

109TH CONGRESS
2^D 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

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.

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

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

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

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

- Sec. 1. Short title; table of contents
- Sec. 2. Office of Health Information Technology and standards development
- Sec. 3. National Institute of Health demonstration program
- Sec. 4. Health care provider HIT loan program
- Sec. 5. Safe harbor from anti-kickback laws for health information technology
- Sec. 6. Uniform Federal and State health information standards

6 **SEC. 2. OFFICE OF HEALTH INFORMATION TECHNOLOGY**
7 **AND STANDARDS DEVELOPMENT.**

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

11 “HEALTH INFORMATION TECHNOLOGY

12 “SEC. 1150A. (a) OFFICE OF HEALTH INFORMATION
13 TECHNOLOGY.—

14 “(1) ESTABLISHMENT.—There is established
15 within the Department of Health and Human Serv-
16 ices an Office of Health Information Technology (re-
17 ferred to in this section as the ‘Office’) that shall be
18 headed by the Chief Health Informatics Officer of
19 Health Information Technology (referred to in this
20 section as the ‘Chief Health Informatics Officer’).

21 The Chief Health Informatics Officer shall be ap-
22 pointed by the Secretary and shall report directly to
23 the Secretary. The Chief Health Informatics Officer

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

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

7 “(A) CONVENIENT AVAILABILITY OF
8 HEALTH INFORMATION.—Ensuring that appro-
9 priate information to guide medical decisions is
10 available on the date on which and at the loca-
11 tion in which health care is provided to an indi-
12 vidual.

13 “(B) IMPROVED HEALTH CARE.—

14 “(i) Improving health care quality.

15 “(ii) Advancing the delivery of appro-
16 priate evidence-based health care.

17 “(iii) Reducing the occurrence of med-
18 ical errors, inefficiency, inappropriate
19 health care, and incomplete information.

20 “(iv) Reducing health costs that result
21 from the occurrences referred to in clause
22 (iii).

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

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

6 “(D) IMPROVED COORDINATION OF
7 HEALTH CARE INFORMATION.—Improving the
8 coordination of health information among hos-
9 pitals, laboratories, physician offices, and ambu-
10 latory care providers through an effective infra-
11 structure for the secure and authorized ex-
12 change of health information.

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

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

21 “(A) DEVELOPMENT, IMPLEMENTATION,
22 AND MODIFICATION OF UNIFORM HIT STAND-
23 ARDS.—Develop, implement, and modify HIT
24 standards, in accordance with subsections (c),
25 (d), and (e), respectively.

1 “(B) DEVELOPMENT, MAINTENANCE, AND
2 IMPLEMENTATION OF INTEROPERABLE HIT
3 STRATEGIC PLAN.—Develop, maintain, and di-
4 rect the implementation of an interoperable
5 HIT strategic plan (described in paragraph (4))
6 to guide the nationwide implementation of
7 interoperable health information technology in
8 the public and private health care sectors.

9 “(C) PRINCIPAL ADVISOR TO SEC-
10 RETARY.—Serve as the principal advisor to the
11 Secretary on the development and use of health
12 information technology.

13 “(D) DIRECTOR OF HHS HEALTH INFOR-
14 MATION TECHNOLOGY PROGRAMS.—Direct any
15 programs related to health information tech-
16 nology that are conducted by the Secretary.

17 “(E) COORDINATOR OF FEDERAL HEALTH
18 INFORMATION POLICY AND ACTIVITIES.—Co-
19 ordinate health information technology policies
20 of the Department of Health and Human Serv-
21 ices and activities related to the transmission,
22 integrity, and security of health information
23 conducted by the Secretary with such policies
24 and activities of Federal agencies to avoid du-
25 plication of effort and to ensure that each such

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

4 “(F) COORDINATOR OF OUTREACH AND
5 CONSULTATION.—Coordinate programs of Fed-
6 eral agencies that are related to health informa-
7 tion technology outreach and consultation by
8 such agencies with public and private entities,
9 including consumers, providers, payers, and ad-
10 ministrators.

11 “(G) COORDINATOR FOR PLANS FOR PRI-
12 VATE SECTOR HEALTH INFORMATION TECH-
13 NOLOGY.—Coordinate plans for Federal efforts
14 to develop and implement interoperable HIT
15 standards for private sector physicians and
16 other health professionals who use electronic
17 health records, electronic prescribing systems,
18 evidence-based clinical support tools, patient
19 registries, or other health information tech-
20 nology.

21 “(H) ADVISOR TO OMB.—Provide to the
22 Director of the Office of Management and
23 Budget comments and advice with respect to
24 specific health information technology pro-
25 grams.

1 “(I) ADMINISTRATOR OF GRANTS PRO-
2 GRAM.—Administer the HIT standards grants
3 program under subsection (j).

4 “(4) INTEROPERABLE HIT STRATEGIC PLAN.—

5 “(A) DESCRIPTION.—For purposes of
6 paragraph (3)(B), an interoperable HIT stra-
7 tegic plan is a plan that is consistent with the
8 following:

9 “(i) ADVANCEMENT OF HIT STAND-
10 ARDS.—Advances the development and na-
11 tional implementation of HIT standards
12 through the collaboration of public and pri-
13 vate interests, and consistent with efforts
14 in existence before the date of the enact-
15 ment of this section.

16 “(ii) ACKNOWLEDGEMENT OF CER-
17 TAIN ISSUES INVOLVED IN ADOPTION OF
18 STANDARDS.—Ensures that the main tech-
19 nical, scientific, economic, and other issues
20 affecting the adoption of HIT standards
21 (in the public and private sectors) are ad-
22 dressed.

23 “(iii) EVALUATION OF BENEFITS AND
24 COSTS OF INTEROPERABLE HEALTH IN-
25 FORMATION TECHNOLOGY.—Evaluates the

1 benefits and costs of interoperable health
2 information technology and identifies the
3 persons affected by such benefits and
4 costs.

5 “(iv) ACKNOWLEDGEMENT OF PRI-
6 VACY AND SECURITY ISSUES.—Addresses
7 the issues of privacy and security related
8 to interoperable health information tech-
9 nology and recommends methods to ensure
10 appropriate authorization, authentication,
11 and encryption of data transmission over
12 the Internet.

13 “(v) SELF-SUFFICIENT PLAN.—Does
14 not assume or depend upon Federal re-
15 sources or spending that is in addition to
16 resources and spending authorized under
17 the Electronic Health Information Tech-
18 nology Act of 2006 to accomplish the
19 adoption of HIT standards and an inter-
20 operable health information technology in-
21 frastructure.

22 “(vi) MEASURABLE OUTCOME
23 GOALS.—Includes measurable outcome
24 goals, such as for determining error reduc-
25 tions in patient care and economic benefits

1 derived from the use of interoperable
2 health information technology.

3 “(B) REPORTS.—Not later than 180 days
4 after the date of the appointment of the Chief
5 Health Informatics Officer, and periodically
6 thereafter, the Chief Health Informatics Officer
7 shall submit to the Secretary a report on the
8 progress of the development and implementa-
9 tion of the interoperable HIT strategic plan.

10 “(b) LIMITATION ON USE OF FEDERAL FUNDS TO
11 PURCHASE HEALTH INFORMATION TECHNOLOGY PROD-
12 UCTS.—

13 “(1) IN GENERAL.—Effective as provided in
14 paragraphs (1)(B) and (2)(C) of subsection (d), no
15 Federal funds (including grants provided under sub-
16 section (j)) may be used for the purchase (or up-
17 date) of a health information technology product un-
18 less the product (or update) is certified by the entity
19 selected under paragraph (2) as complying with HIT
20 standards in effect on the date of certification.

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

1 ards implemented under subsection (d). For pur-
2 poses of the preceding sentence, the Secretary may
3 enter into a contract with a private entity, including
4 the Certification Commission for Healthcare Infor-
5 mation Technology.

6 “(3) CONTRACTING EXCEPTION.—For purposes
7 of paragraph (2) and subsection (c)(3), the Sec-
8 retary may enter into a contract with the Certifi-
9 cation Commission for Healthcare Information Tech-
10 nology for purposes of such paragraph or such sub-
11 section, but not for both.

12 “(c) DEVELOPMENT OF HIT STANDARDS.—

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

17 “(A) INTEROPERABILITY.—The standards
18 shall provide for interoperability among health
19 information systems.

20 “(B) APPLICATION TO ELECTRONIC
21 TRANSACTIONS AND TRANSMISSIONS.—The
22 standards shall apply to electronic transactions
23 and transmissions of health information, to the
24 content of such transactions and transmissions,
25 and to the data elements of such transactions

1 and transmissions, including standards for se-
2 curity and coding of electronic health informa-
3 tion created for the purpose of establishing an
4 interoperable health information infrastructure.

5 “(C) PROPRIETARY NEUTRALITY.—The
6 standards shall not restrict, sponsor, promote,
7 or prejudice in any other way the certification
8 of health information technology products ac-
9 cording to brand, product line, or vendor.

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

14 “(E) NO UNDUE BURDEN.—The standards
15 shall not, to the extent practicable, impose an
16 undue administrative or financial burden on the
17 practice of medicine, or any other health care
18 profession, particularly on small physician prac-
19 tices and practices located in rural areas.

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

1 cerning the privacy of individually identifiable
2 health information).

3 “(2) ACCESS RESTRICTION STANDARDS.—The
4 Chief Health Informatics Officer shall establish
5 standards to restrict access of public and private en-
6 tities to health information transferred, used, or
7 stored by health information technology.

8 “(3) CONTRACTING AUTHORITY.—Subject to
9 subsection (b)(3), the Chief Health Informatics Offi-
10 cer may enter into a contract with the Certification
11 Commission for Healthcare Information Technology,
12 or any other appropriate certification entity, to de-
13 velop HIT standards, access restriction standards
14 described in paragraph (2), or both.

15 “(4) HIT STANDARDS DEFINED.—For purposes
16 of this section, the term ‘HIT standards’ means
17 standards related to the transmission, integrity, and
18 security of health information.

19 “(d) IMPLEMENTATION OF HIT STANDARDS.—

20 “(1) CONSOLIDATED HEALTH INFORMATICS
21 COUNCIL STANDARDS IN EXISTENCE BEFORE DATE
22 OF ENACTMENT.—

23 “(A) IN GENERAL.—Not later than one
24 year after the date of the enactment of this sec-
25 tion, the Chief Health Informatics Officer shall

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

5 “(B) EFFECTIVE DATES.—

6 “(i) FEDERAL AGENCIES.—For pur-
7 poses of subsection (b) and not later than
8 the date that is 30 days after the date on
9 which HIT standards are implemented
10 under subparagraph (A), such standards
11 shall apply to a Federal agency.

12 “(ii) NON-FEDERAL AGENCIES.—For
13 purposes of subsection (b) and not later
14 than 18 months after the date of the en-
15 actment of the Electronic Health Informa-
16 tion Technology Act of 2006, the HIT
17 standards implemented under subpara-
18 graph (A) shall apply to an entity that is
19 not a Federal agency.

20 “(2) STANDARDS DEVELOPED AFTER DATE OF
21 ENACTMENT.—

22 “(A) IN GENERAL.—The Chief Health
23 Informatics Officer shall implement, in accord-
24 ance with subparagraph (B), each HIT stand-
25 ard developed under subsection (c) or modified

1 under subsection (e) unless the Chief Health
2 Informatics Officer determines that the stand-
3 ard would not be effective in promoting an
4 interoperable health information technology in-
5 frastructure.

6 “(B) REGULATIONS.—For purposes of
7 subparagraph (A), the Secretary shall establish
8 guidelines for determining if a standard would
9 not be effective in promoting an interoperable
10 health information technology infrastructure
11 and for specifying dates by which the Chief
12 Health Informatics Officer is required to make
13 a determination under such subparagraph be-
14 fore standards developed under subsection (c)
15 or modified under subsection (e) shall be imple-
16 mented.

17 “(C) EFFECTIVE DATES.—

18 “(i) FEDERAL AGENCIES.—For pur-
19 poses of subsection (b) and not later than
20 18 months after the date on which a HIT
21 standard is implemented under subpara-
22 graph (A), such standard shall apply to a
23 Federal agency.

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

1 than 24 months after the date on which a
2 HIT standard is implemented under sub-
3 paragraph (A), such standard shall apply
4 to an entity that is not a Federal agency.

5 “(3) DOCUMENTATION OF COMPLIANCE.—On
6 the date of the implementation of a HIT standard
7 under this subsection, the Chief Health Informatics
8 Officer shall provide documentation to the Secretary
9 showing that the standard complies with each re-
10 quirement under subsection (c)(1).

11 “(e) MODIFICATION OF STANDARDS.—The Chief
12 Health Informatics Officer may modify, according to a
13 procedure established by the Chief Health Informatics Of-
14 ficer, a HIT standard implemented under subsection (d).
15 A standard modified under this subsection shall be imple-
16 mented in accordance with such subsection.

17 “(f) AUTHORITY TO WAIVE COMPLIANCE.—

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

23 “(2) REPORTS.—Not later than 60 days after
24 the date on which the Chief Health Informatics Offi-
25 cer makes such a waiver, the Chief Health

1 Informatics Officer shall submit to Congress a re-
2 port stating the purpose and circumstances justi-
3 fying the waiver.

4 “(g) PENALTIES.—

5 “(1) FEDERAL AGENCIES.—The Director of the
6 Office of Management and Budget shall develop and
7 implement a system to enforce compliance with HIT
8 standards implemented under subsection (d). Such
9 system shall include appropriate budgetary pen-
10 alties—

11 “(A) for a Federal agency that is not in
12 compliance with such standards and has not re-
13 ceived a waiver under subsection (f)(1); and

14 “(B) for a Federal agency that has re-
15 ceived a waiver under subsection (f)(1) but,
16 starting on a date that is after the date on
17 which the waiver terminates, is not in compli-
18 ance with such standards.

19 “(2) NON-FEDERAL ENTITIES.—An entity that
20 is not a Federal agency shall no longer receive Fed-
21 eral funds for purposes of purchasing a health infor-
22 mation technology product if—

23 “(A) such entity is in violation of sub-
24 section (b) and has not received a waiver under
25 subsection (f)(1); or

1 “(B) such entity has received a waiver
2 under subsection (f)(1) but starting on a date
3 that is after the date on which the waiver ter-
4 minates the entity is not in compliance with
5 HIT standards implemented under subsection
6 (d).

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

11 “(1) STAKEHOLDER CONSULTATION.—The
12 Chief Health Informatics Officer, in accordance with
13 subchapter II of chapter 5 and chapter 7 of title 5,
14 United States Code (popularly known as the Admin-
15 istrative Procedure Act), shall consult with Federal
16 agencies and private entities that are involved in the
17 transfer or collection of health information, includ-
18 ing agencies of the Federal Health Architecture,
19 members of the Consolidated Health Informatics
20 Council, physicians, hospitals, health care delivery
21 systems, health insurance providers, pharmaceutical
22 and biologics manufacturers, medical device manu-
23 facturers, information technology vendors, patient
24 groups, private standards-setting organizations, pub-
25 lic health interest groups, and other health care pro-

1 professionals determined by the Chief Health
2 Informatics Officer necessary to the process of devel-
3 oping and modifying such standards.

4 “(2) NATIONAL COMMITTEE ON VITAL AND
5 HEALTH STATISTICS RECOMMENDATIONS.—Not later
6 than the date that is one year after the date of the
7 enactment of this section, and each year thereafter,
8 the National Committee on Vital and Health Statis-
9 tics shall submit to the Chief Health Informatics Of-
10 ficer recommendations for activities to advance the
11 development and modification of HIT standards.

12 “(i) TREATMENT OF STATE HIT STANDARDS.—A
13 standard implemented under subsection (d) for application
14 to electronic transfers or transactions described in sub-
15 section (c)(1)(B) shall supersede any standard prescribed
16 by a State or local government for a similar application.

17 “(j) HIT GRANTS PROGRAM.—

18 “(1) ESTABLISHMENT OF PROGRAM.—In ac-
19 cordance with this subsection and subject to para-
20 graph (3) and subsection (m), the Chief Health
21 Informatics Officer shall award one-year grants to
22 eligible health information technology entities whose
23 applications under paragraph (2) demonstrate a pro-
24 posal that will benefit an interoperable health infor-

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

3 “(2) APPLICATION.—To be eligible for an
4 award of a grant under this section, an eligible
5 health information technology entity shall submit to
6 the Secretary an application that contains a descrip-
7 tion of how the applicant proposes to use the grant
8 funds. The application shall be submitted in such
9 form, at such time, and containing such other infor-
10 mation as the Chief Health Informatics Officer may
11 require.

12 “(3) SET-ASIDES FOR DSH QUALIFYING FACILI-
13 TIES.—

14 “(A) IN GENERAL.—The Secretary shall
15 use at least 20 percent of the funds authorized
16 under subsection (m) for purposes of this sec-
17 tion to award grants under paragraph (1) to el-
18 igible health information technology entities,
19 which are DSH qualifying facilities.

20 “(B) DSH QUALIFYING FACILITY DE-
21 FINED.—For purposes of subparagraph (A), the
22 term ‘DSH qualifying facility’ means any of the
23 following:

24 “(i) MEDICARE DISPROPORTIONATE
25 SHARE HOSPITAL.—A hospital that quali-

1 fies for an additional payment under sec-
2 tion 1886(d)(4)(F).

3 “(ii) MEDICAID DISPROPORTIONATE
4 SHARE HOSPITAL.—A hospital that quali-
5 fies for an increase in the rate or amount
6 of payment for inpatient hospital services
7 under section 1923(a).

8 “(iii) PROVIDER SERVING A MEDI-
9 CALLY UNDERSERVED POPULATION.—A
10 health care provider that serves a medi-
11 cally underserved population, as defined in
12 section 330(a)(3) of the Public Health
13 Service Act.

14 “(iv) CRITICAL ACCESS HOSPITAL.—A
15 facility designated as a critical access hos-
16 pital in accordance with section
17 1820(c)(2).

18 “(4) PERMISSIBLE USE OF GRANTS.—A grant
19 awarded under paragraph (1) may be used by an eli-
20 gible health information technology entity only for
21 purposes of the proposal submitted by such entity
22 under paragraph (2).

23 “(5) EXTENSION OF GRANTS.—Upon the expi-
24 ration of a grant awarded to an eligible health infor-
25 mation technology entity under paragraph (1) and

1 the request of such entity, the Chief Health
2 Informatics Officer, in accordance with procedures
3 established by the Chief Health Informatics Officer,
4 may extend the duration of the grant once by one
5 year if the Chief Health Informatics Officer deter-
6 mines that the programs established and imple-
7 mented by such group with the grant resulted in (or
8 are likely to result in) significant progress in bene-
9 fitting an interoperable health information technology
10 infrastructure.

11 “(6) DEFINITION OF ELIGIBLE HEALTH INFOR-
12 MATION TECHNOLOGY ENTITY.—For purposes of
13 this subsection, the term ‘eligible health information
14 technology entity’ means an entity of a State or local
15 government or a private entity that seeks (and has
16 the capacity) to participate in the research, develop-
17 ment, or implementation of HIT standards. Such
18 term includes a health care provider, whether or not
19 the provider participates under title XVIII or XIX,
20 a health insurance issuer, and a group health plan.

21 “(k) PROGRESS AND COMPLIANCE REPORTS.—

22 “(1) BIENNIAL PROGRESS REPORTS.—The
23 Chief Health Informatics Officer shall submit to
24 Congress biennial reports on the progress of the de-
25 velopment and implementation of HIT standards.

1 “(2) ANNUAL COMPLIANCE REPORTS.—The
2 Chief Health Informatics Officer shall submit to
3 Congress an annual report that assesses the compli-
4 ance of all Federal Health Architecture agencies
5 with HIT standards.

6 “(3) ADMINISTRATIVE PROVISIONS.—For pur-
7 poses of paragraphs (1) and (2), the Chief Health
8 Informatics Officer shall specify dates on which such
9 reports shall be submitted under such paragraphs,
10 the periods during which progress or compliance
11 shall be assessed under such paragraphs, and a
12 method for assessing such progress or compliance,
13 respectively.

14 “(4) BI-ANNUAL GAP ASSESSMENT.—

15 “(A) IN GENERAL.—Starting on the date
16 that is one year after the date of the enactment
17 of this section, the Chief Health Informatics
18 Officer shall request the Institute of Medicine
19 to enter into an agreement with the Officer
20 under which such Institute conducts a bi-annual
21 assessment that identifies problems that present
22 barriers to adaptation of HIT standards imple-
23 mented during the period of such assessment.
24 Such assessment shall—

1 “(i) analyze the impact and effective-
2 ness of such standards;

3 “(ii) identify the costs and long-term
4 savings to Federal agencies of complying
5 with such standards during the period of
6 the assessment;

7 “(iii) identify the impact of such
8 standards on patient safety, on the quality
9 of medical care provided to patients, and
10 on mortality rates;

11 “(iv) identify significant administra-
12 tive or business practice efficiencies and in-
13 efficiencies that result from the implemen-
14 tation of such standards;

15 “(v) identify ways to improve methods
16 of developing and implementing such
17 standards in public and private sectors;
18 and

19 “(vi) recommend requirements and
20 guidelines for future research and develop-
21 ment of such standards.

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

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

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

4 “(1) HEALTH INFORMATION.—The term ‘health
5 information’ has the meaning given such term in
6 section 1171(4).

7 “(2) HEALTH INFORMATION TECHNOLOGY.—
8 The term ‘health information technology’ means
9 products, devices, or systems that allow for the elec-
10 tronic collection, storage, exchange, or management
11 of health information.

12 “(3) HEALTH CARE PROVIDER.—The term
13 ‘health care provider’ means—

14 “(A) a health care provider defined in sec-
15 tion 1171(3), including a critical access hos-
16 pital; and

17 “(B) a federally qualified health center de-
18 fined in section 1861(aa)(4).

19 “(4) INTEROPERABILITY.—The term ‘interoper-
20 ability’ means the ability of different information
21 systems and software applications to communicate
22 and to exchange information accurately, effectively,
23 and consistently.

24 “(5) FEDERAL AGENCY.—The term ‘Federal
25 agency’ means a department or agency of the Fed-

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

3 “(6) FEDERAL HEALTH ARCHITECTURE.—The
4 term ‘Federal Health Architecture’ means the entity
5 overseen by the Secretary and the Director of the
6 Office of Management and Budget and administered
7 by the National Coordinator for Health Information
8 Technology pursuant to Executive Order 13335 to
9 provide the structure for collaboration and interoper-
10 ability among Federal health efforts.

11 “(7) CONSOLIDATED HEALTH INFORMATICS
12 COUNCIL.—The term ‘Consolidated Health
13 Informatics Council’ means the initiative overseen by
14 the Secretary and the Director of the Office of Man-
15 agement and Budget and administered by the Na-
16 tional Coordinator for Health Information Tech-
17 nology pursuant to Executive Order 13335 to adopt
18 existing health information interoperability stand-
19 ards.

20 “(m) AUTHORIZATION OF APPROPRIATIONS.—There
21 is authorized to be appropriated such funds as are nec-
22 essary, but not more than \$750,000,000, for each of fiscal
23 years 2007 through 2011 to carry out this section. Of such
24 amounts made available for a fiscal year, the Secretary
25 shall allocate—

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

3 “(2) not less than 10 percent for research and
4 development activities and demonstration programs
5 carried out by the Office.”.

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

14 (c) TRANSITION FROM OFFICE OF THE NATIONAL
15 COORDINATOR FOR HEALTH INFORMATION TECH-
16 NOLOGY.—

17 (1) FUNCTIONS, PERSONNEL, ASSETS, AND LI-
18 ABILITIES.—

19 (A) IN GENERAL.—There shall be trans-
20 ferred to the Chief Health Informatics Officer
21 the functions, personnel, assets, and liabilities
22 of the National Coordinator. For purposes of
23 the previous sentence, the term “assets” in-
24 cludes contracts, facilities, property, records,
25 unobligated or unexpended balances of appro-

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

3 (B) EMPLOYMENT PROVISIONS.—The
4 transfer pursuant to subparagraph (A) of per-
5 sonnel shall not alter the terms and conditions
6 of employment, including compensation, of any
7 employee so transferred.

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

11 (i) CHIEF HEALTH INFORMATICS OF-
12 FICER.—The term “Chief Health
13 Informatics Officer” means the Chief
14 Health Informatics Officer of Health In-
15 formation Technology appointed under sec-
16 tion 1150A of the Social Security Act, as
17 added by subsection (a).

18 (ii) NATIONAL COORDINATOR.—The
19 term “National Coordinator” means the
20 National Coordinator for Health Informa-
21 tion Technology appointed under Executive
22 Order 13335.

23 (2) ACTING CHIEF HEALTH INFORMATICS OFFI-
24 CER.—Before the appointment of the Chief Health
25 Informatics Officer, the National Coordinator shall

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

6 (3) COMPLETED ADMINISTRATIVE ACTIONS.—

7 (A) IN GENERAL.—Completed administra-
8 tive actions of the Office of the National Coor-
9 dinator shall continue in effect according to
10 their terms until amended, modified, super-
11 seded, terminated, set aside, or revoked by the
12 Office of the Chief Health Informatics Officer.

13 (B) COMPLETED ADMINISTRATIVE ACTION
14 DESCRIBED.—For purposes of subparagraph
15 (A), the term “completed administrative action”
16 includes orders, determinations, rules, regula-
17 tions, personnel actions, permits, agreements,
18 grants, contracts, certificates, licenses, registra-
19 tions, and privileges.

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

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

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

11 **SEC. 3. NATIONAL INSTITUTE OF HEALTH DEMONSTRATION PROGRAM.**
12

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services, acting through the Director of the Na-
15 tional Institute of Health, shall carry out a demonstration
16 program to determine methods by which contextual access
17 criteria and analysis technologies for specific diseases and
18 health criteria may be used to search patient electronic
19 health records and aggregated health information without
20 using personal identifying information of patients. Partici-
21 pants in the program shall include representatives of Fed-
22 eral health agencies, State health agencies, research facili-
23 ties approved for clinical trials of the National Institute
24 of Health, health insurance organizations, self-insured
25 corporations, and private sector health care providers.

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

6 **SEC. 4. HEALTH CARE PROVIDER HIT LOAN PROGRAM.**

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

11 **“SEC. 1150B HEALTH CARE PROVIDER HIT LOAN PROGRAM.**

12 “(a) PROGRAM ESTABLISHED.—

13 “(1) IN GENERAL.—There is established a pro-
14 gram to be known as the ‘Health Care Provider HIT
15 Loan Program’ (referred to in this section as the
16 ‘Loan Program’.

17 “(2) ENTITLEMENT.—There are hereby made
18 available, in accordance with the provisions of this
19 section, such sums as may be necessary to make
20 loans under the Loan Program to all eligible health
21 care providers, including critical access hospitals and
22 federally qualified health centers, to enable the im-
23 plementation and adoption by such providers of
24 health information technology systems that promote
25 interoperability among health care settings.

1 “(b) ELIGIBILITY.—

2 “(1) APPLICATION.—To be eligible to partici-
3 pate in the Loan Program, a health care provider
4 shall submit to a loan originator center an applica-
5 tion that demonstrates the following:

6 “(A) STATE LICENSED.—The provider is
7 licensed by an appropriate State agency to per-
8 form the duties of the provider.

9 “(B) PARTICIPANT IN THE MEDICARE PRO-
10 GRAM.—The provider participates under title
11 XVIII.

12 “(C) USE OF LOAN FUNDS FOR INTER-
13 OPERABLE HIT PROJECT.—The loan will be
14 used to purchase, implement, or improve health
15 information technology and such health infor-
16 mation technology is interoperable with a
17 shared health facility, hospital, or health system
18 in the community of the provider.

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

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

1 “(c) DUTIES OF THE SECRETARY.—The Secretary,
2 through the Chief Health Informatics Officer of Health
3 Information Technology, shall carry out the Loan Pro-
4 gram. In carrying out the Loan Program, the Secretary
5 shall, with respect to loans made under subsection (a)—

6 “(1) enter into contracts under subsections (d)
7 and (e) for purposes of originating and servicing, re-
8 spectively, such loans;

9 “(2) review requests submitted by a loan origi-
10 nator center for such loans;

11 “(3) transfer loans funds to loan originator cen-
12 ters;

13 “(4) monitor activities performed by loan origi-
14 nator centers under subsection (d) and loan service
15 centers under subsection (e); and

16 “(5) monitor the rate at which eligible health
17 care providers default on such loans made to such
18 providers.

19 “(d) ORIGINATION OF LOANS.—

20 “(1) FUNDS FOR ORIGINATION OF LOANS.—The
21 Secretary shall provide funds, out of funds available
22 pursuant to subsection (a), for loans under this sec-
23 tion through a loan originator center to an eligible
24 health care provider.

1 “(2) CONTRACTS WITH LOAN ORIGINATOR CEN-
2 TERS.—The Secretary of Health and Human Serv-
3 ices shall enter into contracts with loan originator
4 centers under which the loan originator centers
5 shall, with respect to loans under subsection (a)—

6 “(A) assess applications submitted under
7 subsection (b);

8 “(B) originate such loans to eligible pro-
9 viders in accordance with this section, including
10 request loan funds from the Secretary for an eli-
11 gible provider, disburse loan funds to an eligi-
12 ble provider, and notify the Secretary that such
13 funds have been disbursed;

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

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

20 “(E) perform administrative functions, as
21 determined by the Secretary necessary to the
22 origination of loan funds, including monthly ac-
23 count reconciliation.

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

1 Human Services shall enter into contracts with loan serv-
2 ice centers under which the loans service centers shall,
3 with respect to loan funds disbursed to an eligible health
4 care provider—

5 “(1) monitor the eligibility status of such pro-
6 viders to receive such loan funds;

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

11 “(3) conduct initial collection services on delin-
12 quent payments by such providers for loans under
13 this section; and

14 “(4) transfer loans in default to a debt collec-
15 tion system.

16 “(f) TERMS AND CONDITIONS OF LOANS.—

17 “(1) AMOUNTS OF LOANS.—

18 “(A) DETERMINATION OF AMOUNTS.—The
19 determination of the amount of a loan made
20 under subsection (a) to an eligible health care
21 provider shall be calculated, in accordance with
22 a methodology specified by the Secretary, based
23 on the projected health IT cost and the size of
24 the provider (as determined by a method speci-
25 fied by the Secretary.

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

8 “(2) LOAN LIMITS.—

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

13 “(B) CREATION OF LOAN LIMIT CAT-
14 EGORIES.—For purposes of subparagraph (A),
15 the Secretary shall create categories of eligible
16 health care providers that represent various
17 ranges of health IT costs to such providers and
18 sizes of such providers. The Secretary shall as-
19 sign to each category a value that shall be the
20 maximum amount for a loan made under the
21 Loan Program to an eligible health care pro-
22 vider whose projected health IT cost and whose
23 size correspond with the range of costs and
24 sizes represented by such category.

25 “(3) INTEREST RATES.—

1 “(A) DETERMINATION OF INTEREST
2 RATE.—Subject to subparagraph (B), the appli-
3 cable rate of interest for a loan under this sec-
4 tion, during any 12-month period beginning on
5 July 1 and ending on June 30 shall be deter-
6 mined on the preceeding June 1 and be equal
7 to—

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

11 “(ii) 3.1 percent.

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

15 “(C) INTEREST RATE DISCOUNTS.—The
16 Secretary may prescribe by regulation such re-
17 ductions in the interest rate paid by an eligible
18 health care provider for a loan under subsection
19 (a) as the Secretary determines appropriate to
20 encourage on-time repayment of the loan. Such
21 reductions may be offered only if the Secretary
22 determines the reductions are cost neutral and
23 in the best financial interest of the Federal
24 Government.

1 “(4) ORIGINATION FEES.—The Secretary shall
2 charge an eligible health care provider who receives
3 a loan under subsection (a) an origination fee of 4
4 percent of the principal amount of loan and, if appli-
5 cable, a fee for loan insurance.

6 “(g) REPAYMENT OF LOANS.—

7 “(1) REPAYMENT PLANS.—

8 “(A) DESIGN AND SELECTION.—

9 “(i) IN GENERAL.—Consistent with
10 criteria established by the Secretary, the
11 Secretary shall offer an eligible health care
12 provider who receives a loan under the
13 Loan Program (and the provider may
14 choose one of) the plans for repayment of
15 such loan, including repayment of principal
16 and interest on such loan, described in
17 clause (ii). Such criteria shall be different
18 for eligible health care providers that are
19 physicians or medical groups, or that are
20 DSH qualifying facilities described in
21 clause (iii) or (iv) of section
22 1150A(j)(3)(B), in order to take into ac-
23 count the different financial ability of such
24 providers to repay loans made. The Sec-
25 retary shall allow the provider to accel-

1 erate, without penalty, repayment on the
2 loans involved.

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

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

9 “(II) INCOME CONTINGENT RE-
10 PAYMENT PLAN.—An income contin-
11 gent repayment plan, with varying
12 monthly payment amounts based on
13 the income of the eligible health care
14 provider involved, paid over an ex-
15 tended period of time prescribed by
16 the Secretary, not to exceed 25 years.

17 “(B) SELECTION BY SECRETARY.—If an
18 eligible health care provider that receives a loan
19 under the Loan Program does not select a re-
20 payment plan for such loan described in sub-
21 paragraph (A)(ii), the Secretary shall select the
22 repayment plan described in subclause (I) of
23 such subsection.

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

1 the Loan Program may change the selection of
2 such provider of a repayment plan under sub-
3 paragraph (A)(ii), or the Secretary's selection
4 of a plan for the provider under subparagraph
5 (B), as the case may be, under such terms and
6 conditions as may be established by the Sec-
7 retary.

8 “(D) ALTERNATIVE REPAYMENT PLANS.—

9 The Secretary may provide, on a case by case
10 basis, an alternative repayment plan to an eligi-
11 ble health care provider that receives a loan
12 under the Loan Program who demonstrates to
13 the satisfaction of the Secretary that the terms
14 and conditions of the repayment plans available
15 under subparagraph (A)(ii) are not adequate to
16 accommodate an exceptional circumstance of
17 the provider. In designing such an alternative
18 repayment plan, the Secretary shall ensure that
19 such plan does not exceed the cost to the Fed-
20 eral Government, as determined on the basis of
21 the present value of future payments by such
22 providers, of loans made using the plans avail-
23 able under subparagraph (A)(ii).

24 “(2) REPAYMENT RELIEF.—

1 “(A) REQUIRED PROGRAM FOR LOAN FOR-
2 GIVENESS.—The Secretary shall, in accordance
3 with guidelines specified by the Secretary, es-
4 tablish a program for the forgiveness of a loan
5 provided under the Loan Program to an eligible
6 health care provider that is—

7 “(i) a physician or medical group that
8 serves a medically underserved population,
9 as defined in section 330(a)(3) of the Pub-
10 lic Health Service Act; or

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

14 “(B) AUTHORITY FOR ADDITIONAL RE-
15 LIEF.—The Secretary may, in accordance with
16 guidelines specified by the Secretary, provide
17 for the deferment, forbearance, consolidation,
18 discharge, or forgiveness of another loan pro-
19 vided under the Loan Program.

20 “(3) LOAN DEFAULT.—

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

24 “(i) the provider fails to make a pay-
25 ment amount for the loan by the date re-

1 required by the repayment plan of the pro-
2 vider and has failed to make such repay-
3 ment for at least 180 consecutive days; or

4 “(ii) the provider otherwise violates
5 the terms of the promissory note for the
6 loan made to the provider and continues to
7 violate such terms for 180 days.

8 “(B) CONSEQUENCES OF DEFAULT.—If,
9 under subparagraph (A), an eligible health care
10 provider defaults on a loan made under sub-
11 section (a), the Secretary may—

12 “(i) report such default to a major
13 credit bureau;

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

17 “(iii) garnish wages or profits of the
18 provider;

19 “(iv) except for a provider that makes
20 payment amounts for at least six consecu-
21 tive months for such loan in default, dis-
22 qualify the provider from any further loans
23 under subsection (a); and

1 “(v) pursue litigation against the pro-
2 vider for purposes of recovering the
3 amount of the loan in default.

4 “(h) ADMINISTRATIVE PROVISIONS.—The Secretary
5 shall issue regulations for purposes of carrying out the
6 Loans Program. The regulations shall include measures
7 to ensure compliance of loan originator centers, loan serv-
8 ice centers, and eligible health care providers with the
9 Loan Program.

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

11 “(1) LOAN ORIGINATOR CENTERS.—The term
12 ‘loan originator center’ means an entity with the ca-
13 pacity to perform the duties under subsection (d)(2)
14 and with which the Secretary of Health and Human
15 Services enters into a contract under such sub-
16 section.

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

22 “(3) HEALTH CARE PROVIDER.—The term
23 ‘health care provider’ means—

1 “(A) a health care provider defined in sec-
2 tion 1171(3), including a critical access hos-
3 pital; and

4 “(B) a federally qualified health center de-
5 fined in section 1861(aa)(4).

6 “(4) ELIGIBLE HEALTH CARE PROVIDER.—The
7 term ‘eligible health care provider’ means a health
8 care provider that is eligible under subsection (b) to
9 receive a loan under subsection (a).

10 “(j) EFFECTIVE DATE.—Loans under this section
11 shall be available to eligible health care providers starting
12 on the date that is one year after the date of the enact-
13 ment of this section.”.

14 (b) STUDY ON HEALTH CARE PROVIDER HIT LOAN
15 PROGRAM SAVINGS; HIT IMPLEMENTATION INCEN-
16 TIVES.—

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

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

1 mation technology financed through loans made
2 under the Health Care Provider HIT Loan Pro-
3 gram under section 1150B of the Social Secu-
4 rity Act, as added by subsection (a).

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

11 (C) FEDERAL ENTITY OFFICER DE-
12 SCRIBED.—For purposes of this paragraph, a
13 Federal entity officer is each of the following:

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

16 (ii) The Commissioner of the Medi-
17 care Payment Advisory Commission
18 (MedPAC), established by the Balanced
19 Budget Act of 1997 (Public Law 105–33).

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

23 (iv) The Director of the Congressional
24 Budget Office.

25 (2) HIT IMPLEMENTATION INCENTIVES.—

1 (A) STUDY.—The Secretary of Health and
2 Human Services, through the Administrator of
3 the Centers for Medicare and Medicaid Services
4 and after consultation with the Agency for
5 Healthcare Research and Quality, health care
6 providers, and other interested parties, shall
7 specify methods to incentivize the purchase and
8 implementation of health information tech-
9 nology systems. Such incentives may include
10 certain payment incentives made by the Federal
11 Government to entities, such as prompt claims
12 payments, payment differentials, cost differen-
13 tials, direct payments for services provided
14 through health information technology, and
15 bonus payments for meeting quality outcomes.

16 (B) IMPLEMENTATION.—Not later than 18
17 months after the date of the enactment of this
18 Act, the Secretary of Health and Human Serv-
19 ices shall implement the methods specified in
20 subparagraph (A).

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

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

1 “(4)(A) For purposes of this subsection, a payment
2 described in paragraph (1) does not include any nonmone-
3 tary remuneration (in the form of permitted support)
4 made by a hospital or critical access hospital to a physi-
5 cian if—

6 “(i) such remuneration is made (or is believed
7 in good faith to be made) without regard to the
8 amount or quality of referrals made or business gen-
9 erated by the physician to the critical access hospital
10 or hospital; and

11 “(ii) in the case of such remuneration made on
12 or after the date that is four years after the date de-
13 scribed in section 5(d)(2) of the Electronic Health
14 Information Technology Act of 2006, such remu-
15 neration is made (or is believed in good faith to be
16 made) in accordance with the criteria (relating to
17 compliance with interoperability standards) estab-
18 lished by the Secretary under section 5(e) of such
19 Act.

20 “(B) For purposes of subparagraph (A) and sections
21 1128B(b)(3)(J) and 1877(e)(9), the term ‘permitted sup-
22 port’ means any equipment, item, information, right, li-
23 cense, intellectual property, software, or service (or fund-
24 ing used exclusively to provide or pay for such equipment,
25 item, information, right, license, intellectual property,

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

3 (b) FOR CRIMINAL PENALTIES.—Section
4 1128B(b)(3) of such Act (42 U.S.C. 1320a–7b(b)(3)) is
5 amended—

6 (1) in subparagraph (G), by striking “and” at
7 the end;

8 (2) in the subparagraph (H) added by section
9 237(d) of the Medicare Prescription Drug, Improve-
10 ment, and Modernization Act of 2003 (Public Law
11 108–173; 117 Stat. 2213)—

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

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

16 (3) in the subparagraph (H) added by section
17 431(a) of such Act (117 Stat. 2287)—

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

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

22 (C) by striking the period at the end and
23 inserting “; and”; and

24 (4) by adding at the end the following new sub-
25 paragraph:

1 “(J) any nonmonetary remuneration (in the
2 form of permitted support, as defined in section
3 1128A(b)(4)(B)) made to a person if—

4 “(i) such remuneration is solicited or re-
5 ceived (or offered or paid) (or believed in good
6 faith to be solicited, received, offered, or paid)
7 without regard to the amount or quality of re-
8 ferrals made or business generated by the per-
9 son; and

10 “(ii) in the case of such remuneration
11 made on or after the date that is four years
12 after the date described in section 5(d)(2) of
13 the Electronic Health Information Technology
14 Act of 2006, such remuneration is solicited or
15 received (or offered or paid) (or believed in
16 good faith to be solicited, received, offered, or
17 paid) in accordance with the criteria (relating
18 to compliance with interoperability standards)
19 established by the Secretary under section 5(e)
20 of such Act.”.

21 (c) FOR LIMITATION ON CERTAIN PHYSICIAN RE-
22 FERRALS.—Section 1877(e) of such Act (42 U.S.C.
23 1395nn(e)) is amended by adding at the end the following
24 new paragraph:

1 “(9) INFORMATION TECHNOLOGY AND TRAIN-
2 ING SERVICES.—Any nonmonetary remuneration (in
3 the form of permitted support, as defined in section
4 1128A(b)(4)(B)) made by an entity to a physician
5 if—

6 “(A) such remuneration is made (or be-
7 lieved in good faith to be made) without regard
8 to the amount or quality of referrals made or
9 business generated by the physician to the enti-
10 ty; and

11 “(B) in the case of such remuneration
12 made on or after the date that is four years
13 after the date described in section 5(d)(2) of
14 the Electronic Health Information Technology
15 Act of 2006, such remuneration is made (or be-
16 lieved in good faith to be made) in accordance
17 with the criteria (relating to compliance with
18 interoperability standards) established by the
19 Secretary under section 5(e) of such Act.”.

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

22 (1) REGULATIONS.—

23 (A) IN GENERAL.—Subject to subpara-
24 graph (B) and not later than the date that is
25 180 days after the date of the enactment of this

1 Act, the Secretary of Health and Human Serv-
2 ices shall issue such regulations as may be nec-
3 essary to carry out the provisions of this sec-
4 tion.

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

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

17 (2) EFFECTIVE DATE.—The amendments made
18 by this section shall take effect on the date that is
19 180 days after the date of the enactment of this Act.

20 (3) EFFECT OF STATE LAWS.—No State (as de-
21 fined in section 1101(a)) shall have in effect a State
22 law that imposes a criminal or civil penalty for a
23 transaction described in section 1128A(b)(4);
24 1128B(b)(3)(J); or 1877(e)(9) of the Social Security
25 Act, as added by this section, if—

1 (A) the conditions described in the respec-
2 tive section, with respect to such transaction,
3 are met; or

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

7 (4) SAFE HARBORS DESCRIBED.—For purposes
8 of paragraphs (1) and subsection (e), the safe har-
9 bors described in this paragraph are—

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

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

18 (C) the safe harbor under paragraph (9) of
19 section 1877(e) of such Act (42 U.S.C.
20 1395nn(e)), as added by subsection (e).

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

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

11 (1) WIDE ACCEPTANCE OF STANDARD.—The
12 standard is widely accepted within the health care
13 industry and has been used within the industry for
14 a sufficient amount of time to ensure successful im-
15 plementation.

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

19 (3) COST BENEFIT ANALYSIS.—The results of a
20 cost benefit test conducted to determine the effect of
21 applying the standard for purposes of the safe har-
22 bors described in subsection (d)(4).

1 **SEC. 6. UNIFORM FEDERAL AND STATE HEALTH INFORMA-**
2 **TION STANDARDS.**

3 (a) STUDY TO DETERMINE EXTENT OF VARIATION
4 IN STATE HEALTH INFORMATION LAWS AND REGULA-
5 TIONS.—

6 (1) IN GENERAL.—The Secretary of Health and
7 Human Services shall conduct a study of State laws
8 and regulations relating to the security and con-
9 fidentiality of individually identifiable health infor-
10 mation to determine—

11 (A) the degree to which such laws and reg-
12 ulations vary among States, and between the
13 States and the Federal privacy standards estab-
14 lished pursuant to section 264(c) of the Health
15 Insurance Portability and Accountability Act of
16 1996 (42 U.S.C. 1320d–2 note) and security
17 standards established under section 1173(d) of
18 the Social Security Act; and

19 (B) how any such variation may adversely
20 impact the electronic exchange of clinical health
21 information among States, the Federal Govern-
22 ment, and private entities.

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

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

3 (A) a determination by the Secretary
4 whether the State laws and regulations de-
5 scribed in such paragraph should be conformed
6 to a set of Federal standards to protect the se-
7 curity and confidentiality of patient health in-
8 formation and to improve health care quality or
9 efficiency; and

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

13 (3) STATE DEFINED.—For purposes of this
14 subsection, the term “State” has the meaning given
15 such term when used in title XI of the Social Secu-
16 rity Act, as provided under section 1101(a) of such
17 Act (42 U.S.C. 1301(a)).

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

21 (1) IN GENERAL.—Section 1178(a) of the So-
22 cial Security Act (42 U.S.C. 1320d–7(a)) is amend-
23 ed—

1 (A) in paragraph (1) by inserting after
2 “Except as provided in paragraph (2)” the fol-
3 lowing: “and subject to paragraph (3)”; and

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

6 “(3) UNIFORM STANDARDS.—

7 “(A) IN GENERAL.—If legislation to create
8 uniform Federal standards, and to preempt
9 State laws, with respect to the confidentiality
10 and security of individually identifiable health
11 information is not enacted by Congress on the
12 date that is 36 months after the date of the en-
13 actment of the Electronic Health Information
14 Technology Act of 2006, the regulation and
15 standards described in subparagraph (B) shall
16 supersede any contrary provision of State law.

17 “(B) APPLICATION OF UNIFORM STAND-
18 ARDS.—The regulation and standards described
19 in this subparagraph are the regulation promul-
20 gated under section 264(c)(1) of the Health In-
21 surance Portability and Accountability Act of
22 1996 and the standards under section 1173(d),
23 as modified by the Secretary to the extent the
24 Secretary determines, after consideration of the
25 results of the study conducted under section

1 6(a) of the Electronic Health Information Tech-
2 nology Act of 2006, necessary to promote uni-
3 form national standards.”.

4 (2) HIPAA CONFORMING AMENDMENT.—Sec-
5 tion 264(c)(2) of the Health Insurance Portability
6 and Accountability Act of 1996 (42 U.S.C. 1320d-
7 2 note) is amended by striking “A regulation” and
8 inserting “(A) Subject to section 1178(a)(3) of the
9 Social Security Act, a regulation”.

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