) Meeting notices at least 14 days prior to each meeting.

"(D) Meeting agendas at least 7 days prior to each meeting.

"(E) Meeting materials at least 3 days prior to each meeting.

"(6) REQUIREMENT TO INTEGRATE RECOMMENDATIONS.—In carrying out the activities under this section, the HIT Standards Committee shall integrate the recommendations of the HIT Policy Committee.

"(c) MEMBERSHIP.—

"(1) APPOINTMENTS.—The HIT Standards Committee shall be composed of members to be appointed as follows:

"(A) 2 members shall be appointed by the Secretary.

"(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) 9 members shall be appointed by the Comptroller General of the United States of whom—

"(i) 1 member shall be a representative of consumer or patient organizations;

"(ii) 1 member shall be a representative of organizations with expertise in privacy;

"(iii) 1 member shall be a representative of organizations with expertise in security;

"(iv) 2 members shall be a representative of health care providers, one of which shall be a physician;

"(v) 1 member shall be a representative of health plans or other third party payers;

"(vi) 1 member shall be a representative of information technology vendors;

"(vii) 1 member shall be a representative of purchasers or employers; and

"(viii) 1 member shall be a representative of the health research community.

"(G) 1 member shall be appointed by the Director of the National Institute for Standards and Technology.

"(2) NATIONAL COORDINATOR.—The National Coordinator shall be a member of the HIT Standards Committee and act as a liaison among the HIT Standards Committee, the HIT Policy Committee, and the Federal government.

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

"(4) PARTICIPATION.—The members of the HIT Standards Committee appointed under paragraph (1) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

"(5) TERMS.—

"(A) IN GENERAL.—The terms of members of the HIT Standards Committee appointed under paragraph (1) shall be 3 years except that the Comptroller General of the United States shall designate staggered terms for the members first appointed under paragraph (1)(F).

"(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Standards 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 Standards Committee shall be filled in the manner in which the original appointment was made.

"(6) OUTSIDE INVOLVEMENT.—The HIT Standards Committee shall ensure an adequate 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.

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

"(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.

"(a) REVIEW OF ENDORSED STANDARDS, SPECIFICATIONS, AND 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, specifications, or criteria and shall determine whether or not to propose adoption of such standards, specifications, or criteria.

"(b) DETERMINATION TO ADOPT STANDARDS, SPECIFICATIONS, AND CRITERIA.—If the Secretary determines—

"(1) to propose adoption of any grouping of such standards, specifications, or criteria, the Secretary shall, through a rulemaking process, determine whether or not to adopt such grouping of standards, specifications, or criteria; or

"(2) not to propose adoption of any grouping of standards, specifications, or 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.

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

"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(b), see section 111 of the PRO(TECH)T Act of 2008.

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

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

"(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(b) with respect to activities not related to the contract.

"SEC. 3007. HEALTH INFORMATION TECHNOLOGY RESOURCE CENTER.

"(a) DEVELOPMENT.—

"(1) IN GENERAL.—The National Coordinator shall develop a Health Information Technology Resource Center to provide technical assistance and develop best practices to support and accelerate efforts to adopt, implement, and effectively use 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(b).

"(2) PURPOSES.—The purpose of the Center is 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;

"(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;

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

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

"(H) provide technical assistance to promote adoption and utilization of health information technology by health care providers, including in medically underserved communities.

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

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

"(2) learn about standards, implementation specifications, and certification criteria adopted under section 3004(b);

"(3) learn about regional and local health information networks for assistance with health information technology; and

"(4) disseminate additional information determined by the National Coordinator.".

SEC. 102. TRANSITIONS.

(a) ONCHIT.—To the extent consistent with section 3001 of the Public Health Service Act, as added by section 101, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order 13335 or the Office of such National Coordinator on the date before the date of the enactment of this Act shall be transferred to the National Coordinator appointed under section 3001(a) of such Act and the Office of such National Coordinator as of the date of the enactment of this Act.

(b) AHIC.—

(1) To the extent consistent with sections 3002 and 3003 of the Public Health Service Act, as added by section 101, all functions, personnel, assets, and liabilities applicable to the American Health Information Community created in response to Executive Order 13335 as of the day before the date of the enactment of this Act shall be transferred to the HIT Policy Committee or the HIT Standards Committee, established under section 3002(a) or 3003(a) of such Act, as appropriate, as of the date of the enactment of this Act.

(2) In carrying out section 3003(b)(1)(A) of the Public Health Service Act, as so added, 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 the American Health Information Community.

(c) RULES OF CONSTRUCTION.—

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

(2) AHIC.—Nothing in sections 3002 or 3003 of the Public Health Service Act, as added by section 101, or subsection (b) shall be construed as requiring the creation of a new entity to the extent that the American Health Information Community created in response to Executive Order 13335 is consistent with the provisions of such sections 3002 and 3003.

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

SEC. 111. COORDINATION OF FEDERAL ACTIVITIES WITH ADOPTED STANDARDS AND IMPLEMENTATION SPECIFICATIONS.

(a) SPENDING ON HEALTH INFORMATION TECHNOLOGY SYSTEMS.—As each agency (as defined in the Executive Order issued on August 22, 2006, relating to promoting quality and efficient health care in Federal government administered or sponsored health care programs) 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(b) of the Public Health Service Act, as added by section 101.

(b) FEDERAL INFORMATION COLLECTION ACTIVITIES.—With respect to a standard or implementation specification adopted under section 3004(b) of the Public Health

Service Act, as added by section 101, 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 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 101, shall apply for purposes of this part.

SEC. 112. 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(b) of the Public Health Service Act, as added by section 101.

SEC. 113. 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 Committee on Health, Education, Labor, and Pensions and the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce and the Committee on Science and Technology of the House of Representatives 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 Committee on Health, Education, Labor, and Pensions and the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce and the Committee on Science and Technology of the House of Representatives 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 Committee on Health, Education, Labor, and Pensions and the Committee on Commerce, Science, and Transportation of the Senate and the Committee on Energy and Commerce and the Committee on Science and Technology of the House of Representatives 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—Incentives for the Use of Health Information Technology

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

Title XXX of the Public Health Service Act, as added by section 101, is amended by adding at the end the following new subtitle:

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

"SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED HEALTH INFORMATION TECHNOLOGY.

"(a) COMPETITIVE GRANTS TO FACILITATE THE WIDESPREAD ADOPTION OF HEALTH INFORMATION TECHNOLOGY.—

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

"(2) QUALIFIED HEALTH INFORMATION TECHNOLOGY.—For purposes of this section, the term 'qualified health information technology' means health information technology that consists of hardware, software, or the provision of support services and that—

"(A) enables the protection of health information, in accordance with applicable law;

"(B) is (or is necessary for the operation of) an electronic health records system, including the provision of decision support and physician order entry for medications;

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

"(D) is certified under the program developed under section 3001(c)(9) to be in compliance with any applicable standards and implementation specifications adopted under section 3004(b).

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

"(A) submit to the National Coordinator an application at such time and in such manner as the National Coordinator may require, and containing—

"(i) a plan on how the entity intends to maintain and support the qualified health information technology that would be purchased with amounts under such grant, including the type of resources expected to be involved; and

"(ii) such other information as the National Coordinator may require;

"(B) submit to the National Coordinator a plan for how qualified health information technology purchased by the entity will result in the electronic exchange and use of health information;

"(C) be—

"(i) a not for profit hospital or a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act);

"(ii) an individual or group practice; or

"(iii) another health care provider, such as a rural health clinic, not described in clause (i) or (ii);

"(D) demonstrate significant financial need;

"(E) agree to notify individuals in accordance with section 302 of the PRO(TECH)T Act of 2008 (relating to notifications in the case of breaches);

"(F) provide matching funds in accordance with paragraph (5);

"(G) consult with the Health Information Technology Resource Center established under section 3007 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology; and

"(H) link, to the extent practicable, to one or more local or regional health information plans.

"(4) USE OF FUNDS.—Amounts received under a grant under this subsection shall be used to facilitate the purchase of qualified health information technology.

"(5) MATCHING REQUIREMENT.—To be eligible for a grant under this subsection an entity shall contribute non-Federal contributions to the costs of carrying out the activities for which the grant is awarded in an amount equal to $1 for each $3 of Federal funds provided under the grant.

"(6) PREFERENCE IN AWARDING GRANTS.—In awarding grants under this subsection the National Coordinator shall give preference to the following eligible entities:

"(A) Small health care providers.

"(B) 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).

"(C) Nonprofit health care providers.

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

"(A) Medicaid transformation grants under section 1903(z) of the Social Security Act.

"(B) Grants or funding available through the Agency for Healthcare Research and Quality.

"(C) Grants or funding that may be available through the Health Resources and Services Administration for investment in health information technologies or telehealth.

"(D) Grants or funding that may be available through the Department of Agriculture's Rural Development Telecommunications Program for investment in telemedicine.

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

"(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to purchase qualified health information technology.

"(2) 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—

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

"(B) submits to the National Coordinator a strategic plan in accordance with paragraph (4) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such paragraph;

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

"(D) 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 meets each of the conditions described in paragraph (5); and

"(E) agrees to provide matching funds in accordance with paragraph (9).

"(3) ESTABLISHMENT OF FUND.—For purposes of paragraph (2)(C), an eligible entity shall establish a qualified health information 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 subsection shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this subtitle to be used for other purposes specified in this subtitle shall be deposited in any Loan Fund.

"(4) STRATEGIC PLAN.—

"(A) IN GENERAL.—For purposes of paragraph (2)(B), a strategic plan of an eligible entity under this paragraph shall identify the intended uses of amounts available to the Loan Fund of such entity.

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

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

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

"(iii) A description of the financial status of the Loan Fund as of the date of submission of the plan.

"(iv) The short-term and long-term goals of the Loan Fund.

"(5) HEALTH CARE PROVIDER CONDITIONS FOR RECEIPT OF LOANS.—For purposes of paragraph (2)(D), the conditions described in this paragraph, with respect to a health care provider that seeks a loan from a Loan Fund established under this subsection, are the following:

"(A) The health care provider links, to the extent practicable, to one or more local or regional health information networks.

"(B) The health care provider consults with the Health Information Technology Resource Center established under section 3007 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology.

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

"(D) The health care provider submits to the State or Indian tribe involved a plan on how the health care provider intends to maintain and support the qualified health information 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.

"(6) USE OF FUNDS.—

"(A) IN GENERAL.—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 paragraph (8)(D)(i), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under paragraph (1). Loans under this section may be used by a health care provider to purchase qualified health information technology.

"(B) LIMITATION.—Amounts received by an eligible entity under this subsection may not be used—

"(i) for the purchase or other acquisition of any health information technology system that is not a qualified health information technology; or

"(ii) to conduct activities for which Federal funds are expended under this title.

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

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

"(i) The interest rate for each loan shall not exceed the market interest rate.

"(ii) 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.

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

"(B) 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.

"(C) 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.

"(D) To earn interest on the amounts deposited into the Loan Fund.

"(E) To make reimbursements described in paragraph (8)(D)(i).

"(8) ADMINISTRATION OF LOAN FUNDS.—

"(A) 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.

"(B) 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 subsection to pay the reasonable costs of the administra-

tion 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.

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

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

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

"(D) PRIVATE SECTOR CONTRIBUTIONS.—

"(i) IN GENERAL.—A Loan Fund established under this subsection 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.

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

"(9) MATCHING REQUIREMENTS.—

"(A) IN GENERAL.—The National Coordinator may not make a grant under paragraph (1) 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 $1 of Federal funds provided under the grant.

"(B) 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.

"(10) REPORTS.—The National Coordinator shall annually 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 summarizing the reports received by the National Coordinator from each eligible entity that receives a grant under this subsection.

"(c) COMPETITIVE GRANTS FOR THE IMPLEMENTATION OF REGIONAL OR LOCAL HEALTH INFORMATION TECHNOLOGY PLANS.—

"(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities to implement regional or local health information plans to improve health care quality and efficiency through the electronic exchange and use of health information.

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

"(A) facilitate the electronic exchange and use of health information within the local or regional area and among local and regional areas;

"(B) demonstrate financial need to the National Coordinator;

"(C) demonstrate that one of its principal missions or purposes is to use information technology to improve health care quality and efficiency;

"(D) adopt bylaws, memoranda of understanding, or other charter documents that demonstrate that the governance structure and decisionmaking processes of such entity allow for participation on an ongoing basis by multiple stakeholders within a community, including—

"(i) physicians (as defined in section 1861(r) of the Social Security Act), including physicians that provide services to low income populations and populations that are uninsured, underinsured, and medically underserved (including such populations in urban and rural areas);

"(ii) hospitals (including hospitals that provide services to low income and underserved populations);

"(iii) pharmacists and pharmacies;

"(iv) health plans;

"(v) health centers (as defined in section 330(b)) and Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act);

"(vi) rural health clinics (as defined in section 1861(aa) of the Social Security Act);

"(vii) patient or consumer organizations that reflect the population to be served;

"(viii) employers;

"(ix) public health agencies; and

"(x) such other health care providers or other entities, as determined appropriate by the National Coordinator;

"(E) demonstrate the participation, to the extent practicable, of stakeholders in the electronic exchange and use of health information within the local or regional health information plan pursuant to subparagraph (D);

"(F) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation in the regional or local health information plan by all stakeholders;

"(G) comply with applicable standards and implementation specifications adopted under subtitle A of this title;

"(H) prepare and submit to the National Coordinator an application in accordance with paragraph (3); and

"(I) agree to provide matching funds in accordance with paragraph (6).

"(3) APPLICATION.—

"(A) IN GENERAL.—To be eligible to receive a grant under paragraph (1), an entity shall submit to the National Coordinator an application at such time, in such manner, and containing such information (in addition to information required under subparagraph (B)), as the National Coordinator may require.

"(B) REQUIRED INFORMATION.—At a minimum, an application submitted under this paragraph shall include—

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

"(ii) an estimate of costs of the hardware, software, training, and other services necessary to implement the regional or local health information plan;

"(iii) a strategy that includes initiatives to improve health care quality and efficiency;

"(iv) a plan that describes provisions to encourage the electronic exchange and use of health information by all physicians, including single physician practices and small physician groups, participating in the health information plan;

"(v) a plan to ensure the privacy and security of individually identifiable health information that is consistent with applicable Federal and State law;

"(vi) a governance plan that defines the manner in which the stakeholders shall jointly make policy and operational decisions on an ongoing basis;

"(vii) a financial or business plan that describes—

"(I) the sustainability of the plan;

"(II) the financial costs and benefits of the plan; and

"(III) the entities to which such costs and benefits will accrue;

"(viii) a plan on how the entity involved intends to maintain and support the regional or local health information plan, including the type of resources expected to be involved; and

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

"(4) USE OF FUNDS.—Amounts received under a grant under paragraph (1) shall be used to establish and implement a regional or local health information plan in accordance with this subsection.

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

"(6) MATCHING REQUIREMENT.—

"(A) IN GENERAL.—The National Coordinator may not make a grant under this subsection to an entity unless the entity agrees that, with respect to the costs of carrying out the activities for which the grant is awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an

amount equal to not less than 50 percent of such costs ($1 for each $2 of Federal funds provided under the grant).

"(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under subparagraph (A) may be in cash or in kind, fairly evaluated, including equipment, technology, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

"(d) REPORTS.—Not later than 1 year after the date on which the first grant is awarded under this section, and annually thereafter during the grant period, an entity that receives a grant under this section shall submit to the National Coordinator a report on the activities carried out under the grant involved. Each such report shall include—

"(1) a description of the financial costs and benefits of the project involved and of the entities to which such costs and benefits accrue;

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

"(3) a description of any reduction in duplicative or unnecessary care as a result of the project involved;

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

"(5) an analysis of the effectiveness of the project involved on ensuring the privacy and security of individually identifiable health information in accordance with applicable Federal and State law; and

"(6) other information as required by the National Coordinator.

"(e) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this section 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 quality of care and decrease in costs.

"(f) LIMITATION.—An eligible entity may only receive one non-renewable grant under subsection (a), one non-renewable grant under subsection (b), and one non-renewable grant under subsection (c).

"(g) SMALL HEALTH CARE PROVIDER.—For purposes of this section, the term 'small health care provider' means a health care provider that has an average of 10 or fewer full-time equivalent employees during the period involved.

"(h) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—For the purpose of carrying out subsections (a) through (d), there is authorized to be appropriated $115,000,000 for each of the fiscal years 2009 through 2013.

"(2) AVAILABILITY.—Amounts appropriated under paragraph (1) shall remain available through fiscal year 2013.

"SEC. 3012. 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 qualified health information 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 qualified health information technology in the clinical education of health professionals to reduce medical errors 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 qualified health information 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 qualified health information 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) MATCHING FUNDS.—

"(1) IN GENERAL.—The Secretary may award a grant to an entity under this section only if the entity agrees to make available non-Federal contributions toward the costs of the program to be funded under the grant in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

"(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

"(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).

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

"(h) SUNSET.—This section shall not apply after September 30, 2011.".

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

SEC. 201. 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 101, 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 specifications in order to assure the efficient implementation and use of such standards and 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 101, 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. 202. 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 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 coordinate Federal research and development programs related to the development and deployment of health information technology, including activities related to—

(1) computer infrastructure;

(2) data security;

(3) development of large-scale, distributed, reliable computing systems;

(4) wired, wireless, and hybrid high-speed networking;

(5) development of software and software-intensive systems;

(6) human-computer interaction and information management technologies; and

(7) the social and economic implications of information technology.

TITLE III—PRIVACY AND SECURITY PROVISIONS

SEC. 300. DEFINITIONS.

In this title, except as specified otherwise:

(1) BREACH.—The term "breach" means the unauthorized acquisition, access, or disclosure of protected health information which compromises the security, privacy, or integrity of protected health information maintained by or on behalf of a person. Such term does not include any unintentional acquisition, access, or disclosure of such information by an employee or agent of the covered entity or business associate involved if such acquisition, access, or disclosure, respectively, was made in good faith and within the course and scope of the employment or other contractual relationship of such employee or agent, respectively, with the covered entity or business associate and if such information is not further acquired, accessed, or disclosed by such employee or agent.

(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) 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.

(6) 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.

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

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

(9) 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.

(10) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

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

(12) 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.

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

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

(15) VENDOR OF PERSONAL HEALTH RECORDS.—The term "vendor of personal health records" means an entity that offers or maintains a personal health record. Such term does not include an entity that is a covered entity for purposes of offering or maintaining such personal health record.

Subtitle A—Security Provisions

SEC. 301. 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, and 164.312 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.

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

(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, in consultation with industry stakeholders, annually issue guidance on the latest safeguard technologies for use in carrying out the sections described in subsection (a).

SEC. 302. 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 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 subtitle, 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 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 a conspicuous posting 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 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.

(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 1,000 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 protected 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 protected by technology standards 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 315(f), 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.

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

SEC. 303. EDUCATION ON HEALTH INFORMATION PRIVACY AND REPORT ON COMPLIANCE.

(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) 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 Congress a report concerning complaints of alleged violations of the provisions of sections 301 and 302, the provisions of subtitle B, and the provisions of subparts C and E of title 45, Code of Federal Regulations 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 resulted in the imposition of civil money penalties, the amount of the civil money penalty imposed in each such case, and a summary of the basis for each such civil money penalty;

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

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

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

(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.

(c) EDUCATION INITIATIVE ON USES OF HEALTH INFORMATION.—

(1) IN GENERAL.—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.

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

Subtitle B—Improved Privacy Provisions and Additional Security Provisions

SEC. 311. APPLICATION OF PENALTIES TO BUSINESS ASSOCIATES OF COVERED ENTITIES FOR VIOLATIONS OF PRIVACY CONTRACT REQUIREMENTS.

(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.

(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. 312. 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 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.

(2) 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 323 in the same manner that such exceptions apply to section 164.502(b)(1) of such title before such date.

(c) ACCOUNTING OF CERTAIN PROTECTED HEALTH INFORMATION DISCLOSURES REQUIRED IF COVERED ENTITY USES ELECTRONIC MEDICAL 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 medical record with respect to protected health information—

(A) the exception under section paragraph (a)(1)(i) of such section shall not apply to disclosures (other than oral disclosures) 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) ELECTRONIC MEDICAL RECORD DEFINED.—For purposes of paragraph (1), the term "electronic medical record" means an electronic record of individually identifiable health information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff within a single organization.

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

(A) In the case of an entity that does not use or maintain an electronic medical record before the date of the enactment of this Act with respect to such information, the date on which the covered entity first uses or maintains an electronic medical record, with respect to such information, and in the case of an entity that uses or maintains an electronic medical record with respect to such information before such date of enactment, the date on which the covered entity upgrades such electronic medical record.

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

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

(1) IN GENERAL.—In applying section 164.506 of title 45, Code of Federal Regulations, in the case of a covered entity that is a health care provider, with respect to protected health information of an individual that is used or maintained by such entity in an electronic medical record (as defined in subsection (c)(2)), such covered entity may not use or disclose such protected health information for purposes of health care operations unless the covered entity obtains the consent of the individual to use or disclose such information for such purposes.

(2) TREATMENT OF CONSENT AND REVOCABILITY OF CONSENT.—For purposes of paragraph (1), in the case that an individual provides consent to a covered entity described in such paragraph to use or disclose protected health information described in such paragraph for purposes of health care operations—

(A) such consent may be valid and applicable to future uses or disclosures by such covered entity of such information for such purposes unless and until the individual revokes such consent;

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

(C) in the case that an individual revokes such consent, such revocation shall only apply to any information acquired by the covered entity after the date of such revocation.

(3) APPLICATION OF MINIMUM NECESSARY AND LIMITED DATA SET RULES.—The provision of consent under paragraph (1) shall not affect the application of the requirements under section 164.502(b)(1) of title 45, Code of Federal Regulations, and subsection (b) of this section to such entity for purposes of the use or disclosure of protected health information described in such paragraph.

(4) CLARIFICATION.—Nothing in this subsection shall be construed as preventing a covered entity described in paragraph (1) from maintaining protected health information of an individual in an electronic medical record solely on the basis that the covered entity seeks consent of the individual as required under paragraph (1) and the individual does not provide such consent (or revokes any such consent provided).

(5) REGULATIONS.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall promulgate regulations to implement this subsection to ensure the integrity of protected health information in a reasonable and workable manner. In such regulations, the Secretary may exempt certain health care operations specified by the Secretary from the requirements under paragraphs (1) and (7).

(6) RULE OF CONSTRUCTION.—The provision of consent under paragraph (1) by an individual, with respect to protected health information, does not constitute

a waiver of any privilege otherwise applicable to such individual with respect to such information.

(7) DISCLOSURES BY HEALTH PLANS.—In the case that a covered entity seeks consent, with respect to protected health information of an individual, as required under paragraph (1) and the individual does not provide such consent (or revokes any such consent provided) and such information is disclosed to a health plan for a purpose, such plan may only use such information for such purpose.

(8) MODEL INFORMED CONSENT.—

(A) IN GENERAL.—The Secretary, after notice and opportunity for public comment in accordance with section 553 of title 5, United States Code, shall develop and make publicly available model consents of the type described in paragraph (1).

(B) REQUIREMENTS OF MODEL INFORMED CONSENT.—Each model consent developed under subparagraph (A), with respect to the protected health information of an individual, shall—

(i) inform such individual about the matter to which the individual is providing consent;

(ii) inform such individual about the specific purposes for which the information may be used or disclosed;

(iii) explain what activities are considered health care operations; and

(iv) be in a form that is easily accessible and understandable and supports the ability of the individual to decide whether to consent pursuant to paragraph (1).

(C) TREATMENT OF CONSENT OBTAINED ON MODEL FORM.—

(i) IN GENERAL.—Any consent obtained by a health care provider using a model form under subparagraph (A) shall be deemed to meet the requirement under paragraph (1).

(ii) RULE OF CONSTRUCTION.—Clause (i) applies with respect to the use by a health care provider of a model form under subparagraph (A) without regard to whether such provider includes in the form additional provisions in order to meet requirements under State or Federal law that relate to obtaining consent.

(9) EFFECTIVE DATE.—The provisions of this subsection shall apply to disclosures made by a covered entity on or after the date that is 24 months after the date of the enactment of this Act.

(e) PROHIBITION ON SALE OF ELECTRONIC MEDICAL RECORDS OR PROTECTED HEALTH INFORMATION OBTAINED FROM ELECTRONIC MEDICAL RECORDS.—A covered entity or business associate may not sell an electronic medical record (as defined in subsection (c)(2)) of an individual or any protected health information obtained from such electronic medical record unless—

(1) such sale is necessary for treatment of the individual or payment for treatment of the individual; or

(2) the covered entity obtains from the individual, in accordance with section 164.508 of title 45, Code of Federal Regulations, a valid authorization (as described in paragraph (b) of such section) to sell such record or information, respectively.

(f) 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 medical record (as defined in subsection (c)(2)) 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

(2) notwithstanding paragraph (c)(4) of such section, the covered entity may not impose any fee 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.

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

(a) 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.

(b) PAYMENT FOR CERTAIN COMMUNICATIONS.—Subject to paragraph (2), a covered entity or business associate may not receive direct or indirect payment in exchange for making any communication described in subparagraph (i), (ii), or (iii) of para-

graph (1) of the definition of marketing in section 164.501 of title 45, Code of Federal Regulations, except—

(1) a business associate of a covered entity may receive payment from the covered entity for making any such communication on behalf of the covered entity that 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; and

(2) a covered entity may receive payment in exchange for making any such communication if the entity 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.

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

SEC. 314. STUDY ON APPLICATION OF PRIVACY AND SECURITY REQUIREMENTS TO NON-HIPAA COVERED ENTITIES.

Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Federal Trade Commission, shall submit to Congress recommendations—

(1) to identify 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—

(A) vendors of personal health records;

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

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

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

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

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

SEC. 315. 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 subparagraph (B), (C), or (D) of section 314(1), 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 subparagraph (B), (C), or (D) of section 314(1) 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 302 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. 57*a*(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 302(h)(2).

(B) EXCEPTION IN CASE TIMELY GUIDANCE NOT ISSUED.—In the case that the Secretary does not issue guidance under section 302(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 protected by technology standards that are developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

(g) EFFECTIVE DATE.—The provisions of this section shall apply to breaches of security occurring during the 2-year period beginning on the date that is 90 days after the date of the enactment of this Act.

SEC. 316. 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 and that requires access on a routine basis to such protected health information, such as a Health Information Exchange, Regional Health Information Organization, or E-prescribing Gateway, 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 title.

SEC. 317. GUIDANCE ON IMPLEMENTATION SPECIFICATION TO DE-IDENTIFY PROTECTED HEALTH INFORMATION.

Not later than 12 months after the date of the enactment of this Act, 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.

SEC. 318. GAO REPORT ON TREATMENT DISCLOSURES.

Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress 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, including 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.

SEC. 319. 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. 320. IMPROVED ENFORCEMENT.

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

(1) 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

(2) 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.

"(3) REGULATIONS.—Not later than 180 days after the date of the enactment of the PRO(TECH)T Act of 2008, the Secretary shall promulgate regulations to implement this subsection.".

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

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

SEC. 321. 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 title 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 title. The Secretary shall by rule amend such Federal regulations as required to make such regulations consistent with this title.

SEC. 322. REGULATORY REFERENCES.

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

SEC. 323. EFFECTIVE DATE.

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

PURPOSE AND SUMMARY

The purpose of H.R. 6357, the Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008 (or the PRO(TECH)T Act of 2008), is to facilitate the nationwide adoption and use of health information technology (HIT) in the United States while also protecting the privacy and security of each individual's health information. The bill makes permanent the Office of the National Coordinator for Health Informa-

tion Technology (ONCHIT), originally created by Executive Order 13335, within the Department of Health and Human Services (HHS). With the assistance of two Federal advisory committees, ONCHIT will develop HIT, privacy policy, and technical standards, as well as conduct activities to promote the growth of a nationwide HIT infrastructure. That infrastructure will lower health care costs, reduce medical errors, and provide for a more efficient delivery of health care through the use of electronic health records (EHR). Because this legislation encourages the electronic flow of a person's health information, it will also strengthen current privacy and security protections of a person's information. This legislation will ensure that such personal information is only obtained or accessed by appropriate entities for legitimate purposes.

BACKGROUND AND NEED FOR LEGISLATION

The U.S. health care system is characterized by systemic quality and efficiency shortcomings. The system's quality problems are evidenced by high rates of medical and medication errors and a lack of adherence to practice guidelines. In a 2000 study, the Institute of Medicine (IOM) found that as many as 98,000 people die each year due to preventable medical errors.[1] According to the Agency for Healthcare Research and Quality (AHRQ), an average of 17 years is required for findings from randomized clinical trials to be implemented into clinical practice. These documented shortcomings in our quality of care contribute to higher health care costs and place patients at risk. The U.S. is the top spender on health care in the world, with projected spending of over $2 trillion in 2007 (which represents about 16 percent of GDP and over $7,000 per capita).[2] A July 2008 study reports that despite spending two times more per capita than any other major industrialized country on health care, the United States has a mortality rate where 110 per 100,000 deaths are preventable through health care intervention.[3]

Nationwide adoption of health information technology (HIT), that supports the electronic exchange of health information, has the potential to ameliorate many of the quality and efficiency problems endemic to our health care system. HIT would allow for the centralization of patient information, enhanced, real-time communication between providers to improve the coordination of care, improved patient access to medical records, and access to a variety of quality enhancing programs and tools. While HIT includes electronic health records (EHRs), the term also includes the infrastructure required to support EHRs and allow providers to exchange the information in the EHRs. A robust EHR system includes the capability to maintain and access electronic health information about a patient in a timely manner and exchange that information with other providers. This includes computerized prescription order entry and clinical decision support programs.

A 2005 RAND study estimates that implementation of an HIT system that permits providers, insurers, and others to exchange

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[1] To Err is Human. IOM (2000) National Academy Press. Page 1.

[2] Kaiser Family Foundation. "Trends in Health Care Costs and Spending." September 2007. *http://www.kff.org/insurance/upload/7692.pdf.*

[3] The Commonwealth Fund Commission on a High Performance Health System. "Why Not the Best? Results from the National Scorecard on U.S. Health System Performance, 2008." July 2008. Pages 10–11.

and use health information could save an average of $77 billion annually, and this figure only accounts for the efficiency savings. When savings from improvements in quality and safety are included, the study estimates that as much as $147 billion might be saved annually. This reflects improved health outcomes in the form of significant declines in medical and medication errors, increased use of indicated preventive care, and enhanced chronic disease management.[4]

Regardless of these apparent benefits, many obstacles to the successful uptake and widespread implementation of HIT have been documented by policymakers. Currently, only 13 percent of physicians have a basic EHR system, and only 4 percent have a fully functional EHR system.[5] A commonly cited impediment to the adoption of HIT is cost. The average cost of purchasing an EHR system is about $43,000 with approximately $8,000 in annual ongoing costs for such activities as maintenance and support.[6] A recently released study published in the New England Journal of Medicine showed that a large majority of physicians using EHR systems are satisfied and report that those systems have positive effects on the quality of patient care.[7] The study, which surveyed 2,607 physicians, showed that physicians without HIT systems were concerned about financial barriers.[8] Evidence from this study and others strongly indicate that health care providers need guidance and financial support if HIT is to be widely adopted in the United States.[9]

The United States spends, on average, as much as two and a half times more per capita than other similarly situated industrialized nations. Still, in comparison to other countries, the U.S. lags far behind in the adoption of HIT.[10] Nations such as Germany, Canada, the United Kingdom, Norway, and Australia are all significantly ahead of the U.S. in establishing nationwide HIT networks.[11] Many of these countries achieved success in implementing nationwide HIT networks by establishing committees as long ago as 1993 with

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[4] Hillestad, R., et al. "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs" Health Affairs; 24(5): 1103–1117; September/October 2005.

[5] Catherine M. DesRoches, Dr.P.H., Eric G. Campbell, Ph.D., Sowmya R. Rao, Ph.D., Karen Donelan, Sc.D., Timothy G. Ferris, M.D., M.P.H., Ashish Jha, M.D., M.P.H., Rainu Kaushal, M.D., M.P.H., Douglas E. Levy, Ph.D., Sara Rosenbaum, J.D., Alexandra E. Shields, Ph.D., and David Blumenthal, M.D., M.P.P, "Electronic Health Records in Ambulatory Care—A National Survey of Physicians" *The New England Journal of Medicine,* Published at www.nejm.org June 18, 2008 (10.1056/NEJMsa0802005).

[6] Robert H. Miller, Christopher West, Tiffany Martin Brown, Ida Sim, and Chris Ganchoff, "The Value Of Electronic Health Records In Solo Or Small Group Practices," *Health Affairs*—Volume 24 , Number 5, 2005.

[7] Catherine M. DesRoches, Dr.P.H., Eric G. Campbell, Ph.D., Sowmya R. Rao, Ph.D., Karen Donelan, Sc.D., Timothy G. Ferris, M.D., M.P.H., Ashish Jha, M.D., M.P.H., Rainu Kaushal, M.D., M.P.H., Douglas E. Levy, Ph.D., Sara Rosenbaum, J.D., Alexandra E. Shields, Ph.D., and David Blumenthal, M.D., M.P.P, "Electronic Health Records in Ambulatory Care—A National Survey of Physicians" *The New England Journal of Medicine,* Published at www.nejm.org June 18, 2008 (10.1056/NEJMsa0802005).

[8] Id.

[9] Id.

[10] Gerard F. Anderson, Bianca K. Frogner, Roger A. Johns and Uwe E. Reinhardt, "Health Care Spending And Use Of Information Technology In OECD Countries," *Health Affairs,* 25, no. 3 (2006): 819–831 available at http:// content. health affairs. org/ cgi/ content/ full/ 25/ 3/ 819? max to show= &HITS =10 &hits= 10& RESULT FORMAT =& author1= Anderson & full text =spending & and or exact full text =and & search 1A id =1& FIRST INDEX =0 & resource type =HW CIT #R10.

[11] Id.

functions very similar to those vested in the Office of the National Coordinator which will be codified through the bill.[12]

In addition to costs, concerns about the security and privacy of health information have also been regarded as an obstacle to the adoption of HIT. As the electronic transmission of health information between various independent entities is encouraged, the privacy and security of that health information becomes a much greater concern. The Health Insurance Portability and Accountability Act of 1996 (HIPAA; P.L. 104–191) resulted in the Secretary of HHS developing privacy and security standards giving patients the right of access to their medical information and placing restrictions on the use and disclosure of that information without the patient's consent. The HIPAA "Privacy Rule" and "Security Rule" currently provide the Federal standard for the protection of individually identifiable health information.[13] There are, however, clear gaps in the current privacy and security structure established under HIPAA that have become apparent over time. For example, there are no requirements that a person be notified if their information is accessed by an unauthorized party. In addition, between April 2003 and March 2007, HHS documented 26,408 complaints of Privacy Rule violations.[14] Despite the relatively large number of complaints, no civil penalties were levied during that period and only one civil fine has been levied since then.[15]

HIT holds the promise of implementing a seamless nationwide electronic exchange of health information between numerous entities. This will improve health care but can create a greater opportunity for information to be accessed or obtained by an unauthorized party. In testimony before the Committee on Energy and Commerce, however, Deven McGraw, the Director of the Health Privacy Project for the Center for Democracy and Technology, stated that HIT, implemented properly, "has a greater capacity to protect sensitive personal health information than is the case now with paper records."[16] For example, HIT has the capability of employing technical safeguards, such as encryption, to ensure that sensitive data is not accessed when a system has been breached.[17] Mr. McGraw stated in addition that "it is often impossible to tell whether someone has inappropriately accessed a paper record. By contrast, technologies, including strong user authentication and audit trails, can be employed to limit and track access to electronic health information automatically."[18]

H.R. 6357 would address these barriers to adoption and take steps to provide for greater privacy and security of health information and stronger enforcement of violations of Federal law.

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[12] Id.

[13] Stevens, Gina Marie, "Enforcement of the HIPAA Privacy Rule," CRS Report RL33989, April 30, 2007.

[14] Id.

[15] Id.

[16] Statement of Deven McGraw, Director, Health Privacy Project, Center for Democracy and Technology, Testimony Before the Subcommittee on Health of the House Committee on Energy and Commerce, June 4, 2008, available at http://energycommerce. house.gov/ cmte—mtgs/ 110–he-hrg. 060408.HealthIT draft.shtml.

[17] Id.

[18] Id.

LEGISLATIVE AND EXECUTIVE HISTORY

Bills in the 109th Congress.—The 109th Congress was the first in which the House and Senate passed HIT legislation to create a process for the adoption of standards for the nationwide electronic exchange of health information. The legislation was not enacted, however. The House and Senate each passed its own HIT bill. On November 18, 2005, the Senate, by unanimous consent, passed the Wired for Health Care Quality Act (S. 1418, S.Rept. 109–111). On July 27, 2006, the House passed the Health Information Technology Promotion Act (H.R. 4157, H.Rept. 109–603) by a vote of 270–148. The bills contained several important differences, and a House-Senate conference committee to resolve the differences was not convened. Both bills included similar language establishing ONCHIT and its responsibilities for adopting standards for the electronic exchange and use of health information. The bills, however, took different approaches to the public-private entity that would make recommendations to ONCHIT on standards that allow for the electronic exchange and use of health information. Only the Senate bill addressed certification of private health information technology hardware and software that meet such standards. The Senate bill would have authorized grants for health care providers, grants for implementing regional HIT plans, and a State loan program to facilitate HIT adoption. The House bill included an HIT grant program for integrated health care systems and for small physician practices. The House bill also included a provision to expedite updating and modifying the HIPAA electronic transactions and codes standards. The Senate bill contained no such provisions.

Enactment of HIPAA in the 104th Congress.—Prior to the passage of House and Senate HIT bills in the 109th Congress, Congress took an important first step towards promoting HIT and privacy and security of health information when it enacted HIPAA in August 1996.[19] Under the "Administrative Simplification" subtitle of HIPAA, the Secretary of HHS was required to develop standards to support the growth of electronic record keeping and secure claims processing in the health care system. Section 264 of HIPAA required HHS to develop recommendations regarding the rights that an individual who is a subject of individually identifiable health information should have; the procedures that should be established for the exercise of such rights; and the uses and disclosures of such information that should be authorized or required. Eventually, HHS promulgated regulations to fulfill these requirements.

Enactment of Administrative Simplification Compliance Act in 107th Congress.—In 2001, Congress enacted the Administrative Simplification Compliance Act (P.L. 107–105), which, among other things, requires Medicare providers to submit claims electronically.

E-Prescribing.—Besides HIPAA, the other significant legislative action taken by Congress to promote HIT was the inclusion of electronic prescribing (e-prescribing) provisions in the Medicare Modernization Act of 2003 (MMA; P.L. 108–173), which created the Medicare Part D prescription drug benefit. Additionally, the recently enacted Medicare Improvement for Patients and Providers Act of 2008 (P.L. 110–161) includes an e-prescribing mandate and

[19] Public Law 104–191.

authorizes incentive bonus payments for physicians who use e-prescribing between 2009 and 2013; payments would be reduced for those who fail to e-prescribe after 2012.[20]

CMS Grants and Demonstrations.—CMS is administering a number of additional programs to promote HIT adoption. The MMA mandated a demonstration in four States to encourage physicians to adopt and use HIT to improve the care of chronically ill Medicare patients. CMS, using its Medicare waiver authority, has also developed a second demonstration to promote EHR adoption in as many as 1,200 small- to medium-sized Medicare participating physicians' practices in 12 communities across the country. Additionally, the Deficit Reduction Act of 2005 (P.L. 109–171) authorized Medicaid Transformation Grants to states totaling $150 million over two years. Most of the funds are being used for HIT-related initiatives.

Office of the National Coordinator for Health Information Technology; Other Administrative Actions.—On April 27, 2004, the President signed Executive Order 13335, which created the ONCHIT within the Department of HHS. The mission of ONCHIT is to develop, maintain, and direct a strategic plan to guide the nationwide implementation of HIT in the public and private health care sectors.

In 2005, the Secretary created the American Health Information Community (AHIC), a federally chartered commission, to make recommendations to the Secretary on how to make health records digital and exchangeable, encourage market-led adoption of electronic health records that allow for the electronic exchange and use of health information, and ensure the privacy and security of those records. ONCHIT provides management of and logistical support for the AHIC.

In August 2006, the President signed Executive Order 13410, which required Federal agencies that purchase and deliver health care to acquire and use, where available, HIT that is based on technical standards recognized by the Secretary. The order also applied to entities that contract with Federal agencies, such as Medicare carriers.

HEARINGS

On June 4, 2008, the Subcommittee on Health held a hearing entitled "Discussion Draft of Health Information Technology and Privacy Legislation." The witnesses included Steven J. Stack, M.D., Chairman of the American Medical Association's HIT Advisory Group; Byron Thames, M.D., member of the Board of Directors of AARP; Frances Dare, Director of the Cisco Internet Business Solutions Group; Marc C. Reed, Executive Vice President of Corporate Human Resources of Verizon Corporate Services Group Inc.; James A. Ferguson, Executive Director of Health I.T. Strategy and Policy of Kaiser Permanente; Joycelyn Elders, M.D., former U.S. Surgeon General and Co-Chair of the African American Health Alliance; Deborah C. Peel, M.D., Founder and Chair of Patient Privacy Rights; Deven McGraw, Director of the Health Privacy Project of the Center for Democracy and Technology; Carolyn M. Clancy, M.D., Director of the Agency for Healthcare Research and Quality

[20] E-Prescribing: Overview available at http://www.cms.hhs.gov/EPrescribing.

of the Department of Health and Human Services; and Susan D. McAndrew, J.D., Deputy Director for Health Information Privacy of the Office for Civil Rights of the Department of Health and Human Services.

COMMITTEE CONSIDERATION

On Wednesday, June 25, 2008, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 6357 to the full Committee for consideration, by a voice vote. On Wednesday, July 23, 2008, the full Committee met in open markup session and ordered H.R. 6357 favorably reported to the House, amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. No record votes were taken on amendments or in connection with ordering H.R. 6357 reported to the House. A motion by Mr. Dingell to order H.R. 6357 favorably reported to the House, amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Subcommittee on Health held a legislative hearing on a draft concerning HIT that was later modified and introduced as H.R. 6357, and the oversight findings of the Committee regarding the bill are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of H.R. 6357 is to facilitate the nationwide adoption and use of HIT in the United States while also protecting the privacy and security of each individual's health information.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 6357 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 6357 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 6357 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 6357 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, September 5, 2008.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 6357, the Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Stephanie Cameron and Kirstin Nelson.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag, Director).

Enclosure.

H.R. 6357—Protecting Records, Optimizing Treatment, and Easing Communication Through Healthcare Technology Act of 2008

Summary: On April 27, 2004, the President issued Executive Order 13335, which established within the Office of the Secretary of Health and Human Services (HHS) the position of National Health Information Technology Coordinator. The Secretary subsequently established the Office of the National Coordinator of Health Information Technology (ONCHIT) and the American Health Information Community (AHIC) to support the adoption of health information technology (HIT). H.R. 6357 would amend the Public Health Service Act to codify the establishment and responsibilities of those entities. In addition, the bill would authorize funding for programs to facilitate the development of HIT standards and the widespread adoption of qualified HIT, and to enhance the security of private health information.

H.R. 6357 would authorize the appropriation of $193 million in 2009 and $960 million over the 2009–2013 period. CBO estimates that implementing the bill would cost an additional $58 million in 2009 and $743 million over the 2009–2013 period, when compared to current law, assuming the appropriation of the authorized amounts. Enacting H.R. 6357 would not affect direct spending or revenues.

Over the long term, widespread adoption of health IT could facilitate cost savings in the health care system as a whole and thus for government programs. Research indicates that in certain settings, health IT appears to make it easier to reduce health spending if other steps in the broader health care system are also taken to alter incentives to promote savings. By itself, however, the adoption of more health IT is generally not sufficient to produce significant cost savings.

H.R. 6357 contains both intergovernmental and private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) because it would require governmental and private-sector entities, as providers and insurers of health care, to comply with new federal standards regarding protected health information. CBO believes that the costs to the private sector to comply with the new requirements would probably exceed the threshold established in UMRA for private-sector mandates ($136 million in 2008, adjusted for inflation) in the first year or two following enactment. The cost to state, local and tribal governments to comply with the mandates in the bill, however, would not exceed the threshold established in UMRA for intergovernmental mandates ($68 million in 2008, adjusted for inflation).

Estimated cost to the Federal Government: The estimated cost of H.R. 6357 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, millions of dollars—					
	2008	2009	2010	2011	2012	2013
SPENDING SUBJECT TO APPROPRIATION						
Spending Under Current Law:						
Budget Authority	68	0	0	0	0	0
Estimated Outlays	59	46	8	1	0	0
Proposed Changes:						
Estimated Authorization Level	0	193	195	196	187	189
Estimated Outlays	0	58	141	177	184	183
Estimated Spending Under H.R. 6357:						
Estimated Authorization Level	68	193	195	196	187	189
Estimated Outlays	59	104	150	179	184	183

Basis of estimate: H.R. 6357 would amend the Public Health Service Act to add title 30—which would specify the responsibilities of ONCHIT and related committees, as well as establish several grant and loan programs. The bill also would establish privacy and security provisions for certain health information. For this estimate, CBO assumes that H.R. 6357 will be enacted near the end of fiscal year 2008, that the necessary amounts will be appropriated each year, and that outlays will follow historical patterns for similar activities of the Department of Health and Human Services. CBO estimates that implementing H.R. 6357 would cost $58 million in 2009 and $743 million over the 2009–2013 period.

HEALTH INFORMATION TECHNOLOGY AND QUALITY

The National Coordinator of Health Information Technology serves as the senior advisor to the Secretary of HHS and the President on HIT programs and initiatives, and is responsible for:

- Developing, maintaining, and updating a strategic plan to guide the nationwide implementation of electronic health records in both the public and private health care sectors; and
- Coordinating HIT policy across federal agencies.

H.R. 6357 would add title 30 to the Public Health Service Act to further specify the responsibilities of ONCHIT and create two committees to assume the current functions of the AHIC—the HIT Policy Committee and the HIT Standards Committee.

This bill would require the National Coordinator to ensure that standards for the secure electronic exchange of information incor-

porate adequate privacy and security protections. The bill would also require the National Coordinator to develop a program for the voluntary certification of products as meeting the standards developed for the secure electronic exchange of health information. In addition, the National Coordinator would be responsible for:

- Reviewing and determining the endorsement of industry standards;
- Implementing specifications and certifying criteria for the electronic exchange and use of health information; and
- Evaluating and reporting progress toward implementation of electronic health records, barriers to access to technology, and the benefits and costs of HIT, including those in medically underserved communities.

The HIT Policy Committee would serve as a federal advisory committee comprised of public and private stakeholders to provide input and assistance to the National Coordinator. The committee would be responsible for recommending a policy framework and prioritizing the technical standards necessary for the development of an HIT infrastructure. The HIT Standards Committee would also serve as a federal advisory committee of public and private stakeholders and be responsible for developing, recognizing, or harmonizing the technical standards necessary for secure electronic exchange of health information.

This bill would require private entities contracting with the federal government to carry out health care activities to adopt the standards established in this bill for the electronic exchange of health care information.

H.R. 6357 would authorize the appropriation of $66 million for fiscal year 2009 for those purposes. Because ONCHIT's responsibilities would be ongoing, the estimate assumes that amount, with adjustments for inflation, would be appropriated in subsequent years. Assuming the appropriation of the necessary amounts, CBO estimates that spending for those activities resulting from this bill would total $20 million in 2009 and $265 million over the 2009–2013 period.

INCENTIVES FOR THE USE OF HEALTH INFORMATION TECHNOLOGY

H.R. 6357 would also establish several grant and loan programs to promote the widespread adoption of qualified HIT, including programs for health care providers, states and Indian tribes, and local or regional organizations. The grant programs would require that recipients provide matching funds. Small health care providers, those in medically underserved or rural areas, and others who may have difficulty acquiring electronic health records without outside assistance would be given preference in awarding the grants. The bill also would create a demonstration program to integrate HIT in the clinical education of health professionals.

H.R. 6357 would authorize appropriations for the grant programs of $115 million a year for fiscal years 2009 through 2013. It would authorize the appropriation of $10 million a year for fiscal years 2009 through 2011 for the demonstration projects. Assuming appropriation of the authorized amounts, CBO estimates that implementing those programs would cost $38 million in 2009 and $470 million over the 2009–2013 period.

PRIVACY AND SECURITY PROVISIONS

H.R. 6357 would establish federal standards regarding the privacy and security of protected health information (PHI), and would require health care providers and insurers to comply with those standards.

The bill also would require the Secretary of HHS to implement an education program to enhance public transparency regarding the uses of PHI, and would authorize the appropriation of $10 million during the 2009–2013 period for that purpose. Assuming the appropriation of the authorized amount, CBO estimates that implementing that provision would cost $8 million over the 2009–2013 period.

Intergovernmental and private-sector impact: H.R. 6357 contains both intergovernmental and private-sector mandates as defined in UMRA. In aggregate, CBO estimates that the cost to private-sector entities to comply with the mandates in the bill would probably exceed the UMRA threshold of $136 million per year (adjusted for inflation); the cost to state, local and tribal governments to comply with the mandates in the bill, however, would not exceed the UMRA threshold ($68 million per year, adjusted for inflation). Precise estimates are difficult, given the lack of available data.

The bill would require providers and insurers of health care, both in the private sector and as operated by state, local, and tribal governments, to notify individuals whose health information has been, or is reasonably believed to have been, breached. Such a requirement would be an intergovernmental and private-sector mandate. CBO estimates, however, that few breaches of health information would occur that would require a notice as specified in the bill; thus, the cost of this provision would be small.

The bill also would impose intergovernmental and private-sector mandates by requiring providers and insurers to comply with a patient's request that they not disclose protected health information if the information pertains solely to a health care item or service that has been paid for completely out of pocket. Disclosures for purposes of carrying out treatment or as otherwise required by law would be exempt from this requirement.

Providers and insurers that use electronic medical record systems also would be prohibited from using or disclosing an individual's PHI for purposes of health care operations unless they obtain the consent of the individual. Such a requirement would constitute an intergovernmental and private-sector mandate as defined in UMRA. Due to the bill's relatively broad definition of an "electronic medical record," most health care entities, including pharmacies, physicians, ancillary service providers, and hospitals, would be considered to have electronic medical records. Thus, because of the large number of consents required by this provision, CBO believes that the cost would probably exceed the threshold for private-sector mandates established under UMRA in the first year or two following enactment. Because most health care providers are private entities, CBO does not believe that the cost to state, local and tribal governments would exceed the threshold.

H.R. 6357 also would require private-sector entities and state, local, and tribal governments with electronic medical records to maintain a six-year log of disclosures of an individual's PHI for

treatment, payment, and health care operations. Covered entities would be required to provide a copy of the log to the individual upon request. CBO believes that the cost of this provision would be relatively small, however, because under the Health Insurance Portability and Accountability Act (HIPAA), providers already must provide logs of disclosures of PHI for purposes other than for treatment, payment, and health care operations, and therefore, already must have capabilities for maintaining such logs. Indeed, most electronic medical record systems used by providers have audit trail capabilities that can maintain logs of disclosures and transactions. In addition, requests for such logs would probably be infrequent.

With some exceptions, HIPAA preempts state laws that impose standards less stringent than the federal standard. H.R. 6357 would apply HIPAA's criteria for preempting state laws. Therefore, state standards with respect to health information technology and the privacy of unsecured protected health information that are less stringent than the new federal standard would be preempted by the bill. That preemption would be an intergovernmental mandate as defined in UMRA. CBO estimates that the costs to state, local, and tribal government of this provision would be minimal.

Other provisions in the bill would benefit state, local, and tribal governments that participate in grant and loan programs to facilitate the adoption of health information technology; any costs they incur to comply with grant or loan conditions would be incurred voluntarily.

Estimate prepared by: Federal Costs: Stephanie Cameron and Kirstin Nelson; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Keisuke Nakagawa.

Estimate approved by: Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 6357 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

Regarding section 5(b) of the Federal Advisory Committee Act, H.R. 6357 provides for two advisory committees, an HIT Policy Committee and an HIT Standards Committee. See sections 3002 and 3003 of the Public Health Service Act, respectively, as added by section 101 of the bill. The Committee finds that establishing these advisory committees is the most efficient way of carrying out the policies involved.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 6357 is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian Tribes, and in the provisions of Article I, section 8, clause 1, that relate

to expending funds to provide for the general welfare of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 6357 does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act of 1995.

EXCHANGE OF COMMITTEE LETTERS

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

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September 9, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Dingell:

I write to you regarding H.R. 6357, the "PRO(TECH)T Act of 2008." This important legislation promotes the creation and adoption of health information technology.

H.R. 6357 contains provisions that fall within the jurisdiction of the Committee on Science and Technology. I recognize and appreciate your desire to bring this legislation before the House in an expeditious manner and, accordingly, I will waive further consideration of the bill in Committee. However, agreeing to waive consideration of this bill should not be construed as the Committee on Science and Technology waiving its jurisdiction over H.R. 6357.

Further, I request your support for the appointment of Science and Technology Committee conferees during any House-Senate conference convened on this legislation on provisions of the bill that are within the Committee's jurisdiction. I also ask that a copy of this letter and your response be placed in your Committee's report on this measure and in the Congressional Record during consideration of the bill on the House floor.

I very much appreciate the collaboration between our respective committees in crafting H.R. 6357, and I look forward to continuing to work with you as we prepare to pass this important legislation.

Sincerely,

Bart Gordon
Chairman

cc: The Honorable Nancy Pelosi, Speaker
The Honorable Joe Barton, Ranking Member
The Honorable Ralph M. Hall, Ranking Member, Committee on Science and Technology
The Honorable John Sullivan, Parliamentarian

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

September 10, 2008

The Honorable Bart Gordon
Chairman
Committee on Science and Technology
U.S. House of Representatives
2320 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Gordon:

Thank you for your letter regarding H.R. 6357, the Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008.

The letter expresses the jurisdictional interest of the Committee on Science and Technology in the bill. The Committee on Energy and Commerce recognizes that your Committee has jurisdiction on certain provisions of the bill. I appreciate your decision to forgo a markup of the bill, and I agree with you that the decision does not in any way prejudice the Committee on Science and Technology with respect to its jurisdictional prerogatives, including the appointment of conferees, on this bill or similar legislation in the future. If a House-Senate conference is convened on H.R. 6357, I would support a request by the Committee on Science and Technology for an appropriate number of conferees with respect to provisions within its jurisdiction.

I will include our letters on this matter in the Committee's report on the bill, and will also include the letters in the Congressional Record during consideration of the bill on the House floor. I appreciate the collaboration between our committees in crafting H.R. 6357, and I look forward to continuing to work with you to pass this important legislation.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Ralph M. Hall, Ranking Member
Committee on Science and Technology

The Honorable Nancy Pelosi
Speaker of the House of Representatives

Mr. John Sullivan, Parliamentarian
U.S. House of Representatives

September 10, 2008

The Honorable John D. Dingell
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Dingell:

I write regarding H.R. 6357, the "Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008," which the Energy and Commerce Committee ordered reported to the House on July 23, 2008.

As you know, the Committee on Oversight and Government Reform has a jurisdictional interest in certain provisions of this bill. I am pleased that the consultation process between our Committees before the passage of H.R. 6357 in the Committee on Energy and Commerce led to consideration of the interests of our Committee. In the interest of expediting consideration of H.R. 6357, and in recognition of your efforts to work with the Oversight Committee on this bill, the Oversight Committee will not request a sequential referral of this bill.

This letter should not be construed as a waiver of the Oversight Committee's legislative jurisdiction over the subjects addressed in H.R. 6357 that fall within the jurisdiction of the Oversight Committee. We also retain our right to representation in any conference consideration of the bill, and request your assurances that we will have your support for the appointment of an appropriate number of conferees from the Oversight Committee should H.R. 6357 or a similar bill be considered with the Senate.

I would appreciate your response to this letter, confirming this understanding with respect to this bill. I would also ask that a copy of our exchange of letters be included in the Energy and Commerce report on H.R. 6357 and in the *Congressional Record* during consideration of this legislation on the House floor.

Sincerely,

Henry A. Waxman

Henry Waxman

cc: Tom Davis
Ranking Minority Member

ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

September 10, 2008

The Honorable Henry A. Waxman
Chairman
Committee on Oversight and Government Reform
U.S. House of Representatives
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Waxman:

Thank you for your letter regarding H.R. 6357, the Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008.

The letter expresses the jurisdictional interest of the Committee on Oversight and Government Reform in the bill as ordered reported on July 23, 2008. The Committee on Energy and Commerce recognizes that the Committee on Oversight and Government Reform has jurisdiction on certain provisions of the bill. I appreciate your decision to forgo a sequential referral of the bill, and I agree with you that the decision does not in any way prejudice the Committee on Oversight and Government Reform with respect to any of its jurisdictional prerogatives, including the appointment of conferees, on this bill or similar legislation in the future. If a House-Senate conference is convened on H.R. 6357, I would support a request by the Committee on Oversight and Government Reform for an appropriate number of conferees with respect to provisions within its jurisdiction.

I will include our letters on this matter in the Committee's report on the bill, and will also include the letters in the Congressional Record during consideration of the bill on the House floor. I appreciate the collaboration between our committees in crafting H.R. 6357, and I look forward to continuing to work with you to pass this important legislation.

Sincerely,

JOHN D. DINGELL
CHAIRMAN

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Thomas M. Davis III, Ranking Member
Committee on Oversight and Government Reform

The Honorable Nancy Pelosi
Speaker of the House of Representatives

Mr. John Sullivan, Parliamentarian
U.S. House of Representatives

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title; table of contents

Section 1 establishes the short title of H.R. 6357 as the "Protecting Records, Optimizing Treatment, and Easing Communication through Healthcare Technology Act of 2008" or the "PRO(TECH)T Act of 2008" and provides the table of contents of the bill.

TITLE I—HEALTH INFORMATION TECHNOLOGY

Subtitle A—Promotion of Health Information Technology

Part 1—Improving Health Care Quality, Safety, and Efficiency

Section 101. ONCHIT; standards development and adoption; Health Information Technology Resource Center

Section 101 adds a new title XXX to the Public Health Service Act:

"TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY"

"Section 3000. Definitions"

Section 3000 defines key terms related to the promotion of health information technology.

"Subtitle A—Promotion of Health Information Technology"

"Section 3001. Office of the National Coordinator of Health Information Technology"

The Office of the National Coordinator of Health Information Technology (ONCHIT), which was originally created administratively by Executive Order 13335, would by statute be established within the Department of Health and Human Services (HHS). The head of ONCHIT, the National Coordinator, will lead the efforts for the development of policies and recognition of standards to allow for the secure electronic exchange of health information.

The National Coordinator is required to maintain and update the strategic plan on how to achieve these goals. The plan should include steps to encourage the nationwide utilization of an electronic health record for each person in the United States by 2014 and ensure the incorporation of adequate privacy and security protections into those electronic records. The National Coordinator is additionally charged with evaluating and reporting on progress toward these goals, on barriers to accessing technology, and on the benefits and costs of health information technology. The National Coordinator shall also report on the impact of HIT in medically underserved communities.

The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall develop a program for the voluntary certification of products that meet the standards developed for the secure electronic exchange of health information. This provision is not intended to ratify or eliminate existing organizations and entities not mentioned, such as the Certification Commission for Healthcare Information Technology (CCHIT). Their future will depend on their ability to comply with the requirements of this section or their ability to coordinate with or create added value to the certification structure developed under

section 3001. In addition, current work and certifications made by the CCHIT shall be transitioned into the certification program developed under section 3001(c)(9).

The authorization of appropriations for these purposes is $66 million for fiscal year 2009.

"Section 3002. HIT Policy Committee"

Section 3002 establishes a Federal advisory committee of public and private stakeholders to provide input and assistance to the National Coordinator. The HIT Policy Committee will recommend a policy framework and prioritize the technical standards necessary for the electronic exchange and use of health information with the goal of each American having an electronic health record by 2014. In addition, the HIT Policy Committee shall make recommendations on standards to protect the privacy of and promote the security of health information. These standards should also allow for an accounting of all disclosures made of a person's health information from an electronic medical record. In addition, the HIT Policy Committee can consider a number of other areas of standards and technologies. This includes the ability for the HIT Policy Committee to look at technologies that reduce medical errors, ensuring that technologies are not improperly causing medical errors. Their recommendations will then be forwarded to the HIT Standards Committee, a technical advisory committee.

"Section 3003. HIT Standards Committee"

Section 3003 establishes a second Federal advisory committee of public and private stakeholders. The purpose of this committee is to develop, recognize, or harmonize the technical standards necessary for the secure electronic exchange of health information. The HIT Standards Committee shall develop a schedule for the assessment of policy recommendations by the HIT Policy Committee.

The membership of both committees under sections 3002 and 3003 is intended to include a broad and diverse cross-section of individuals with expertise and background in the issues to be reviewed. In particular, the provider positions and other appointments should be used to ensure a broad array of representatives as necessary. Additionally, the committees shall ensure that those with expertise in areas of consideration are included in the process for determining standards. For example, research representatives appointed to both committees should therefore have extensive understanding and experience with medical and clinical research, the use and reporting of aggregated research data, and such related issues as drug safety, biosurveillance, and public health reporting.

"Section 3004. Process for adoption of endorsed recommendations"

"Section 3005. Application and use of adopted standards and implementation specifications by Federal agencies"

"Section 3006. Voluntary application and use of adopted standards and implementation specifications by private entities"

These sections direct the Secretary, in consultation with other relevant agencies, to review standards recommended by the HIT Standards Committee and, where appropriate, provide for adoption by the Federal Government through a rulemaking process. Section

3004 is intended to require that all standards for adoption go through the Federal rulemaking process. Sections 3005 and 3006, which refer to sections 111 and 112, respectively, are intended to track the implementation of Executive Order 13410, signed August 22, 2006, and entitled "Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs." These standards would not be binding on private entities, but may be voluntarily adopted.

"Section 3007. Health Information Technology Resource Center"

Section 3007 directs the National Coordinator to establish an HIT Resource Center to provide technical assistance, develop best practices, and serve as a forum for the exchange of knowledge and experience with regard to the adoption of HIT.

Section 102. Transitions

Section 102 of the bill provides for transitions to allow for the current development and harmonization of standards to continue once ONCHIT is established by statute and the functions of the current American Health Information Collaborative are subsumed by the HIT Policy and Standards Committees.

This section is not intended to ratify or eliminate existing organizations and entities not mentioned, such as the Health Information Technology Standard Panel and National Committee of Vital and Health Statistics. Their future will depend on their role, their usefulness, and ability to coordinate with or create added value to the structure developed under the bill.

Part 2—Application and Use of Adopted Health Information Technology Standards; Reports

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

Section 111 requires that Federal agencies implementing, acquiring, or upgrading HIT systems for the electronic exchange of identifiable health information use HIT products meeting standards adopted by the Federal Government in accordance with the bill, where available. It also requires that the President ensure that Federal activities involving the collection and submission of health information be consistent with standards established under the bill for the electronic exchange of health information.

Section 112. Application to private entities

Section 112 requires that all Federal contracts with health care providers, health plans, or health insurance issuers include a requirement to meet standards adopted by the Federal Government in accordance with the bill, where available. These standards would apply as the entity implements, acquires, or upgrades HIT systems for the electronic exchange of identifiable health information.

Sections 111 and 112 are intended to track how the August 22, 2006, Executive Order has been applied by the Federal Government. To satisfy the requirements in sections 111 and 112, the Government will have flexibility to ensure that products meeting standards adopted by the Government are certified in a timely

manner. In addition, the Committee does not intend section 112 to apply to Medicare Part A and B providers.

Section 113. Reports

Section 113 requires the Secretary to submit an annual report to Congress on the efforts toward, and barriers to, facilitating the electronic exchange of health information nationwide. It also requires the Secretary to study methods for creating efficient reimbursement incentives to improve health care quality in Federally-qualified health centers, rural health clinics, and free clinics. This reimbursement study should consider the expected benefits and efficiencies that health information technology and electronic medical records provide. Finally, it requires the study of aging services technology to help seniors and individuals with disabilities.

Subtitle B—Incentives for the Use of Health Information Technology

Sec. 121. Grant, loan, and demonstration programs

Section 121 of the bill adds a subtitle B to the title XXX of the Public Health Service Act that was added by section 101 of the bill:

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

"Section 3011. Grants and loans to facilitate the widespread adoption of qualified health information technology"

Section 3011 provides incentives for the widespread adoption and use of electronic health records through the creation of three separate competitive grant programs.

The first grant program offers matching funds to eligible health care providers for the purchase of qualified health information technology.

The second competitive grant program offers funds to States and Indian Tribes to develop loan programs that will leverage private-sector funds. The program will also provide low-interest loans to health care providers to purchase health information technology as described above.

The third grant program provides support for local or regional organizations to develop HIT plans. These plans must provide for the exchange of health information among physicians, pharmacies, hospitals, health centers, health plans, and others within a given region.

Preference in awarding these grants will be given to small health care providers, to providers in rural and other areas that service uninsured, underinsured, medically underserved individuals, and to nonprofit health care providers.

The authorization of appropriations for these grants is $115 million for each of the fiscal years 2009 through 2013, a total of $675 million over five years.

"Section 3012. Demonstration program to integrate information technology into clinical education"

Section 3012 creates a demonstration program to integrate HIT into the clinical education of health care professionals. The authorization of appropriations is $10 million for each of the fiscal years

2009 through 2011. Competitive funding will be offered to current and future health care educational institutions to provide for training on the use of HIT that promotes quality of care. The Secretary shall consider any health professions school, including those not specifically listed, such as optometry and chiropractic schools.

TITLE II—TESTING OF HEALTH INFORMATION TECHNOLOGY

Section 201. National Institute for Standards and Technology testing

Section 201 of the bill requires that the National Institute for Standards and Technology (NIST) work in coordination with the HIT Standards Committee to test technical standards. These are standards being developed or recognized for the electronic exchange of health information by the HIT Standards Committee. It additionally requires the director of NIST, in coordination with the HIT Standards Committee, to support the establishment of accredited testing laboratories for the voluntary testing of products for certification by the National Coordinator that they meet standards for the electronic exchange of information.

Section 202. Research and development programs

Section 202 requires that the Director of NIST, in consultation with the Director of the National Science Foundation and other appropriate Federal agencies, award competitive grants to institutes of higher education for research of innovative approaches for the use of HIT in the delivery of health care. Additionally, it directs the National High-Performance Computing Program, created by the High Performance Computing Act of 1991, to coordinate Federal research and programs related to the development and deployment of HIT.

TITLE III—PRIVACY AND SECURITY PROVISIONS

Section 300. Definitions

Section 300 defines key terms related to the privacy and security provisions of the bill.

Subtitle A—Security Provisions

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

Section 301 requires that security safeguards, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the penalties for violation of those safeguards, be applied to business associates under HIPAA in the same manner as applied to covered entities. This section also requires that the Secretary, in consultation with stakeholders, annually issue guidance on the latest safeguard technologies for protecting information. (Pursuant to section 300, (1) covered entities are defined as providers, such as physicians, health plans and health care clearinghouses, such as claims processors; and (2) business associates are defined as entities that assist covered entities with particular routine business functions.)

Section 302. Notification in the case of breach

Section 302 requires that, in the case of a breach of unsecured protected health information (PHI), a covered entity must notify each individual whose information has been, or is reasonably believed to have been, breached. PHI is individually identifiable health information maintained or transmitted by the covered entity. In the case of a breach of unsecured PHI that is under the control of a business associate, that business associate is required to notify the covered entity. All breach notifications must be made without unreasonable delay and no later than 60 calendar days after discovery. This section provides instruction for the required methods by which an individual must be notified and the content of the notification. Finally, the section provides that this notification may be delayed if it could impede a criminal investigation or damage national security.

The Secretary, after consultation with stakeholders, will issue guidance within 60 days of enactment that will define unsecured PHI, specifying technologies and methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized individuals. If the Secretary fails to issue this guidance within 60 days, unsecured PHI shall mean information that is not protected by technology standards developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute (ANSI).

Breach, as defined, does not include unintentional acquisition, access, or disclosure, such as inadvertently looking at a person's medical record, mailing an explanation of benefits to an address on file that is outdated, or having the post office deliver it to the wrong address.

Section 303. Education on health information privacy and report on compliance

Section 303 requires that the Secretary, not later than 6 months after enactment, designate an individual in each regional HHS office 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 PHI. It requires that the Secretary annually report to Congress on complaints of alleged violations. Finally, the provision requires that HHS develop and maintain a multi-faceted national education initiative to enhance public transparency regarding the potential uses of their PHI, the effects of such uses, and the rights of individuals with respect to such uses.

Subtitle B—Improved Privacy Provisions and Additional Security Provisions

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

Section 311 requires that the penalties for violating the business associate contract standard in the HIPAA Privacy Rule apply to business associates under HIPAA in the same manner as applied to covered entities.

Section 312. 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.—

If a patient has paid in full out-of-pocket for an item or service, subsection (a) permits a patient to request that his PHI not be disclosed by a covered entity to a health plan for purposes of payment or health care operations, unless otherwise required by law. In such a circumstance, the covered entity is required to honor the patient's request. The Committee intends that this provision override all conflicting contractual requirements.

(b) Disclosures required to be limited to the limited data set or the minimum necessary.—

Subsection (b) requires covered entities, to the extent practicable, when sharing PHI with other entities, make a reasonable effort to restrict the use, disclosure, or request of PHI to a limited data set of information as defined in regulation. If the limited data set is insufficient, the covered entity must restrict the use, disclosure, or request of PHI to the minimum necessary to achieve the purpose.

(c) Accounting of certain protected health information disclosures required if covered entity uses electronic medical record.—

Subsection (c) gives an individual the right to request an accounting of disclosures of PHI made by a covered entity to another party for treatment, payment, and health care operations in the three years prior to the request if that entity is utilizing an electronic medical record. Covered entities would not be required to make an accounting for uses of PHI or oral disclosures of such information. The provision takes effect either when an entity acquires or upgrades its electronic medical record, or six months after a technical standard is developed pursuant to section 3002(b)(2)(B)(iv) of the Public Health Service Act (as added by title I of the bill) that relates to a standard for accounting for disclosures and is adopted by the Federal Government, whichever is sooner. This provision provides the entity flexibility in determining when it will integrate such technology into its electronic medical record systems if it already utilizes one. Alternatively, the provision ensures future electronic health records are built with the capability to account for disclosures.

(d) Application of consent requirements for certain uses and disclosures by health care providers with electronic medical records.—

Subsection (d) requires that a health care provider who creates or maintains an electronic medical record for the patients of the provider receive a patient's consent to use or disclose the patient's PHI for health care operations. If the patient gives consent, the requirements under subsection (b) regarding limiting PHI to the limited data set where practicable still apply. In addition, the provision clarifies (1) that the consent may be a one-time aggregated consent; (2) that revocation of consent can only be for data collected prospectively, not retrospectively; (3) that whether or not a pro-

vider receives consent, the provider can maintain the patient's information in an electronic medical record; and (4) that the consent shall not constitute a waiver of any evidentiary privilege. In addition, consistent with the current regulations, the Committee intends that a provider be allowed to refuse treatment if a patient does not provide consent to share the patient's PHI for health care operations. Also, the Committee intends that the consent provision does not override other permitted uses and disclosures enumerated under HIPAA, such as those in section 164.512 or section 164.514, and only applies to uses and disclosures as defined in health care operations.

The consent provision takes effect 24 months after enactment. The Secretary is required to promulgate regulations implementing the provision in a manner that ensures the integrity of PHI in a reasonable and workable manner. The Secretary may exempt certain health care operations from the consent provision and is required to develop and make publically available a model consent form. The Committee strongly encourages the Secretary to consider whether requiring patient consent for certain health care operations would impede the ability of medical schools and providers to provide access to health care and train and evaluate health professionals; reduce health care quality or safety; impede treatment of payment activities of the provider; or impact any of the permitted uses and disclosures under the HIPAA Privacy Rule other than health care operations (e.g., the exception for information to flow to a public health authority or for research purposes).

(e) Prohibition on sale of electronic medical records or protected health information obtained from electronic medical records.—

Subsection (e) further enhances privacy protections by prohibiting the sale of electronic medical records or PHI obtained from electronic medical records. Covered entities and business associates are prohibited from selling a person's electronic medical record or PHI without authorization from the person unless it is necessary for treatment or to receive payment for the treatment of the person.

(f) Access to certain information in electronic format.—

Subsection (f) gives a patient the right to receive the patient's medical information in an electronic format without charge if a provider maintains the patient's medical record in an electronic format.

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

Section 313 clarifies the definition of marketing under HIPAA to include receiving direct or indirect payment to make the communication, and it precludes covered entities from marketing to patients unless the patient authorizes the communication pursuant to the HIPAA Privacy Rule authorization requirements.

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

Section 314 requires the Secretary, in consultation with the Federal Trade Commission (FTC), to submit recommendations to Con-

gress to identify requirements relating to security, privacy, and notification in the case of a breach that should be applied to vendors of personal health records. The recommendations would include which Federal agency is best equipped to enforce such requirements.

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

Section 315 requires that each vendor of personal health records, following the discovery of a breach of an individual's unsecured personal health record (PHR) identifiable health information, notify the individual and the FTC. The provision requires that any third party service provider that provides services to a vendor of PHRs or others, notify such vendor or entity of such breach. The provision requires that the notification requirements applicable to covered entities under section 302 of the bill be applied to notifications required under this section and that FTC notify HHS of breach notices received by FTC. The provision gives the FTC enforcement authority regarding breaches of health information under this section. The provision sunsets two years after enactment of the bill.

The term "unsecured PHR identifiable health information" is information that is not protected through the use of a technology or methodology specified by the Secretary in the guidance issued under section 302(h)(2). If the Secretary fails to issue this guidance within 60 days, unsecured PHR identifiable health information shall mean information that is not protected by technology standards developed or endorsed by a standards developing organization that is accredited by the American National Standards Institute.

Section 316. Business associate contracts required for certain entities

Section 316 requires organizations such as Health Information Exchanges, Regional Health Information Organizations, or E-prescribing Gateways to have business associate contracts.

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

Section 317 requires the Secretary, in consultation with stakeholders, to issue guidance on how to best implement regulatory requirements for the de-identification of PHI.

Section 318. GAO report on treatment disclosures

Section 318 directs the Government Accountability Office to submit a report to Congress on best practices related to the disclosure of PHI among health care providers for the purposes of treatment.

Section 319. Clarification of application of wrongful disclosures criminal penalties

Section 319 clarifies that criminal penalties for violations of HIPAA can be applied directly to individuals. Currently, the Department of Justice has interpreted the law as not permitting criminal enforcement against an individual working within an entity, only against the entity itself. This section permits the Depart-

ment of Justice to prosecute the bad actor whether acting on his or her own or while working within an entity.

Section 320. Improved enforcement

Section 320 amends section 1176 of the Social Security Act to require a formal investigation of complaints and the imposition of civil monetary penalties for violations that rise to the level of willful neglect. This provision still preserves current tools for informal resolution, technical assistance, and correction within 30 days without the imposition of a penalty in situations where the violation was due to a reasonable cause.

In addition, the amendments to section 1176 permit the Department of Health and Human Services to pursue an investigation and impose civil monetary penalties against a person under section 1176 as long as a criminal penalty has not been imposed under section 1177 for that same act of the person. The amendments do not affect section 1176(b)(2), relating to acts that are not knowing violations.

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

Section 321. Relationship to other laws

Section 321 applies the preemption in section 1178 of the Social Security Act to the provisions of title III of the bill and preserves the HIPAA and the regulations promulgated pursuant to that Act to the extent that they are consistent with title III of the bill.

Section 322. Regulatory references

Section 322 clarifies that each reference in this title to a provision of the Code of Federal Regulations refers to such provision as in effect on the date of the enactment of this Act (or to the most recent update of such provision).

Section 323. Effective date

With the exception of certain specified provisions, section 323 provides that the bill shall become effective 12 months after the date of enactment.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE XXX—HEALTH INFORMATION TECHNOLOGY AND QUALITY

SEC. 3000. DEFINITIONS.

In this title:

(1) 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.

(2) HEALTH CARE PROVIDER.—The term "health care provider" means a hospital, skilled nursing facility, nursing facility, home health entity, health care clinic, Federally qualified health center, group practice (as defined in section 1877(h)(4) of the Social Security Act), 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, and any other category of facility or clinician determined appropriate by the Secretary.

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

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

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

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

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

(8) 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.

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

(10) 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).

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

(12) 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, 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) ensures that appropriate information to help guide medical decisions is available 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 reporting 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 prevention 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 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). The Coordinator shall make such determination, and report to the Secretary such determination, not later than 90 days after the date the recommendation is received by the Coordinator.

(2) HIT POLICY COORDINATION.—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.

(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), maintain and update a strategic plan with specific objectives, milestones, and metrics for 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, and in improving the continuity of care among health care settings.

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

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

(D) PUBLICATION.—The National Coordinator shall publish 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 that includes the following:

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

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

(C) Recommendations of the HIT Standards Committee under section 3003.

(D) Sources of Federal grant funds and technical assistance that are available to facilitate the purchase of, or enhance the utilization of, health information technology systems.

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

(F) The assessment by the National Coordinator under paragraph (6).

(G) The evaluation by the National Coordinator under paragraph (7).

(H) The annual estimate of resources required under paragraph (8).

(5) 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 systems, including information on whether the systems and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(6) 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 that serve 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.

(7) 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.

(8) 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 the required level of Federal funding, expectations for regional, State, and private investment, and the expected contributions by volunteers to activities for the utilization of such records.

(9) CERTIFICATION.—

(A) IN GENERAL.—The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall develop a program (either directly or by contract) for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle. Such program shall include testing of the technology in ac-

cordance with section 201(b) of the PRO(TECH)T Act of 2008.

(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.

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

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.—Not later than 1 year after the date of the enactment of this title, 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). Annually thereafter 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(b) and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and 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, including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information, in accordance with applicable law, and for the use and disclosure of limited data sets (as defined for purposes of regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996) of such information.

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

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

(iv) Technologies that 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).

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

(A) Established governance rules.

(B) A business plan.

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

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

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

(c) MEMBERSHIP.—

(1) APPOINTMENTS.—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) 11 members shall be appointed by the Comptroller General of the United States of whom—

(i) 1 member shall be an advocate 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 privacy and security;

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

(vi) 1 member shall be from the health 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.

(2) NATIONAL COORDINATOR.—The National Coordinator shall be a member of the HIT Policy Committee and act as a liaison among the HIT Policy Committee, the HIT Standards Committee, and the Federal Government.

(3) CHAIRPERSON AND VICE CHAIRPERSON.—The HIT Policy Committee shall designate 1 member to serve as the chairperson and 1 member to serve as the vice chairperson of the HIT Policy Committee.

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

(5) TERMS.—

(A) IN GENERAL.—The terms of members of the HIT Policy Committee appointed under paragraph (1) shall be 3 years except that the Comptroller General of the United States shall designate staggered terms for the members first appointed under paragraph (1)(G).

(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.

(6) OUTSIDE INVOLVEMENT.—The HIT Policy Committee shall ensure an adequate 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.

(7) QUORUM.—Ten members of the HIT Policy Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.

(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(b), consistent with the implementation of the strategic plan described in section 3001(c)(3).

(b) DUTIES.—

(1) STANDARD DEVELOPMENT.—

(A) IN GENERAL.—Beginning not later than 1 year after the date of the enactment of this title, 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 Committee. Annually thereafter the Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(b)(2). Such recommendations shall be consistent with the latest recommendations made by the HIT Policy Committee.

(B) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications, the HIT Standards Committee, as appropriate, shall provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 201 of the PRO(TECH)T Act of 2008.

(C) 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) WEBSITE.—The HIT Standards Committee shall develop and maintain an Internet website on which there is posted information that includes the following:

(A) Established governance rules.

(B) A business plan.

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

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

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

(6) REQUIREMENT TO INTEGRATE RECOMMENDATIONS.—In carrying out the activities under this section, the HIT Standards Committee shall integrate the recommendations of the HIT Policy Committee.

(c) MEMBERSHIP.—

(1) APPOINTMENTS.—The HIT Standards Committee shall be composed of members to be appointed as follows:

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

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

(i) 1 member shall be a representative of consumer or patient organizations;

(ii) 1 member shall be a representative of organizations with expertise in privacy;

(iii) 1 member shall be a representative of organizations with expertise in security;

(iv) 2 members shall be a representative of health care providers, one of which shall be a physician;

(v) 1 member shall be a representative of health plans or other third party payers;

(vi) 1 member shall be a representative of information technology vendors;

(vii) 1 member shall be a representative of purchasers or employers; and

(viii) 1 member shall be a representative of the health research community.

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

(2) NATIONAL COORDINATOR.—The National Coordinator shall be a member of the HIT Standards Committee and act as a liaison among the HIT Standards Committee, the HIT Policy Committee, and the Federal government.

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

(4) PARTICIPATION.—The members of the HIT Standards Committee appointed under paragraph (1) shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee.

(5) TERMS.—

(A) IN GENERAL.—The terms of members of the HIT Standards Committee appointed under paragraph (1) shall be 3 years except that the Comptroller General of the

United States shall designate staggered terms for the members first appointed under paragraph (1)(F).

(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Standards 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 Standards Committee shall be filled in the manner in which the original appointment was made.

(6) OUTSIDE INVOLVEMENT.—The HIT Standards Committee shall ensure an adequate 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.

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

(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.

(a) REVIEW OF ENDORSED STANDARDS, SPECIFICATIONS, AND 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, specifications, or criteria and shall determine whether or not to propose adoption of such standards, specifications, or criteria.

(b) DETERMINATION TO ADOPT STANDARDS, SPECIFICATIONS, AND CRITERIA.—If the Secretary determines—

(1) to propose adoption of any grouping of such standards, specifications, or criteria, the Secretary shall, through a rulemaking process, determine whether or not to adopt such grouping of standards, specifications, or criteria; or

(2) not to propose adoption of any grouping of standards, specifications, or 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.

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

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(b), see section 111 of the PRO(TECH)T Act of 2008.

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

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

(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(b) with respect to activities not related to the contract.

SEC. 3007. HEALTH INFORMATION TECHNOLOGY RESOURCE CENTER.

(a) DEVELOPMENT.—

(1) IN GENERAL.—The National Coordinator shall develop a Health Information Technology Resource Center to provide technical assistance and develop best practices to support and accelerate efforts to adopt, implement, and effectively use 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(b).

(2) PURPOSES.—The purpose of the Center is 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;

(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;

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

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

(H) provide technical assistance to promote adoption and utilization of health information technology by health care

providers, including in medically underserved communities.

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

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

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

(3) learn about regional and local health information networks for assistance with health information technology; and

(4) disseminate additional information determined by the National Coordinator.

Subtitle B—Incentives for the Use of Health Information Technology

SEC. 3011. GRANTS AND LOANS TO FACILITATE THE WIDESPREAD ADOPTION OF QUALIFIED HEALTH INFORMATION TECHNOLOGY.

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

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

(2) QUALIFIED HEALTH INFORMATION TECHNOLOGY.—For purposes of this section, the term "qualified health information technology" means health information technology that consists of hardware, software, or the provision of support services and that—

(A) enables the protection of health information, in accordance with applicable law;

(B) is (or is necessary for the operation of) an electronic health records system, including the provision of decision support and physician order entry for medications;

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

(D) is certified under the program developed under section 3001(c)(9) to be in compliance with any applicable standards and implementation specifications adopted under section 3004(b).

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

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

(i) a plan on how the entity intends to maintain and support the qualified health information technology that would be purchased with amounts under such grant, including the type of resources expected to be involved; and

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

(B) submit to the National Coordinator a plan for how qualified health information technology purchased by the entity will result in the electronic exchange and use of health information;

(C) be—

(i) a not for profit hospital or a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act);

(ii) an individual or group practice; or

(iii) another health care provider, such as a rural health clinic, not described in clause (i) or (ii);

(D) demonstrate significant financial need;

(E) agree to notify individuals in accordance with section 302 of the PRO(TECH)T Act of 2008 (relating to notifications in the case of breaches);

(F) provide matching funds in accordance with paragraph (5);

(G) consult with the Health Information Technology Resource Center established under section 3007 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology; and

(H) link, to the extent practicable, to one or more local or regional health information plans.

(4) USE OF FUNDS.—Amounts received under a grant under this subsection shall be used to facilitate the purchase of qualified health information technology.

(5) MATCHING REQUIREMENT.—To be eligible for a grant under this subsection an entity shall contribute non-Federal contributions to the costs of carrying out the activities for which the grant is awarded in an amount equal to $1 for each $3 of Federal funds provided under the grant.

(6) PREFERENCE IN AWARDING GRANTS.—In awarding grants under this subsection the National Coordinator shall give preference to the following eligible entities:

(A) Small health care providers.

(B) 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).

(C) Nonprofit health care providers.

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

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

(B) Grants or funding available through the Agency for Healthcare Research and Quality.

(C) Grants or funding that may be available through the Health Resources and Services Administration for investment in health information technologies or telehealth.

(D) Grants or funding that may be available through the Department of Agriculture's Rural Development Telecommunications Program for investment in telemedicine.

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

(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities for the establishment of programs for loans to health care providers to purchase qualified health information technology.

(2) 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—

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

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

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

(D) 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 meets each of the conditions described in paragraph (5); and

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

(3) ESTABLISHMENT OF FUND.—For purposes of paragraph (2)(C), an eligible entity shall establish a qualified health information 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 subsection shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this subtitle to be used for other purposes specified in this subtitle shall be deposited in any Loan Fund.

(4) STRATEGIC PLAN.—

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

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

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

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

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

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

(5) HEALTH CARE PROVIDER CONDITIONS FOR RECEIPT OF LOANS.—For purposes of paragraph (2)(D), the conditions described in this paragraph, with respect to a health care provider that seeks a loan from a Loan Fund established under this subsection, are the following:

(A) The health care provider links, to the extent practicable, to one or more local or regional health information networks.

(B) The health care provider consults with the Health Information Technology Resource Center established under section 3007 to access the knowledge and experience of existing initiatives regarding the successful implementation and effective use of health information technology.

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

(D) The health care provider submits to the State or Indian tribe involved a plan on how the health care provider intends to maintain and support the qualified health information 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.

(6) USE OF FUNDS.—

(A) IN GENERAL.—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 paragraph (8)(D)(i), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under paragraph (1). Loans under this section may be used by a health care provider to purchase qualified health information technology.

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

(i) for the purchase or other acquisition of any health information technology system that is not a qualified health information technology; or

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

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

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

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

(ii) 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.

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

(B) 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.

(C) 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.

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

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

(8) ADMINISTRATION OF LOAN FUNDS.—

(A) 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.

(B) 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 subsection 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.

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

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

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

(D) PRIVATE SECTOR CONTRIBUTIONS.—

(i) IN GENERAL.—A Loan Fund established under this subsection 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.

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

(9) MATCHING REQUIREMENTS.—

(A) IN GENERAL.—The National Coordinator may not make a grant under paragraph (1) 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 $1 of Federal funds provided under the grant.

(B) 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.

(10) REPORTS.—The National Coordinator shall annually 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 summarizing the reports received by the National Coordinator from each eligible entity that receives a grant under this subsection.

(c) COMPETITIVE GRANTS FOR THE IMPLEMENTATION OF REGIONAL OR LOCAL HEALTH INFORMATION TECHNOLOGY PLANS.—

(1) IN GENERAL.—The National Coordinator may award competitive grants to eligible entities to implement regional or local health information plans to improve health care quality and efficiency through the electronic exchange and use of health information.

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

(A) facilitate the electronic exchange and use of health information within the local or regional area and among local and regional areas;

(B) demonstrate financial need to the National Coordinator;

(C) demonstrate that one of its principal missions or purposes is to use information technology to improve health care quality and efficiency;

(D) adopt bylaws, memoranda of understanding, or other charter documents that demonstrate that the governance structure and decisionmaking processes of such entity allow for participation on an ongoing basis by multiple stakeholders within a community, including—

(i) physicians (as defined in section 1861(r) of the Social Security Act), including physicians that provide services to low income populations and populations that are uninsured, underinsured, and medically underserved (including such populations in urban and rural areas);

(ii) hospitals (including hospitals that provide services to low income and underserved populations);

(iii) pharmacists and pharmacies;

(iv) health plans;

(v) health centers (as defined in section 330(b)) and Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act);

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

(vii) patient or consumer organizations that reflect the population to be served;

(viii) employers;

(ix) public health agencies; and

(x) such other health care providers or other entities, as determined appropriate by the National Coordinator;

(E) demonstrate the participation, to the extent practicable, of stakeholders in the electronic exchange and use of health information within the local or regional health information plan pursuant to subparagraph (D);

(F) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation in the regional or local health information plan by all stakeholders;

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

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

(I) agree to provide matching funds in accordance with paragraph (6).

(3) APPLICATION.—

(A) IN GENERAL.—To be eligible to receive a grant under paragraph (1), an entity shall submit to the National Coordinator an application at such time, in such manner, and containing such information (in addition to information required under subparagraph (B)), as the National Coordinator may require.

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

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

(ii) an estimate of costs of the hardware, software, training, and other services necessary to implement the regional or local health information plan;

(iii) a strategy that includes initiatives to improve health care quality and efficiency;

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

(v) a plan to ensure the privacy and security of individually identifiable health information that is consistent with applicable Federal and State law;

(vi) a governance plan that defines the manner in which the stakeholders shall jointly make policy and operational decisions on an ongoing basis;

(vii) a financial or business plan that describes—

(I) the sustainability of the plan;

(II) the financial costs and benefits of the plan; and

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

(viii) a plan on how the entity involved intends to maintain and support the regional or local health information plan, including the type of resources expected to be involved; and

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

(4) USE OF FUNDS.—Amounts received under a grant under paragraph (1) shall be used to establish and implement a regional or local health information plan in accordance with this subsection.

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

(6) MATCHING REQUIREMENT.—

(A) IN GENERAL.—The National Coordinator may not make a grant under this subsection to an entity unless the entity agrees that, with respect to the costs of carrying out the activities for which the grant is awarded, the entity will make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount equal to not less than 50 percent of such costs ($1 for each $2 of Federal funds provided under the grant).

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required under subparagraph (A) may be in cash or in kind, fairly evaluated, including equipment, technology, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(d) REPORTS.—Not later than 1 year after the date on which the first grant is awarded under this section, and annually thereafter during the grant period, an entity that receives a grant under this section shall submit to the National Coordinator a report on the activities carried out under the grant involved. Each such report shall include—

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

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

(3) a description of any reduction in duplicative or unnecessary care as a result of the project involved;

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

(5) an analysis of the effectiveness of the project involved on ensuring the privacy and security of individually identifiable health information in accordance with applicable Federal and State law; and

(6) other information as required by the National Coordinator.

(e) REQUIREMENT TO IMPROVE QUALITY OF CARE AND DECREASE IN COSTS.—The National Coordinator shall annually evaluate the activities conducted under this section 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 quality of care and decrease in costs.

(f) LIMITATION.—An eligible entity may only receive one non-renewable grant under subsection (a), one non-renewable grant under subsection (b), and one non-renewable grant under subsection (c).

(g) SMALL HEALTH CARE PROVIDER.—For purposes of this section, the term "small health care provider" means a health care provider that has an average of 10 or fewer full-time equivalent employees during the period involved.

(h) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out subsections (a) through (d), there is authorized to be appropriated $115,000,000 for each of the fiscal years 2009 through 2013.

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

SEC. 3012. 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 qualified health information 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 qualified health information technology in the clinical education of health professionals to reduce medical errors 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 qualified health information 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 qualified health information 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) MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may award a grant to an entity under this section only if the entity agrees to make available non-Federal contributions toward the costs of the program to be funded under the grant in an amount that is not less than $1 for each $2 of Federal funds provided under the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(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).

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

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

SOCIAL SECURITY ACT

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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PART C—ADMINISTRATIVE SIMPLIFICATION

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GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

SEC. 1176. (a) * * *

(b) LIMITATIONS.—

(1) OFFENSES OTHERWISE PUNISHABLE.—A penalty may not be imposed under subsection (a) with respect to an act if [the act constitutes an offense punishable under section 1177] *a penalty has been imposed under section 1177 with respect to such act*.

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(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.

(3) REGULATIONS.—Not later than 180 days after the date of the enactment of the PRO(TECH)T Act of 2008, the Secretary shall promulgate regulations to implement this subsection.

WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

SEC. 1177. (a) OFFENSE.—A person who knowingly and in violation of this part—

(1) * * *

* * * * * * *

shall be punished as provided in subsection (b). *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.*

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DISSENTING VIEWS

The future of health care reform in the United States depends greatly on the widespread adoption of health information technology. Replacing paper-based records with secure electronic systems will save billions in taxpayer dollars through greater efficiencies, and more importantly, will prevent thousands of deaths each year by virtually eliminating medical errors. We are pleased that the Committee continues to work toward a common goal: ensuring that health information technology can be implemented by providers with effective guidelines to protect patient privacy and information security.

Clearly, the federal government can play a critical role in advancing health information technology by moving forward on the standard setting process and incentivizing adoption. For example, the American Health Information Community (AHIC), a federal advisory body created in 2005, has already made significant progress toward these goals by making recommendations to the Secretary of the Department of Health and Human Services (HHS) on how to accelerate the development and adoption of health information technology. AHIC has provided input to HHS on key issues including how to make health records digital and interoperable, and how to ensure that the privacy and security of those records are protected.

We applaud the Committee for its efforts to pass legislation to encourage the widespread adoption of health IT. Specifically, we share the goals outlined in H.R. 6357, including codifying the Office of the National Coordinator for Health Information Technology, strengthening the federal standard-setting process, and incentivizing providers to use health IT. These elements of H.R. 6357 serve as a critical first step.

We are concerned, however, that H.R. 6357 in its current form could obstruct these objectives. The goal of health IT legislation should be to create incentives for the adoption of new technologies, not to discourage their use. We believe several of the privacy and security provisions contained in Title III of H.R. 6357 are unnecessary, duplicative of existing Health Insurance Portability and Accountability Act (HIPAA) regulations, and could potentially discourage providers from investing in health IT.

Section 312(d) of H.R. 6357 requires covered entities to obtain the consent of an individual before using or disclosing that individual's protected health information, which is maintained in an electronic medical record, for the purposes of health care operations. As defined in 45 CFR 164.501, "health care operations" include many basic functions of health care providers that are integral to ensuring appropriate payment, preventing fraud and abuse, and ensuring quality of care.

We believe there could be adverse health consequences in requiring health care providers to obtain prior consent from individuals to perform basic health care functions. In addition, allowing patient consent for the use and disclosure of protected health information to be revocable at any time will likely inject uncertainty and confusion into critical health functions like physician training, care coordination, and public health research. In many cases, because treatment and operations functions are intertwined, this new requirement may force health care providers to obtain consent from patients even for just providing treatment. Requiring prior patient consent would impose significant burdens on providers, while providing little to no privacy benefit to patients.

Furthermore, we believe that existing HIPAA rules strike the appropriate balance between protecting patient privacy and ensuring that critical medical information is available to providers for treatment and vital medical research purposes, especially given the scrutiny that both rules received during the rulemaking process. The initial HIPPA privacy regulations were the subject of over 50,000 comments and years of careful consideration. As part of this balanced process, the Privacy Rule permitted individuals to request restrictions on the uses and disclosures of their information for all purposes, but did not explicitly require providers to obtain consent before carrying out critical health care functions.

We support maintaining the existing HIPAA framework as we look for ways to expand privacy and security provisions related to entities that have emerged since the drafting of these rules. We support provisions in H.R. 6357 aimed at exploring what types of rules may be appropriate for these entities, including vendors of personal health records. We also support efforts to ensure existing HIPAA privacy rules are being enforced in an appropriate manner.

Section 312(c) of H.R. 6357 requires health care providers (covered entities) to afford individuals an accounting of protected health information used or maintained in an electronic medical record that was disclosed to carry out treatment, payment or health care operations. 45 CFR 164.528 currently exempts from this "accounting of disclosures" provision all disclosures made to carry out treatment, payment or health care operations, as such disclosures are routine. As routine disclosures, a patient would be notified about these disclosures by the covered entity's Notice of Privacy Practices. Consequently, we believe this provision is unnecessary.

We are also concerned that this accounting requirement could overwhelm patients with unhelpful information and will adversely affect providers' ability to provide patients with safe, efficient health care services. For example, most health care providers make countless disclosures every day in order to process claims for payment and provide health services. Most IT systems in a doctor's office, hospital, or pharmacy have not been designed to comply with this type of requirement for the millions of routine transactions that would be required to be recorded and stored for a minimum of three years.

Section 302 of H.R. 6357 requires a covered entity, in the case of a breach of protected health information, to notify each individual whose unsecured protected health information has been, or

reasonably believed by the covered entity to have been accessed, acquired, or disclosed. H.R. 6357 defines "breach" as the unauthorized acquisition, access or disclosure of protected health information which compromises the security, privacy or integrity of protected health information maintained by or on behalf of a person.

We support breach notification requirements as a potential tool to keep patients informed, and ensure provider compliance with privacy rules. However, we believe that the definition of "breach" should be more clearly defined, and based upon risk to the individual. Instead of a blanket notification requirement, it would be more useful if patients were notified in instances where there is a substantial likelihood of identity theft or medical harm. Similarly, unintentional, inconsequential breaches should not be included in the notification requirement. A risk-based definition for breach notification would set an objective standard that would guide covered entities and health care providers about when a breach occurred, and would provide clear guidance to patients as to why they are receiving such notification.

To be clear, we do support changes the Committee made to Title III of H.R. 6357 after the Subcommittee on Health markup, including requiring the consent provision to go through a transparent rulemaking process, creating exceptions for protected data and "good faith" disclosures in breach notification requirements, and requiring the Secretary to certify a technology that can handle the accounting of disclosures requirement.

However, we believe that adoption of the new requirements contained in Title III, which would be in addition to existing HIPAA rules, would create numerous disincentives for providers to adopt health IT, and add little benefit to patient privacy or information security. Instead of creating a new regulatory regime, we believe this Committee should focus on protecting patient privacy by strengthening existing HIPAA rules and protecting data security by incentivizing the adoption of new technologies.

Right now, doctors and hospitals find it hard to justify the cost of installing health IT into their practices. At the same time, health IT innovators are waiting at the gate to provide new technology to providers and patients alike. Tools like secure electronic medical records and e-prescribing software all promise to dramatically improve how our health care system is administered. But these innovators are also holding back investment because standards for interoperability still do not exist. If the federal government continues to delay the process of setting interoperability standards, we may miss an important opportunity to advance the widespread adoption of health IT. Likewise, if health care providers are burdened with a new set of privacy rules that provide little benefit to their patients, they may never be able to, or see the need to, invest in health IT systems.

MIKE ROGERS.
STEVE BUYER.

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