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109TH CONGRESS
2D SESSION

H. R. 4832

To amend the Social Security Act to establish an Office of Health Information Technology for the purpose of creating a national interoperable health information infrastructure, to provide loans to health care entities seeking to implement such infrastructure, and to provide exceptions to certain health anti-kickback laws to encourage the dissemination of health information technology.

IN THE HOUSE OF REPRESENTATIVES

MARCH 1, 2006

Mr. CLAY (for himself and Mr. PORTER) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Social Security Act to establish an Office of Health Information Technology for the purpose of creating a national interoperable health information infrastructure, to provide loans to health care entities seeking to implement such infrastructure, and to provide exceptions to certain health anti-kickback laws to encourage the dissemination of health information technology.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Electronic Health Information Technology Act of 2006''.

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

SEC. 2. OFFICE OF HEALTH INFORMATION TECHNOLOGY AND STANDARDS DEVELOPMENT.

(a) IN GENERAL.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new section:

''HEALTH INFORMATION TECHNOLOGY

''SEC. 1150A. (a) OFFICE OF HEALTH INFORMATION TECHNOLOGY.—

''(1) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of Health Information Technology (referred to in this section as the 'Office') that shall be headed by the Chief Health Informatics Officer of Health Information Technology (referred to in this section as the 'Chief Health Informatics Officer'). The Chief Health Informatics Officer shall be appointed by the Secretary and shall report directly to the Secretary. The Chief Health Informatics Officer

shall be paid at a rate equal to the rate of basic pay for level IV of the Executive Schedule.

''(2) OBJECTIVES OF OFFICE.—In fulfilling the duties under paragraph (3), the work of the Chief Health Informatics Officer shall be consistent with the following objectives:

''(A) CONVENIENT AVAILABILITY OF HEALTH INFORMATION.—Ensuring that appropriate information to guide medical decisions is available on the date on which and at the location in which health care is provided to an individual.

''(B) IMPROVED HEALTH CARE.—

''(i) Improving health care quality.

''(ii) Advancing the delivery of appropriate evidence-based health care.

''(iii) Reducing the occurrence of medical errors, inefficiency, inappropriate health care, and incomplete information.

''(iv) Reducing health costs that result from the occurrences referred to in clause (iii).

''(C) PROMOTION OF EFFECTIVE HEALTH CARE MARKETPLACE.—Promoting an effective marketplace for health care consumption, great-

er competition, and increased choice through the wider availability of accurate information about the costs, quality, and outcomes (based on measurable public health improvements) of health care.

''(D) IMPROVED COORDINATION OF HEALTH CARE INFORMATION.—Improving the coordination of health information among hospitals, laboratories, physician offices, and ambulatory care providers through an effective infrastructure for the secure and authorized exchange of health information.

''(E) SECURE AND PROTECTED HEALTH INFORMATION.—Ensuring that the individually identifiable health information (as defined in section 1171(6)) of an individual is secure and protected.

''(3) DUTIES OF CHIEF HEALTH INFORMATICS OFFICER.—The Chief Health Informatics Officer shall perform the following duties:

''(A) DEVELOPMENT, IMPLEMENTATION, AND MODIFICATION OF UNIFORM HIT STANDARDS.—Develop, implement, and modify HIT standards, in accordance with subsections (c), (d), and (e), respectively.

"(B) DEVELOPMENT, MAINTENANCE, AND IMPLEMENTATION OF INTEROPERABLE HIT STRATEGIC PLAN.—Develop, maintain, and direct the implementation of an interoperable HIT strategic plan (described in paragraph (4)) to guide the nationwide implementation of interoperable health information technology in the public and private health care sectors.

"(C) PRINCIPAL ADVISOR TO SECRETARY.—Serve as the principal advisor to the Secretary on the development and use of health information technology.

"(D) DIRECTOR OF HHS HEALTH INFORMATION TECHNOLOGY PROGRAMS.—Direct any programs related to health information technology that are conducted by the Secretary.

"(E) COORDINATOR OF FEDERAL HEALTH INFORMATION POLICY AND ACTIVITIES.—Coordinate health information technology policies of the Department of Health and Human Services and activities related to the transmission, integrity, and security of health information conducted by the Secretary with such policies and activities of Federal agencies to avoid duplication of effort and to ensure that each such

agency performs activities within the area of the greatest expertise and technical capability of such agency.

''(F) COORDINATOR OF OUTREACH AND CONSULTATION.—Coordinate programs of Federal agencies that are related to health information technology outreach and consultation by such agencies with public and private entities, including consumers, providers, payers, and administrators.

''(G) COORDINATOR FOR PLANS FOR PRIVATE SECTOR HEALTH INFORMATION TECHNOLOGY.—Coordinate plans for Federal efforts to develop and implement interoperable HIT standards for private sector physicians and other health professionals who use electronic health records, electronic prescribing systems, evidence-based clinical support tools, patient registries, or other health information technology.

''(H) ADVISOR TO OMB.—Provide to the Director of the Office of Management and Budget comments and advice with respect to specific health information technology programs.

''(I) ADMINISTRATOR OF GRANTS PROGRAM.—Administer the HIT standards grants program under subsection (j).

''(4) INTEROPERABLE HIT STRATEGIC PLAN.—

''(A) DESCRIPTION.—For purposes of paragraph (3)(B), an interoperable HIT strategic plan is a plan that is consistent with the following:

''(i) ADVANCEMENT OF HIT STANDARDS.—Advances the development and national implementation of HIT standards through the collaboration of public and private interests, and consistent with efforts in existence before the date of the enactment of this section.

''(ii) ACKNOWLEDGEMENT OF CERTAIN ISSUES INVOLVED IN ADOPTION OF STANDARDS.—Ensures that the main technical, scientific, economic, and other issues affecting the adoption of HIT standards (in the public and private sectors) are addressed.

''(iii) EVALUATION OF BENEFITS AND COSTS OF INTEROPERABLE HEALTH INFORMATION TECHNOLOGY.—Evaluates the

benefits and costs of interoperable health information technology and identifies the persons affected by such benefits and costs.

''(iv) ACKNOWLEDGEMENT OF PRIVACY AND SECURITY ISSUES.—Addresses the issues of privacy and security related to interoperable health information technology and recommends methods to ensure appropriate authorization, authentication, and encryption of data transmission over the Internet.

''(v) SELF-SUFFICIENT PLAN.—Does not assume or depend upon Federal resources or spending that is in addition to resources and spending authorized under the Electronic Health Information Technology Act of 2006 to accomplish the adoption of HIT standards and an interoperable health information technology infrastructure.

''(vi) MEASURABLE OUTCOME GOALS.—Includes measurable outcome goals, such as for determining error reductions in patient care and economic benefits

derived from the use of interoperable health information technology.

''(B) REPORTS.—Not later than 180 days after the date of the appointment of the Chief Health Informatics Officer, and periodically thereafter, the Chief Health Informatics Officer shall submit to the Secretary a report on the progress of the development and implementation of the interoperable HIT strategic plan.

''(b) LIMITATION ON USE OF FEDERAL FUNDS TO PURCHASE HEALTH INFORMATION TECHNOLOGY PRODUCTS.—

''(1) IN GENERAL.—Effective as provided in paragraphs (1)(B) and (2)(C) of subsection (d), no Federal funds (including grants provided under subsection (j)) may be used for the purchase (or update) of a health information technology product unless the product (or update) is certified by the entity selected under paragraph (2) as complying with HIT standards in effect on the date of certification.

''(2) SELECTION OF CERTIFICATION ENTITY.—For purposes of paragraph (1) and subject to paragraph (3), the Secretary shall enter into a contract with an entity to certify that a health information technology product (or update) meets HIT stand-

ards implemented under subsection (d). For purposes of the preceding sentence, the Secretary may enter into a contract with a private entity, including the Certification Commission for Healthcare Information Technology.

''(3) CONTRACTING EXCEPTION.—For purposes of paragraph (2) and subsection (c)(3), the Secretary may enter into a contract with the Certification Commission for Healthcare Information Technology for purposes of such paragraph or such subsection, but not for both.

''(c) DEVELOPMENT OF HIT STANDARDS.—

''(1) REQUIREMENTS.—The Chief Health Informatics Officer shall provide for the development of HIT standards. Such standards shall comply with the following:

''(A) INTEROPERABILITY.—The standards shall provide for interoperability among health information systems.

''(B) APPLICATION TO ELECTRONIC TRANSACTIONS AND TRANSMISSIONS.—The standards shall apply to electronic transactions and transmissions of health information, to the content of such transactions and transmissions, and to the data elements of such transactions

and transmissions, including standards for security and coding of electronic health information created for the purpose of establishing an interoperable health information infrastructure.

''(C) PROPRIETARY NEUTRALITY.—The standards shall not restrict, sponsor, promote, or prejudice in any other way the certification of health information technology products according to brand, product line, or vendor.

''(D) PATIENT SAFETY AND QUALITY OF CARE.—The standards shall be consistent with the objectives of improving patient safety and the quality of care provided to patients.

''(E) NO UNDUE BURDEN.—The standards shall not, to the extent practicable, impose an undue administrative or financial burden on the practice of medicine, or any other health care profession, particularly on small physician practices and practices located in rural areas.

''(F) COMPATIBILITY WITH HIPAA PRIVACY LAWS.—The standards shall be consistent with the standards under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) (con-

cerning the privacy of individually identifiable health information).

''(2) ACCESS RESTRICTION STANDARDS.—The Chief Health Informatics Officer shall establish standards to restrict access of public and private entities to health information transferred, used, or stored by health information technology.

''(3) CONTRACTING AUTHORITY.—Subject to subsection (b)(3), the Chief Health Informatics Officer may enter into a contract with the Certification Commission for Healthcare Information Technology, or any other appropriate certification entity, to develop HIT standards, access restriction standards described in paragraph (2), or both.

''(4) HIT STANDARDS DEFINED.—For purposes of this section, the term 'HIT standards' means standards related to the transmission, integrity, and security of health information.

''(d) IMPLEMENTATION OF HIT STANDARDS.—

''(1) CONSOLIDATED HEALTH INFORMATICS COUNCIL STANDARDS IN EXISTENCE BEFORE DATE OF ENACTMENT.—

''(A) IN GENERAL.—Not later than one year after the date of the enactment of this section, the Chief Health Informatics Officer shall

implement all standards that were developed, implemented, or modified by the Consolidated Health Informatics Council before such date of enactment.

''(B) EFFECTIVE DATES.—

''(i) FEDERAL AGENCIES.—For purposes of subsection (b) and not later than the date that is 30 days after the date on which HIT standards are implemented under subparagraph (A), such standards shall apply to a Federal agency.

''(ii) NON-FEDERAL AGENCIES.—For purposes of subsection (b) and not later than 18 months after the date of the enactment of the Electronic Health Information Technology Act of 2006, the HIT standards implemented under subparagraph (A) shall apply to an entity that is not a Federal agency.

''(2) STANDARDS DEVELOPED AFTER DATE OF ENACTMENT.—

''(A) IN GENERAL.—The Chief Health Informatics Officer shall implement, in accordance with subparagraph (B), each HIT standard developed under subsection (c) or modified

under subsection (e) unless the Chief Health Informatics Officer determines that the standard would not be effective in promoting an interoperable health information technology infrastructure.

''(B) REGULATIONS.—For purposes of subparagraph (A), the Secretary shall establish guidelines for determining if a standard would not be effective in promoting an interoperable health information technology infrastructure and for specifying dates by which the Chief Health Informatics Officer is required to make a determination under such subparagraph before standards developed under subsection (c) or modified under subsection (e) shall be implemented.

''(C) EFFECTIVE DATES.—

''(i) FEDERAL AGENCIES.—For purposes of subsection (b) and not later than 18 months after the date on which a HIT standard is implemented under subparagraph (A), such standard shall apply to a Federal agency.

''(ii) NON-FEDERAL AGENCIES.—For purposes of subsection (b) and not later

than 24 months after the date on which a HIT standard is implemented under subparagraph (A), such standard shall apply to an entity that is not a Federal agency.

''(3) DOCUMENTATION OF COMPLIANCE.—On the date of the implementation of a HIT standard under this subsection, the Chief Health Informatics Officer shall provide documentation to the Secretary showing that the standard complies with each requirement under subsection (c)(1).

''(e) MODIFICATION OF STANDARDS.—The Chief Health Informatics Officer may modify, according to a procedure established by the Chief Health Informatics Officer, a HIT standard implemented under subsection (d). A standard modified under this subsection shall be implemented in accordance with such subsection.

''(f) AUTHORITY TO WAIVE COMPLIANCE.—

''(1) IN GENERAL.—The Chief Health Informatics Officer may waive the application of HIT standards implemented under subsection (d) for not more than a one-year period, on a case-by-case basis, in unusual or extreme circumstances.

''(2) REPORTS.—Not later than 60 days after the date on which the Chief Health Informatics Officer makes such a waiver, the Chief Health

Informatics Officer shall submit to Congress a report stating the purpose and circumstances justifying the waiver.

''(g) PENALTIES.—

''(1) FEDERAL AGENCIES.—The Director of the Office of Management and Budget shall develop and implement a system to enforce compliance with HIT standards implemented under subsection (d). Such system shall include appropriate budgetary penalties—

''(A) for a Federal agency that is not in compliance with such standards and has not received a waiver under subsection (f)(1); and

''(B) for a Federal agency that has received a waiver under subsection (f)(1) but, starting on a date that is after the date on which the waiver terminates, is not in compliance with such standards.

''(2) NON-FEDERAL ENTITIES.—An entity that is not a Federal agency shall no longer receive Federal funds for purposes of purchasing a health information technology product if—

''(A) such entity is in violation of subsection (b) and has not received a waiver under subsection (f)(1); or

"(B) such entity has received a waiver under subsection (f)(1) but starting on a date that is after the date on which the waiver terminates the entity is not in compliance with HIT standards implemented under subsection (d).

"(h) CONSULTATION AND RECOMMENDATIONS.—For purposes of developing HIT standards under subsection (c) and modifying such standards under subsection (e), the following applies:

"(1) STAKEHOLDER CONSULTATION.—The Chief Health Informatics Officer, in accordance with subchapter II of chapter 5 and chapter 7 of title 5, United States Code (popularly known as the Administrative Procedure Act), shall consult with Federal agencies and private entities that are involved in the transfer or collection of health information, including agencies of the Federal Health Architecture, members of the Consolidated Health Informatics Council, physicians, hospitals, health care delivery systems, health insurance providers, pharmaceutical and biologics manufacturers, medical device manufacturers, information technology vendors, patient groups, private standards-setting organizations, public health interest groups, and other health care pro-

fessionals determined by the Chief Health Informatics Officer necessary to the process of developing and modifying such standards.

''(2) NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS RECOMMENDATIONS.—Not later than the date that is one year after the date of the enactment of this section, and each year thereafter, the National Committee on Vital and Health Statistics shall submit to the Chief Health Informatics Officer recommendations for activities to advance the development and modification of HIT standards.

''(i) TREATMENT OF STATE HIT STANDARDS.—A standard implemented under subsection (d) for application to electronic transfers or transactions described in subsection (c)(1)(B) shall supersede any standard prescribed by a State or local government for a similar application.

''(j) HIT GRANTS PROGRAM.—

''(1) ESTABLISHMENT OF PROGRAM.—In accordance with this subsection and subject to paragraph (3) and subsection (m), the Chief Health Informatics Officer shall award one-year grants to eligible health information technology entities whose applications under paragraph (2) demonstrate a proposal that will benefit an interoperable health infor-

mation technology infrastructure and is consistent with the mission of such an entity.

''(2) APPLICATION.—To be eligible for an award of a grant under this section, an eligible health information technology entity shall submit to the Secretary an application that contains a description of how the applicant proposes to use the grant funds. The application shall be submitted in such form, at such time, and containing such other information as the Chief Health Informatics Officer may require.

''(3) SET-ASIDES FOR DSH QUALIFYING FACILITIES.—

''(A) IN GENERAL.—The Secretary shall use at least 20 percent of the funds authorized under subsection (m) for purposes of this section to award grants under paragraph (1) to eligible health information technology entities, which are DSH qualifying facilities.

''(B) DSH QUALIFYING FACILITY DEFINED.—For purposes of subparagraph (A), the term 'DSH qualifying facility' means any of the following:

''(i) MEDICARE DISPROPORTIONATE SHARE HOSPITAL.—A hospital that quali-

fies for an additional payment under section 1886(d)(4)(F).

''(ii) MEDICAID DISPROPORTIONATE SHARE HOSPITAL.—A hospital that qualifies for an increase in the rate or amount of payment for inpatient hospital services under section 1923(a).

''(iii) PROVIDER SERVING A MEDICALLY UNDERSERVED POPULATION.—A health care provider that serves a medically underserved population, as defined in section 330(a)(3) of the Public Health Service Act.

''(iv) CRITICAL ACCESS HOSPITAL.—A facility designated as a critical access hospital in accordance with section 1820(c)(2).

''(4) PERMISSIBLE USE OF GRANTS.—A grant awarded under paragraph (1) may be used by an eligible health information technology entity only for purposes of the proposal submitted by such entity under paragraph (2).

''(5) EXTENSION OF GRANTS.—Upon the expiration of a grant awarded to an eligible health information technology entity under paragraph (1) and

the request of such entity, the Chief Health Informatics Officer, in accordance with procedures established by the Chief Health Informatics Officer, may extend the duration of the grant once by one year if the Chief Health Informatics Officer determines that the programs established and implemented by such group with the grant resulted in (or are likely to result in) significant progress in benefiting an interoperable health information technology infrastructure.

''(6) DEFINITION OF ELIGIBLE HEALTH INFORMATION TECHNOLOGY ENTITY.—For purposes of this subsection, the term 'eligible health information technology entity' means an entity of a State or local government or a private entity that seeks (and has the capacity) to participate in the research, development, or implementation of HIT standards. Such term includes a health care provider, whether or not the provider participates under title XVIII or XIX, a health insurance issuer, and a group health plan.

''(k) PROGRESS AND COMPLIANCE REPORTS.—

''(1) BIENNIAL PROGRESS REPORTS.—The Chief Health Informatics Officer shall submit to Congress biennial reports on the progress of the development and implementation of HIT standards.

''(2) ANNUAL COMPLIANCE REPORTS.—The Chief Health Informatics Officer shall submit to Congress an annual report that assesses the compliance of all Federal Health Architecture agencies with HIT standards.

''(3) ADMINISTRATIVE PROVISIONS.—For purposes of paragraphs (1) and (2), the Chief Health Informatics Officer shall specify dates on which such reports shall be submitted under such paragraphs, the periods during which progress or compliance shall be assessed under such paragraphs, and a method for assessing such progress or compliance, respectively.

''(4) BI-ANNUAL GAP ASSESSMENT.—

''(A) IN GENERAL.—Starting on the date that is one year after the date of the enactment of this section, the Chief Health Informatics Officer shall request the Institute of Medicine to enter into an agreement with the Officer under which such Institute conducts a bi-annual assessment that identifies problems that present barriers to adaptation of HIT standards implemented during the period of such assessment. Such assessment shall—

''(i) analyze the impact and effectiveness of such standards;

''(ii) identify the costs and long-term savings to Federal agencies of complying with such standards during the period of the assessment;

''(iii) identify the impact of such standards on patient safety, on the quality of medical care provided to patients, and on mortality rates;

''(iv) identify significant administrative or business practice efficiencies and inefficiencies that result from the implementation of such standards;

''(v) identify ways to improve methods of developing and implementing such standards in public and private sectors; and

''(vi) recommend requirements and guidelines for future research and development of such standards.

''(B) REPORT.—Not later than 60 days after the last day of each period of semi-annual assessment conducted under subparagraph (A),

the Secretary shall submit to Congress a report on the findings of such assessment.

''(l) DEFINITIONS.—For purposes of this section:

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

''(2) HEALTH INFORMATION TECHNOLOGY.—The term 'health information technology' means products, devices, or systems that allow for the electronic collection, storage, exchange, or management of health information.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' means—

''(A) a health care provider defined in section 1171(3), including a critical access hospital; and

''(B) a federally qualified health center defined in section 1861(aa)(4).

''(4) INTEROPERABILITY.—The term 'interoperability' means the ability of different information systems and software applications to communicate and to exchange information accurately, effectively, and consistently.

''(5) FEDERAL AGENCY.—The term 'Federal agency' means a department or agency of the Fed-

eral Government that possesses, uses, or transfers health information.

''(6) FEDERAL HEALTH ARCHITECTURE.—The term 'Federal Health Architecture' means the entity overseen by the Secretary and the Director of the Office of Management and Budget and administered by the National Coordinator for Health Information Technology pursuant to Executive Order 13335 to provide the structure for collaboration and interoperability among Federal health efforts.

''(7) CONSOLIDATED HEALTH INFORMATICS COUNCIL.—The term 'Consolidated Health Informatics Council' means the initiative overseen by the Secretary and the Director of the Office of Management and Budget and administered by the National Coordinator for Health Information Technology pursuant to Executive Order 13335 to adopt existing health information interoperability standards.

''(m) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such funds as are necessary, but not more than $750,000,000, for each of fiscal years 2007 through 2011 to carry out this section. Of such amounts made available for a fiscal year, the Secretary shall allocate—

''(1) not less than 60 percent for the HIT grants program under subsection (j); and

''(2) not less than 10 percent for research and development activities and demonstration programs carried out by the Office.''.

(b) APPOINTMENT OF CHIEF HEALTH INFORMATICS OFFICER OF THE OFFICE OF HEALTH INFORMATION TECHNOLOGY.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall appoint a Chief Health Informatics Officer of the Office of Health Information Technology under section 1150A(a) of the Social Security Act, as added by subsection (a).

(c) TRANSITION FROM OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.—

(1) FUNCTIONS, PERSONNEL, ASSETS, AND LIABILITIES.—

(A) IN GENERAL.—There shall be transferred to the Chief Health Informatics Officer the functions, personnel, assets, and liabilities of the National Coordinator. For purposes of the previous sentence, the term ''assets'' includes contracts, facilities, property, records, unobligated or unexpended balances of appro-

priations, and other funds or resources (other than personnel).

(B) EMPLOYMENT PROVISIONS.—The transfer pursuant to subparagraph (A) of personnel shall not alter the terms and conditions of employment, including compensation, of any employee so transferred.

(C) CHIEF HEALTH INFORMATICS OFFICER AND NATIONAL COORDINATOR DEFINED.—For purposes of this subsection:

(i) CHIEF HEALTH INFORMATICS OFFICER.—The term ''Chief Health Informatics Officer'' means the Chief Health Informatics Officer of Health Information Technology appointed under section 1150A of the Social Security Act, as added by subsection (a).

(ii) NATIONAL COORDINATOR.—The term ''National Coordinator'' means the National Coordinator for Health Information Technology appointed under Executive Order 13335.

(2) ACTING CHIEF HEALTH INFORMATICS OFFICER.—Before the appointment of the Chief Health Informatics Officer, the National Coordinator shall

act as the Chief Health Informatics Officer until the office is filled as provided in section 1150A(a) of the Social Security Act. The Secretary may appoint the National Coordinator as the Chief Health Informatics Officer.

(3) COMPLETED ADMINISTRATIVE ACTIONS.—

(A) IN GENERAL.—Completed administrative actions of the Office of the National Coordinator shall continue in effect according to their terms until amended, modified, superseded, terminated, set aside, or revoked by the Office of the Chief Health Informatics Officer.

(B) COMPLETED ADMINISTRATIVE ACTION DESCRIBED.—For purposes of subparagraph (A), the term ''completed administrative action'' includes orders, determinations, rules, regulations, personnel actions, permits, agreements, grants, contracts, certificates, licenses, registrations, and privileges.

(4) REFERENCES.—References relating to the Office of the National Coordinator that precede the effective date of this Act shall be deemed to refer, as appropriate, to the Office of the Chief Health Informatics Officer.

(5) STATUTORY REPORTING REQUIREMENTS.—Any statutory reporting requirement that applied to the Office of the National Coordinator immediately before the effective date of this Act shall apply to the Office of the Chief Health Informatics Officer following such date.

(6) TREATMENT OF EXECUTIVE ORDER 13335.—Executive Order 13335 shall not have any force or effect after the date of the appointment of the first Chief Health Informatics Officer.

SEC. 3. NATIONAL INSTITUTE OF HEALTH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institute of Health, shall carry out a demonstration program to determine methods by which contextual access criteria and analysis technologies for specific diseases and health criteria may be used to search patient electronic health records and aggregated health information without using personal identifying information of patients. Participants in the program shall include representatives of Federal health agencies, State health agencies, research facilities approved for clinical trials of the National Institute of Health, health insurance organizations, self-insured corporations, and private sector health care providers.

(b) REPORT.—Not later than two years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the findings of the demonstration program under subsection (a).

SEC. 4. HEALTH CARE PROVIDER HIT LOAN PROGRAM.

(a) PROGRAM ESTABLISHED.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 2, is further amended by adding at the end the following new section:

"SEC. 1150B HEALTH CARE PROVIDER HIT LOAN PROGRAM.

''(a) PROGRAM ESTABLISHED.—

''(1) IN GENERAL.—There is established a program to be known as the 'Health Care Provider HIT Loan Program' (referred to in this section as the 'Loan Program'.

''(2) ENTITLEMENT.—There are hereby made available, in accordance with the provisions of this section, such sums as may be necessary to make loans under the Loan Program to all eligible health care providers, including critical access hospitals and federally qualified health centers, to enable the implementation and adoption by such providers of health information technology systems that promote interoperability among health care settings.

''(b) ELIGIBILITY.—

''(1) APPLICATION.—To be eligible to participate in the Loan Program, a health care provider shall submit to a loan originator center an application that demonstrates the following:

''(A) STATE LICENSED.—The provider is licensed by an appropriate State agency to perform the duties of the provider.

''(B) PARTICIPANT IN THE MEDICARE PROGRAM.—The provider participates under title XVIII.

''(C) USE OF LOAN FUNDS FOR INTEROPERABLE HIT PROJECT.—The loan will be used to purchase, implement, or improve health information technology and such health information technology is interoperable with a shared health facility, hospital, or health system in the community of the provider.

''(D) NO DEFAULT ON EXISTING LOANS.—The provider is not in default on an existing Federal loan.

''(2) ADMINISTRATION OF APPLICATION.—The application shall be submitted in such form, at such time, and containing such additional information as the Secretary may require.

''(c) DUTIES OF THE SECRETARY.—The Secretary, through the Chief Health Informatics Officer of Health Information Technology, shall carry out the Loan Program. In carrying out the Loan Program, the Secretary shall, with respect to loans made under subsection (a)—

''(1) enter into contracts under subsections (d) and (e) for purposes of originating and servicing, respectively, such loans;

''(2) review requests submitted by a loan originator center for such loans;

''(3) transfer loans funds to loan originator centers;

''(4) monitor activities performed by loan originator centers under subsection (d) and loan service centers under subsection (e); and

''(5) monitor the rate at which eligible health care providers default on such loans made to such providers.

''(d) ORIGINATION OF LOANS.—

''(1) FUNDS FOR ORIGINATION OF LOANS.—The Secretary shall provide funds, out of funds available pursuant to subsection (a), for loans under this section through a loan originator center to an eligible health care provider.

''(2) CONTRACTS WITH LOAN ORIGINATOR CENTERS.—The Secretary of Health and Human Services shall enter into contracts with loan originator centers under which the loan originator centers shall, with respect to loans under subsection (a)—

''(A) assess applications submitted under subsection (b);

''(B) originate such loans to eligible providers in accordance with this section, including request loan funds from the Secretary for an eligible provider, disburse loan funds to an eligible provider, and notify the Secretary that such funds have been disbursed;

''(C) obtain from an eligible provider a note or evidence of obligation on such a loan and provide that such note or evidence shall be the property of the Secretary;

''(D) set forth a schedule for disbursement of the proceeds of the loan in installments; and

''(E) perform administrative functions, as determined by the Secretary necessary to the origination of loan funds, including monthly account reconciliation.

''(e) CONTRACTS WITH LOAN SERVICE CENTERS FOR SERVICING LOANS.—The Secretary of Health and

Human Services shall enter into contracts with loan service centers under which the loans service centers shall, with respect to loan funds disbursed to an eligible health care provider—

''(1) monitor the eligibility status of such providers to receive such loan funds;

''(2) submit to such providers bills and collect from such providers payments for such loan funds in accordance with the applicable repayment plan of the provider under subsection (g)(1);

''(3) conduct initial collection services on delinquent payments by such providers for loans under this section; and

''(4) transfer loans in default to a debt collection system.

''(f) TERMS AND CONDITIONS OF LOANS.—

''(1) AMOUNTS OF LOANS.—

''(A) DETERMINATION OF AMOUNTS.—The determination of the amount of a loan made under subsection (a) to an eligible health care provider shall be calculated, in accordance with a methodology specified by the Secretary, based on the projected health IT cost and the size of the provider (as determined by a method specified by the Secretary.

"(B) DEFINITION OF PROJECTED HEALTH IT COST.—For purposes of this paragraph and paragraph (2), the term 'projected health IT cost' means the cost to the eligible health care provider to purchase, implement, or improve the health information technology involved in the application under subsection (b)(1).

"(2) LOAN LIMITS.—

"(A) ESTABLISHMENT OF LIMITS.—The Secretary shall establish limits on loans under the Loan Program, based on categories under subparagraph (B).

"(B) CREATION OF LOAN LIMIT CATEGORIES.—For purposes of subparagraph (A), the Secretary shall create categories of eligible health care providers that represent various ranges of health IT costs to such providers and sizes of such providers. The Secretary shall assign to each category a value that shall be the maximum amount for a loan made under the Loan Program to an eligible health care provider whose projected health IT cost and whose size correspond with the range of costs and sizes represented by such category.

"(3) INTEREST RATES.—

"(A) DETERMINATION OF INTEREST RATE.—Subject to subparagraph (B), the applicable rate of interest for a loan under this section, during any 12-month period beginning on July 1 and ending on June 30 shall be determined on the preceeding June 1 and be equal to—

"(i) the bond equivalent rate of 91-day Treasury bills auctioned at the first auction held prior to such June 1; plus

"(ii) 3.1 percent.

"(B) MAXIMUM INTEREST RATE.—A rate of interest determined under subparagraph (A) shall not exceed 8.25 percent.

"(C) INTEREST RATE DISCOUNTS.—The Secretary may prescribe by regulation such reductions in the interest rate paid by an eligible health care provider for a loan under subsection (a) as the Secretary determines appropriate to encourage on-time repayment of the loan. Such reductions may be offered only if the Secretary determines the reductions are cost neutral and in the best financial interest of the Federal Government.

''(4) ORIGINATION FEES.—The Secretary shall charge an eligible health care provider who receives a loan under subsection (a) an origination fee of 4 percent of the principal amount of loan and, if applicable, a fee for loan insurance.

''(g) REPAYMENT OF LOANS.—

''(1) REPAYMENT PLANS.—

''(A) DESIGN AND SELECTION.—

''(i) IN GENERAL.—Consistent with criteria established by the Secretary, the Secretary shall offer an eligible health care provider who receives a loan under the Loan Program (and the provider may choose one of) the plans for repayment of such loan, including repayment of principal and interest on such loan, described in clause (ii). Such criteria shall be different for eligible health care providers that are physicians or medical groups, or that are DSH qualifying facilities described in clause (iii) or (iv) of section 1150A(j)(3)(B), in order to take into account the different financial ability of such providers to repay loans made. The Secretary shall allow the provider to accel-

erate, without penalty, repayment on the loans involved.

''(ii) REPAYMENT PLANS.—The plans described in this clause are the following:

''(I) STANDARD REPAYMENT PLAN.—A standard repayment plan, with annual payment amount paid over a fixed period of time.

''(II) INCOME CONTINGENT REPAYMENT PLAN.—An income contingent repayment plan, with varying monthly payment amounts based on the income of the eligible health care provider involved, paid over an extended period of time prescribed by the Secretary, not to exceed 25 years.

''(B) SELECTION BY SECRETARY.—If an eligible health care provider that receives a loan under the Loan Program does not select a repayment plan for such loan described in subparagraph (A)(ii), the Secretary shall select the repayment plan described in subclause (I) of such subsection.

''(C) CHANGES IN SELECTION.—An eligible health care provider that receives a loan under

the Loan Program may change the selection of such provider of a repayment plan under subparagraph (A)(ii), or the Secretary's selection of a plan for the provider under subparagraph (B), as the case may be, under such terms and conditions as may be established by the Secretary.

''(D) ALTERNATIVE REPAYMENT PLANS.—The Secretary may provide, on a case by case basis, an alternative repayment plan to an eligible health care provider that receives a loan under the Loan Program who demonstrates to the satisfaction of the Secretary that the terms and conditions of the repayment plans available under subparagraph (A)(ii) are not adequate to accommodate an exceptional circumstance of the provider. In designing such an alternative repayment plan, the Secretary shall ensure that such plan does not exceed the cost to the Federal Government, as determined on the basis of the present value of future payments by such providers, of loans made using the plans available under subparagraph (A)(ii).

''(2) REPAYMENT RELIEF.—

''(A) REQUIRED PROGRAM FOR LOAN FORGIVENESS.—The Secretary shall, in accordance with guidelines specified by the Secretary, establish a program for the forgiveness of a loan provided under the Loan Program to an eligible health care provider that is—

''(i) a physician or medical group that serves a medically underserved population, as defined in section 330(a)(3) of the Public Health Service Act; or

''(ii) a participant in the National Health Service Corps Loan Repayment Program under section 338B of such Act.

''(B) AUTHORITY FOR ADDITIONAL RELIEF.—The Secretary may, in accordance with guidelines specified by the Secretary, provide for the deferment, forbearance, consolidation, discharge, or forgiveness of another loan provided under the Loan Program.

''(3) LOAN DEFAULT.—

''(A) TERMS OF DEFAULT.—An eligible health care provider that receives a loan under subsection (a) has defaulted on such loan if—

''(i) the provider fails to make a payment amount for the loan by the date re-

quired by the repayment plan of the provider and has failed to make such repayment for at least 180 consecutive days; or

''(ii) the provider otherwise violates the terms of the promissory note for the loan made to the provider and continues to violate such terms for 180 days.

''(B) CONSEQUENCES OF DEFAULT.—If, under subparagraph (A), an eligible health care provider defaults on a loan made under subsection (a), the Secretary may—

''(i) report such default to a major credit bureau;

''(ii) offset a tax refund for which the provider is eligible by the amount of the loan in default;

''(iii) garnish wages or profits of the provider;

''(iv) except for a provider that makes payment amounts for at least six consecutive months for such loan in default, disqualify the provider from any further loans under subsection (a); and

''(v) pursue litigation against the provider for purposes of recovering the amount of the loan in default.

''(h) ADMINISTRATIVE PROVISIONS.—The Secretary shall issue regulations for purposes of carrying out the Loans Program. The regulations shall include measures to ensure compliance of loan originator centers, loan service centers, and eligible health care providers with the Loan Program.

''(i) DEFINITIONS.—For purposes of this section:

''(1) LOAN ORIGINATOR CENTERS.—The term 'loan originator center' means an entity with the capacity to perform the duties under subsection (d)(2) and with which the Secretary of Health and Human Services enters into a contract under such subsection.

''(2) LOAN SERVICE CENTERS.—The term 'loan service center' means an entity with the capacity to perform the duties under subsection (e) and with which the Secretary of Health and Human Services enters into a contract under such subsection.

''(3) HEALTH CARE PROVIDER.—The term 'health care provider' means—

''(A) a health care provider defined in section 1171(3), including a critical access hospital; and

''(B) a federally qualified health center defined in section 1861(aa)(4).

''(4) ELIGIBLE HEALTH CARE PROVIDER.—The term 'eligible health care provider' means a health care provider that is eligible under subsection (b) to receive a loan under subsection (a).

''(j) EFFECTIVE DATE.—Loans under this section shall be available to eligible health care providers starting on the date that is one year after the date of the enactment of this section.''.

(b) STUDY ON HEALTH CARE PROVIDER HIT LOAN PROGRAM SAVINGS; HIT IMPLEMENTATION INCENTIVES.—

(1) STUDY ON HEALTH CARE PROVIDER HIT LOAN PROGRAM SAVINGS.—

(A) STUDY.—Each Federal entity officer described in subparagraph (C) shall conduct a study to determine any savings realized or costs incurred by Federal health care programs (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))) because of the implementation or adoption of health infor-

mation technology financed through loans made under the Health Care Provider HIT Loan Program under section 1150B of the Social Security Act, as added by subsection (a).

(B) REPORT.—Not later than the date that is one year after the date of the enactment of this Act, each Federal entity officer described in subparagraph (C) shall submit a report to Congress on the results of the study conducted under subparagraph (A).

(C) FEDERAL ENTITY OFFICER DESCRIBED.—For purposes of this paragraph, a Federal entity officer is each of the following:

(i) The Comptroller General of the Government Accountability Office.

(ii) The Commissioner of the Medicare Payment Advisory Commission (MedPAC), established by the Balanced Budget Act of 1997 (Public Law 105–33).

(iii) The Administrator of the Centers for Medicare and Medicaid Services (CMS).

(iv) The Director of the Congressional Budget Office.

(2) HIT IMPLEMENTATION INCENTIVES.—

(A) STUDY.—The Secretary of Health and Human Services, through the Administrator of the Centers for Medicare and Medicaid Services and after consultation with the Agency for Healthcare Research and Quality, health care providers, and other interested parties, shall specify methods to incentivize the purchase and implementation of health information technology systems. Such incentives may include certain payment incentives made by the Federal Government to entities, such as prompt claims payments, payment differentials, cost differentials, direct payments for services provided through health information technology, and bonus payments for meeting quality outcomes.

(B) IMPLEMENTATION.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall implement the methods specified in subparagraph (A).

SEC. 5. SAFE HARBOR FROM ANTI-KICKBACK LAWS FOR HEALTH INFORMATION TECHNOLOGY.

(a) FOR CIVIL PENALTIES.—Section 1128A(b) of the Social Security Act (42 U.S.C. 1320a–7a(b)) is amended by adding at the end the following new paragraph:

''(4)(A) For purposes of this subsection, a payment described in paragraph (1) does not include any nonmonetary remuneration (in the form of permitted support) made by a hospital or critical access hospital to a physician if—

''(i) such remuneration is made (or is believed in good faith to be made) without regard to the amount or quality of referrals made or business generated by the physician to the critical access hospital or hospital; and

''(ii) in the case of such remuneration made on or after the date that is four years after the date described in section 5(d)(2) of the Electronic Health Information Technology Act of 2006, such remuneration is made (or is believed in good faith to be made) in accordance with the criteria (relating to compliance with interoperability standards) established by the Secretary under section 5(e) of such Act.

''(B) For purposes of subparagraph (A) and sections 1128B(b)(3)(J) and 1877(e)(9), the term 'permitted support' means any equipment, item, information, right, license, intellectual property, software, or service (or funding used exclusively to provide or pay for such equipment, item, information, right, license, intellectual property,

software, or service) that is used for at least the purpose of exchanging health information.''.

(b) FOR CRIMINAL PENALTIES.—Section 1128B(b)(3) of such Act (42 U.S.C. 1320a–7b(b)(3)) is amended—

(1) in subparagraph (G), by striking ''and'' at the end;

(2) in the subparagraph (H) added by section 237(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2213)—

(A) by moving such subparagraph 2 ems to the left; and

(B) by striking the period at the end and inserting a semicolon;

(3) in the subparagraph (H) added by section 431(a) of such Act (117 Stat. 2287)—

(A) by redesignating such subparagraph as subparagraph (I);

(B) by moving such subparagraph 2 ems to the left; and

(C) by striking the period at the end and inserting ''; and''; and

(4) by adding at the end the following new subparagraph:

''(J) any nonmonetary remuneration (in the form of permitted support, as defined in section 1128A(b)(4)(B)) made to a person if—

''(i) such remuneration is solicited or received (or offered or paid) (or believed in good faith to be solicited, received, offered, or paid) without regard to the amount or quality of referrals made or business generated by the person; and

''(ii) in the case of such remuneration made on or after the date that is four years after the date described in section 5(d)(2) of the Electronic Health Information Technology Act of 2006, such remuneration is solicited or received (or offered or paid) (or believed in good faith to be solicited, received, offered, or paid) in accordance with the criteria (relating to compliance with interoperability standards) established by the Secretary under section 5(e) of such Act.''.

(c) FOR LIMITATION ON CERTAIN PHYSICIAN REFERRALS.—Section 1877(e) of such Act (42 U.S.C. 1395nn(e)) is amended by adding at the end the following new paragraph:

''(9) INFORMATION TECHNOLOGY AND TRAINING SERVICES.—Any nonmonetary remuneration (in the form of permitted support, as defined in section 1128A(b)(4)(B)) made by an entity to a physician if—

''(A) such remuneration is made (or believed in good faith to be made) without regard to the amount or quality of referrals made or business generated by the physician to the entity; and

''(B) in the case of such remuneration made on or after the date that is four years after the date described in section 5(d)(2) of the Electronic Health Information Technology Act of 2006, such remuneration is made (or believed in good faith to be made) in accordance with the criteria (relating to compliance with interoperability standards) established by the Secretary under section 5(e) of such Act.''.

(d) REGULATIONS, EFFECTIVE DATE, AND EFFECT ON STATE LAWS.—

(1) REGULATIONS.—

(A) IN GENERAL.—Subject to subparagraph (B) and not later than the date that is 180 days after the date of the enactment of this

Act, the Secretary of Health and Human Services shall issue such regulations as may be necessary to carry out the provisions of this section.

(B) NOTICE AND COMMENT.—Not later than the date that is 60 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue a notice of proposed rulemaking, with respect to the regulations issued under subparagraph (A).

(C) SUBSEQUENT REGULATIONS.—Any regulation issued by the Secretary on a date after the date described in subparagraph (A), with respect to the safe harbors described in paragraph (4), shall be issued after notice and comment.

(2) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 180 days after the date of the enactment of this Act.

(3) EFFECT OF STATE LAWS.—No State (as defined in section 1101(a)) shall have in effect a State law that imposes a criminal or civil penalty for a transaction described in section 1128A(b)(4); 1128B(b)(3)(J); or 1877(e)(9) of the Social Security Act, as added by this section, if—

(A) the conditions described in the respective section, with respect to such transaction, are met; or

(B) the person or entity involved in such transaction acted in good faith under the belief that such conditions are met.

(4) SAFE HARBORS DESCRIBED.—For purposes of paragraphs (1) and subsection (e), the safe harbors described in this paragraph are—

(A) the safe harbor under paragraph (4) of section 1128A(b) of the Social Security Act (42 U.S.C. 1320a–7a(b)), as added by subsection (a);

(B) the safe harbor under subparagraph (J) of section 1128B(b)(3) of such Act (42 U.S.C. 1320a–7b(b)(3)), as added by subsection (b); and

(C) the safe harbor under paragraph (9) of section 1877(e) of such Act (42 U.S.C. 1395nn(e)), as added by subsection (c).

(e) INTEROPERABILITY CRITERIA FOR PERMISSIBLE HEALTH INFORMATION TECHNOLOGY REMUNERATION UNDER SAFE HARBORS.—Starting on the date that is four years after the effective date described in subsection (d)(2) and every two years thereafter, the Secretary of

Health and Human Services may issue regulations that establish criteria for nonmonetary remuneration (in the form of permitted support defined under section 1128A(b)(4) of the Social Security Act, as added by subsection (a)) for purposes of the safe harbors described in subsection (d)(4). The Secretary shall base such criteria on the extent to which the permitted support conforms to a standard implemented under section 1150A(d) of the Social Security Act, as added by section 2, based on the following considerations:

(1) WIDE ACCEPTANCE OF STANDARD.—The standard is widely accepted within the health care industry and has been used within the industry for a sufficient amount of time to ensure successful implementation.

(2) NECESSITY.—The standard is necessary to improve the quality of health care or patient safety, or to provide greater administrative efficiencies.

(3) COST BENEFIT ANALYSIS.—The results of a cost benefit test conducted to determine the effect of applying the standard for purposes of the safe harbors described in subsection (d)(4).

SEC. 6. UNIFORM FEDERAL AND STATE HEALTH INFORMATION STANDARDS.

(a) STUDY TO DETERMINE EXTENT OF VARIATION IN STATE HEALTH INFORMATION LAWS AND REGULATIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study of State laws and regulations relating to the security and confidentiality of individually identifiable health information to determine—

(A) the degree to which such laws and regulations vary among States, and between the States and the Federal privacy standards established pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and security standards established under section 1173(d) of the Social Security Act; and

(B) how any such variation may adversely impact the electronic exchange of clinical health information among States, the Federal Government, and private entities.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Con-

gress a report on the study under paragraph (1) and shall include in such report—

(A) a determination by the Secretary whether the State laws and regulations described in such paragraph should be conformed to a set of Federal standards to protect the security and confidentiality of patient health information and to improve health care quality or efficiency; and

(B) recommendations for legislation to conform such State laws and regulations to such a set of Federal standards.

(3) STATE DEFINED.—For purposes of this subsection, the term ''State'' has the meaning given such term when used in title XI of the Social Security Act, as provided under section 1101(a) of such Act (42 U.S.C. 1301(a)).

(b) CONFIDENTIALITY AND SECURITY REGULATIONS PREEMPTION OF STATE LAWS IF CONGRESS FAILS TO ESTABLISH UNIFORM STANDARDS.—

(1) IN GENERAL.—Section 1178(a) of the Social Security Act (42 U.S.C. 1320d–7(a)) is amended—

(A) in paragraph (1) by inserting after ''Except as provided in paragraph (2)'' the following: ''and subject to paragraph (3)''; and

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

''(3) UNIFORM STANDARDS.—

''(A) IN GENERAL.—If legislation to create uniform Federal standards, and to preempt State laws, with respect to the confidentiality and security of individually identifiable health information is not enacted by Congress on the date that is 36 months after the date of the enactment of the Electronic Health Information Technology Act of 2006, the regulation and standards described in subparagraph (B) shall supersede any contrary provision of State law.

''(B) APPLICATION OF UNIFORM STANDARDS.—The regulation and standards described in this subparagraph are the regulation promulgated under section 264(c)(1) of the Health Insurance Portability and Accountability Act of 1996 and the standards under section 1173(d), as modified by the Secretary to the extent the Secretary determines, after consideration of the results of the study conducted under section

6(a) of the Electronic Health Information Technology Act of 2006, necessary to promote uniform national standards.''.

(2) HIPAA CONFORMING AMENDMENT.—Section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) is amended by striking ''A regulation'' and inserting ''(A) Subject to section 1178(a)(3) of the Social Security Act, a regulation''.

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