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HEALTH INFORMATION TECHNOLOGY PROMOTION ACT OF 2006

JULY 26, 2006.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. THOMAS, from the Committee on Ways and Means, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 4157]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 4157) to amend the Social Security Act to encourage the dissemination, security, confidentiality, and usefulness of health information technology, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

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

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

Sec. 1. Short title and table of contents.
Sec. 2. Office of the National Coordinator for Health Information Technology.
Sec. 3. Safe harbors for provision of health information technology and services to health care professionals.
Sec. 4. Commonality and variation in health information laws and regulations.
Sec. 5. Implementing modern coding system; application under part A of the Medicare program.
Sec. 6. Procedures to ensure timely updating of standards that enable electronic exchanges.
Sec. 7. Report on the American Health Information Community.
Sec. 8. Strategic plan for coordinating implementation of health information technology.
Sec. 9. Promotion of telehealth services.

SEC. 2. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

(a) IN GENERAL.—Title II of the Public Health Service Act is amended by adding at the end the following new part:

"PART D—HEALTH INFORMATION TECHNOLOGY

"SEC. 271. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

"(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology that shall be headed by the National Coordinator for Health Information Technology (referred to in this section as the 'National Coordinator'). The National Coordinator shall be appointed by the President and shall report directly to the Secretary. The National Coordinator shall be paid at a rate equal to the rate of basic pay for level IV of the Executive Schedule.

"(b) GOALS OF NATIONWIDE INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide interoperable health information technology infrastructure that—

"(1) improves health care quality, reduces medical errors, increases the efficiency of care, and advances the delivery of appropriate, evidence-based health care services;

"(2) promotes wellness, disease prevention, and management of chronic illnesses by increasing the availability and transparency of information related to the health care needs of an individual for such individual;

"(3) ensures that appropriate information necessary to make medical decisions is available in a usable form at the time and in the location that the medical service involved is provided;

"(4) produces greater value for health care expenditures by reducing health care costs that result from inefficiency, medical errors, inappropriate care, and incomplete information;

"(5) promotes a more effective marketplace, greater competition, greater systems analysis, increased choice, enhanced quality, and improved outcomes in health care services;

"(6) improves the coordination of information and the provision of such services through an effective infrastructure for the secure and authorized exchange and use of health care information; and

"(7) ensures that the confidentiality of individually identifiable health information of a patient is secure and protected.

"(c) DUTIES OF NATIONAL COORDINATOR.—

"(1) STRATEGIC PLANNER FOR INTEROPERABLE HEALTH INFORMATION TECHNOLOGY.—The National Coordinator shall maintain, direct, and oversee the continuous improvement of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors consistent with subsection (b).

"(2) PRINCIPAL ADVISOR TO HHS.—The National Coordinator shall serve as the principal advisor of the Secretary on the development, application, and use of health information technology, and coordinate the health information technology programs of the Department of Health and Human Services.

"(3) COORDINATOR OF FEDERAL GOVERNMENT ACTIVITIES.—

"(A) IN GENERAL.—The National Coordinator shall serve as the coordinator of Federal Government activities relating to health information technology.

"(B) SPECIFIC COORDINATION FUNCTIONS.—In carrying out subparagraph (A), the National Coordinator shall provide for—

"(i) the development and approval of standards used in the electronic creation, maintenance, or exchange of health information; and

"(ii) the certification and inspection of health information technology products, exchanges, and architectures to ensure that such products, exchanges, and architectures conform to the applicable standards approved under clause (i).

"(C) USE OF PRIVATE ENTITIES.—The National Coordinator shall, to the maximum extent possible, contract with or recognize private entities in carrying out subparagraph (B).

"(D) UNIFORM APPLICATION OF STANDARDS.—A standard approved under subparagraph (B)(i) for use in the electronic creation, maintenance, or exchange of health information shall preempt a standard adopted under State law, regulation, or rule for such a use.

"(4) INTRAGOVERNMENTAL COORDINATOR.—The National Coordinator shall ensure that health information technology policies and programs of the Department of Health and Human Services are coordinated with those of relevant executive branch agencies and departments with a goal to avoid duplication of effort and to ensure that each agency or department conducts programs within the areas of its greatest expertise and its mission in order to create a national interoperable health information system capable of meeting national public health needs effectively and efficiently.

"(5) ADVISOR TO OMB.—The National Coordinator shall provide to the Director of the Office of Management and Budget comments and advice with respect to specific Federal health information technology programs.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for each of fiscal years 2006 through 2010.".

(b) TREATMENT OF EXECUTIVE ORDER 13335.—Executive Order 13335 shall not have any force or effect after the date of the enactment of this Act.

(c) TRANSITION FROM ONCHIT UNDER EXECUTIVE ORDER.—

(1) IN GENERAL.—All functions, personnel, assets, liabilities, administrative actions, and statutory reporting requirements applicable to the old National Coordinator or the Office of the old National Coordinator on the date before the date of the enactment of this Act shall be transferred, and applied in the same manner and under the same terms and conditions, to the new National Coordinator and the Office of the new National Coordinator as of the date of the enactment of this Act.

(2) ACTING NATIONAL COORDINATOR.—Before the appointment of the new National Coordinator, the old National Coordinator shall act as the National Coordinator for Health Information Technology until the office is filled as provided in section 271(a) of the Public Health Service Act, as added by subsection (a). The President may appoint the old National Coordinator as the new National Coordinator.

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

(A) NEW NATIONAL COORDINATOR.—The term "new National Coordinator" means the National Coordinator for Health Information Technology appointed under section 271(a) of the Public Health Service Act, as added by subsection (a).

(B) OLD NATIONAL COORDINATOR.—The term "old National Coordinator" means the National Coordinator for Health Information Technology appointed under Executive Order 13335.

SEC. 3. SAFE HARBORS FOR PROVISION OF HEALTH INFORMATION TECHNOLOGY AND SERVICES TO HEALTH CARE PROFESSIONALS.

(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 health information technology and related services) made on or after the HIT effective date (as defined in subparagraph (B)(ii)) by a hospital or critical access hospital to a physician if the following requirements are met:

"(i) The provision of such remuneration is made without a condition that—

"(I) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the location of the hospital or critical access hospital providing such technology;

"(II) limits or restricts the use of the health information technology in conjunction with other health information technology; or

"(III) takes into account the volume or value of referrals (or other business generated) by the physician to the hospital or critical access hospital.

"(ii) Such remuneration is arranged for in a written agreement that is signed by a representative of the hospital or critical access hospital and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.

"(B) For purposes of subparagraph (A) and sections 1128B(b)(3)(J) and 1877(e)(9)—

"(i) the term 'health information technology' means hardware, software, license, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) or related services used for the electronic creation, maintenance, and exchange of clinical health information; and

"(ii) the term 'HIT effective date' means the date that is 180 days after the date of the enactment of this paragraph.".

(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) as 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 health information technology, as defined in section 1128A(b)(4)(B)(i), and related services) solicited or received by a person on or after the HIT effective date (as defined in section 1128A(b)(4)(B)(ii)) (or offered or paid to a person on or after such date) if—

"(i) such remuneration is solicited or received (or offered or paid) without a condition that—

"(I) limits or restricts the use of the health information technology to services provided by the person to individuals receiving services at the location of the entity providing such technology;

"(II) limits or restricts the use of the health information technology in conjunction with other health information technology; or

"(III) takes into account the volume or value of referrals (or other business generated) by the person to the entity providing such technology; and

"(ii) such remuneration is arranged for in a written agreement that is signed by a representative of the entity and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.".

(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 SERVICES.—Any nonmonetary remuneration (in the form of health information technology, as defined in section 1128A(b)(4)(B)(i), and related services) made on or after the HIT effective date (as defined in section 1128A(b)(4)(B)(ii)) by an entity to a physician if the following requirements are met:

"(A) The provision of such remuneration is made without a condition that—

"(i) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the location of the entity providing such technology;

"(ii) limits or restricts the use of the health information technology in conjunction with other health information technology; or

"(iii) takes into account the volume or value of referrals (or other business generated) by the physician to the entity providing such technology.

"(B) Such remuneration is arranged for in a written agreement that is signed by a representative of the entity and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.".

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

(1) REGULATIONS.—Not later than the HIT effective date, the Secretary of Health and Human Services shall promulgate such regulations as may be necessary to carry out the provisions of this section.

(2) HIT EFFECTIVE DATE DEFINED.—For purposes of this subsection and subsection (e), the term "HIT effective date" has the meaning given such term in section 1128A(b)(4)(B)(ii) of the Social Security Act, as added by subsection (a).

(3) PREEMPTION OF STATE LAWS.—No State (as defined in section 4(c)(3)) 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 the conditions described in the respective section of such Act, with respect to such transaction, are met.

(e) STUDY AND REPORT TO ASSESS EFFECT OF SAFE HARBORS AND EXCEPTION ON HEALTH SYSTEM.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the impact of each of the safe harbors and the exception described in paragraph (3). In particular, the study shall examine the following:

(A) The effectiveness of each safe harbor and exception in increasing the adoption of health information technology.

(B) The types of health information technology provided under each safe harbor and exception.

(C) The extent to which the financial or other business relationships between providers under each safe harbor or exception have changed as a result of the safe harbor or exception in a way that affects the health care system, affects choices available to consumers, or affects health care expenditures.

(2) REPORT.—Not later than three years after the HIT effective date, the Secretary of Health and Human Services shall submit to Congress a report on the study under paragraph (1) and shall include such recommendations for changes in the safe harbors and exception as the Secretary determines may be appropriate.

(3) SAFE HARBORS AND EXCEPTION DESCRIBED.—For purposes of this subsection, the safe harbors and exception described in this paragraph are—

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

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

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

SEC. 4. COMMONALITY AND VARIATION IN HEALTH INFORMATION LAWS AND REGULATIONS.

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

(1) IN GENERAL.—For purposes of promoting the development of a nationwide interoperable health information technology infrastructure consistent with section 271(b) of the Public Health Service Act (as added by section 2(a)), the Secretary of Health and Human Services shall conduct a study of the impact of variation in State security and confidentiality laws and current Federal security and confidentiality standards on the timely exchanges of health information in order to ensure the availability of health information necessary to make medical decisions at the location in which the medical care involved is provided. Such study shall examine—

(A)(i) the degree of variation and commonality among the requirements of such laws for States; and

(ii) the degree of variation and commonality between the requirements of such laws and the current Federal standards;

(B) insofar as there is variation among and between such requirements, the strengths and weaknesses of such requirements; and

(C) the extent to which such variation may adversely impact the secure, confidential, and timely exchange of health information among States, the Federal government, and public and private entities, or may otherwise impact the reliability of such information.

(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 Congress a

report on the study under paragraph (1) and shall include in such report the following:

(A) ANALYSIS OF NEED FOR GREATER COMMONALITY.—A determination by the Secretary on the extent to which there is a need for greater commonality of the requirements of State security and confidentiality laws and current Federal security and confidentiality standards to better protect or strengthen the security and confidentiality of health information in the timely exchange of health information among States, the Federal government, and public and private entities.

(B) RECOMMENDATIONS FOR GREATER COMMONALITY.—Insofar as the Secretary determines under subparagraph (A) that there is a need for greater commonality of such requirements, the extent to which (and how) the current Federal standards should be changed, and the extent to which (and how) the State laws should be conformed, in order to provide the commonality needed to better protect or strengthen the security and confidentiality of health information in the timely exchange of health information.

(b) IMPLEMENTATION OF RECOMMENDATIONS IF CONGRESS FAILS TO ACT.—

(1) IN GENERAL.—If the conditions under paragraph (2) are met, the Secretary shall, by regulation, modify the current Federal security and confidentiality standards to the extent that the Secretary determines it necessary in order to achieve the needed degree of commonality to better protect or strengthen the security and confidentiality of health information in the timely exchange of health information. Such a modification shall be based upon the recommendations described in subsection (a)(2)(B), and if the Secretary modifies a current Federal security and confidentiality standard, the modified standard shall supersede (and the Secretary shall limit the permissibility of) any State security and confidentiality law that relates to (but is different from) such standard.

(2) CONDITIONS.—The conditions under this paragraph are the following:

(A) NEED FOR GREATER COMMONALITY.—The Secretary determines under subsection (a)(2)(A) that there is a need for greater commonality in the requirements of State security and confidentiality laws and current Federal security and confidentiality standards to better protect or strengthen the security and confidentiality of health information in the timely exchange of health information among States, the Federal government, and public and private entities.

(B) CONGRESSIONAL FAILURE TO ACT.—The Congress fails to enact, within 18 months after the date of receipt of the report under subsection (a)(2), legislation that specifically responds to the recommendations described in subsection (a)(2)(B). Such legislation may include any action described in paragraph (1) (relating to modifying Federal security and confidentiality standards).

(3) TREATMENT OF CURRENT LAWS AND STANDARDS.—

(A) CONTINUATION OF CURRENT FEDERAL STANDARDS AND STATE LAWS PERMITTED.—Nothing in this subsection shall be construed as preventing the Secretary from continuing to apply the current Federal security and confidentiality standards and from permitting the continuance of State security and confidentiality laws if such standards are not modified.

(B) NO PREEMPTION OF STATE LAW UNLESS RULE ADOPTED.—A State security and confidentiality law shall not be preempted under paragraph (1), except to the extent the Secretary limits the application of such law under such paragraph. The Secretary's exercise of such authority supercedes the provisions of section 1178(a) of the Social Security Act (42 U.S.C. 1320d–7(a)) and section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

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

(1) CURRENT FEDERAL SECURITY AND CONFIDENTIALITY STANDARDS.—The term "current Federal security and confidentiality standards" means 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.

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

(3) STATE.—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)).

(4) STATE SECURITY AND CONFIDENTIALITY LAWS.—The term "State security and confidentiality laws" means State laws and regulations relating to the privacy and confidentiality of health information or to the security of such information.

(d) CONFORMING AMENDMENTS.—

(1) HIPAA.—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 "Subject to section 4(b) of the Health Information Technology Promotion Act of 2006, a regulation".

(2) TITLE XI.—Section 1178(a) of the Social Security Act (42 U.S.C. 1320d–7(a)) is amended, in the matter preceding paragraph (1), by inserting "Subject to section 4(b) of the Health Information Technology Promotion Act of 2006—" after "GENERAL EFFECT.—".

SEC. 5. IMPLEMENTING MODERN CODING SYSTEM; APPLICATION UNDER PART A OF THE MEDICARE PROGRAM.

(a) UPGRADING ASC X12 AND NCPDP STANDARDS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall provide by notice published in the Federal Register for the following replacements of standards to apply, including for purposes of part A of title XVIII of such Act:

(A) ACCREDITED STANDARDS COMMITTEE X12 (ASC X12) STANDARD.—The replacement of the Accredited Standards Committee X12 (ASC X12) version 4010 adopted under section 1173(a) of such Act (42 U.S.C. 1320d–2(a)) with the ASC X12 version 5010, as reviewed by the National Committee on Vital Health Statistics.

(B) NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS (NCPDP) TELECOMMUNICATIONS STANDARDS.—The replacement of the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standards version 5.1 adopted under section 1173(a) of such Act (42 U.S.C. 1320d–2(a)) with whichever is the latest version (as determined by the Secretary) of the NCPDP Telecommunications Standards that has been approved by such Council and reviewed by the National Committee on Vital Health Statistics as of April 1, 2008.

(2) APPLICATION.—The replacements made by paragraph (1) shall apply, for purposes of section 1175(b)(2) of the Social Security Act (42 U.S.C. 1320d–4(b)(2)), to transactions occurring on or after April 1, 2009.

(3) NO JUDICIAL REVIEW.—The determination of the latest version under paragraph (1)(B) shall not be subject to judicial review.

(b) UPGRADING ICD CODES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall provide by notice published in the Federal Register for the replacement of the International Classification of Diseases, 9th revision, Clinical Modification (ICD–9–CM) under the regulation promulgated under section 1173(c) of the Social Security Act (42 U.S.C. 1320d–2(c)), including for purposes of part A of title XVIII of such Act, with both of the following:

(A) The International Classification of Diseases, 10th revision, Clinical Modification (ICD–10–CM).

(B) The International Classification of Diseases, 10th revision, Procedure Coding System (ICD–10–PCS).

(2) APPLICATION .—The replacement made by paragraph (1) shall apply, for purposes of section 1175(b)(2) of the Social Security Act (42 U.S.C. 1320d–4(b)(2)), to services furnished on or after October 1, 2009.

(3) RULES OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

(A) as affecting the application of classification methodologies or codes, such as CPT or HCPCS codes, other than under the International Classification of Diseases (ICD); or

(B) as superseding the authority of the Secretary of Health and Human Services to maintain and modify the coding set for ICD–10–CM and ICD–10–PCS, including under the amendments made by section 6.

(c) APPLICATION OF UPGRADED STANDARDS UNDER PART A OF THE MEDICARE PROGRAM.—Section 1816 of the Social Security Act (42 U.S.C. 1395h) is amended by inserting after subsection (a) the following new subsection:

"(b) With respect to—

"(1) transactions under this part occurring on or after April 1, 2009, all providers of services shall use ASC X12 version 5010 with respect to services provided under this part in compliance with section 5(a) of the Health Information Technology Promotion Act of 2006; and

"(2) services furnished on or after October 1, 2009—

"(A) all providers of services shall use ICD–10–CM codes with respect to services provided under this part in compliance with section 5(b) of such Act; and

"(B) hospitals shall use ICD–10–PCS codes (as well as ICD–10–CM codes) with respect to inpatient hospital services provided under this part in compliance with such section.".

SEC. 6. PROCEDURES TO ENSURE TIMELY UPDATING OF STANDARDS THAT ENABLE ELECTRONIC EXCHANGES.

Section 1174(b) of the Social Security Act (42 U.S.C. 1320d–3(b)) is amended—

(1) in paragraph (1)—

(A) in the first sentence, by inserting "and in accordance with paragraph (3)" before the period; and

(B) by adding at the end the following new sentence: "For purposes of this subsection and section 1173(c)(2), the term 'modification' includes a new version or a version upgrade."; and

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

"(3) EXPEDITED PROCEDURES FOR ADOPTION OF ADDITIONS AND MODIFICATIONS TO STANDARDS.—

"(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall provide for an expedited upgrade program (in this paragraph referred to as the 'upgrade program'), in accordance with this paragraph, to develop and approve additions and modifications to the standards adopted under section 1173(a) to improve the quality of such standards or to extend the functionality of such standards to meet evolving requirements in health care.

"(B) PUBLICATION OF NOTICES.—Under the upgrade program:

"(i) VOLUNTARY NOTICE OF INITIATION OF PROCESS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization is initiating a process to develop an addition or modification to a standard adopted under section 1173, the Secretary shall publish a notice in the Federal Register that—

"(I) identifies the subject matter of the addition or modification;

"(II) provides a description of how persons may participate in the development process; and

"(III) invites public participation in such process.

"(ii) VOLUNTARY NOTICE OF PRELIMINARY DRAFT OF ADDITIONS OR MODIFICATIONS TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has prepared a preliminary draft of an addition or modification to a standard adopted by section 1173, the Secretary shall publish a notice in the Federal Register that—

"(I) identifies the subject matter of (and summarizes) the draft;

"(II) specifies the procedure for obtaining documentation for the draft;

"(III) provides a description of how persons may submit comments in writing and at any public hearing or meeting held by the organization on the draft; and

"(IV) invites submission of such comments and participation in such hearing or meeting.

"(iii) NOTICE OF PROPOSED ADDITION OR MODIFICATION TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has a proposed addition or modification to a standard adopted under section 1173 that the organization intends to submit under subparagraph (D)(iii), the Secretary shall publish a notice in the Federal Register that contains, with respect to the proposed addition or modification, the information required in the notice under clause (ii) with respect to a preliminary draft of an addition or modification.

"(iv) CONSTRUCTION.—Nothing in this paragraph shall be construed as requiring a standard setting organization to request the notices described in clauses (i) and (ii) with respect to an addition or modification to a standard in order to qualify for an expedited determination under subparagraph (C) with respect to a proposal submitted to the Secretary for adoption of such addition or modification.

"(C) PROVISION OF EXPEDITED DETERMINATION.—Under the upgrade program and with respect to a proposal by a standard setting organization for an addition or modification to a standard adopted under section 1173, if the Secretary determines that the standard setting organization developed such addition or modification in accordance with the requirements of subparagraph (D) and the National Committee on Vital and Health Statistics recommends approval of such addition or modification under subparagraph (E), the Secretary shall provide for expedited treatment of such proposal in accordance with subparagraph (F).

"(D) REQUIREMENTS.—The requirements under this subparagraph with respect to a proposed addition or modification to a standard by a standard setting organization are the following:

"(i) REQUEST FOR PUBLICATION OF NOTICE.—The standard setting organization submits to the Secretary a request for publication in the Federal Register of a notice described in subparagraph (B)(iii) for the proposed addition or modification.

"(ii) PROCESS FOR RECEIPT AND CONSIDERATION OF PUBLIC COMMENT.—The standard setting organization provides for a process through which, after the publication of the notice referred to under clause (i), the organization—

"(I) receives and responds to public comments submitted on a timely basis on the proposed addition or modification before submitting such proposed addition or modification to the National Committee on Vital and Health Statistics under clause (iii); and

"(II) makes publicly available a written explanation for its response in the proposed addition or modification to comments submitted on a timely basis.

"(iii) SUBMITTAL OF FINAL PROPOSED ADDITION OR MODIFICATION TO NCVHS.—After completion of the process under clause (ii), the standard setting organization submits the proposed addition or modification to the National Committee on Vital and Health Statistics for review and consideration under subparagraph (E). Such submission shall include information on the organization's compliance with the notice and comment requirements (and responses to those comments) under clause (ii).

"(E) HEARING AND RECOMMENDATIONS BY NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.—Under the upgrade program, upon receipt of a proposal submitted by a standard setting organization under subparagraph (D)(iii) for the adoption of an addition or modification to a standard, the National Committee on Vital and Health Statistics shall provide notice to the public and a reasonable opportunity for public testimony at a hearing on such addition or modification. The Secretary may participate in such hearing in such capacity (including presiding ex officio) as the Secretary shall determine appropriate. Not later than 120 days after the date of receipt of the proposal, the Committee shall submit to the Secretary its recommendation to adopt (or not adopt) the proposed addition or modification.

"(F) DETERMINATION BY SECRETARY TO ACCEPT OR REJECT NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS RECOMMENDATION.—

"(i) TIMELY DETERMINATION.—Under the upgrade program, if the National Committee on Vital and Health Statistics submits to the Secretary a recommendation under subparagraph (E) to adopt a proposed addition or modification, not later than 90 days after the date of receipt of such recommendation the Secretary shall make a determination to accept or reject the recommendation and shall publish notice of such determination in the Federal Register not later than 30 days after the date of the determination.

"(ii) CONTENTS OF NOTICE.—If the determination is to reject the recommendation, such notice shall include the reasons for the rejection. If the determination is to accept the recommendation, as part of such notice the Secretary shall promulgate the modified standard (including the accepted proposed addition or modification accepted) as a final rule under this subsection without any further notice or public comment period.

"(iii) LIMITATION ON CONSIDERATION.—The Secretary shall not consider a proposal under this subparagraph unless the Secretary determines that the requirements of subparagraph (D) (including publication of notice and opportunity for public comment) have been met with respect to the proposal.

"(G) TREATMENT AS SATISFYING REQUIREMENTS FOR NOTICE-AND-COMMENT.—Any requirements under section 553 of title 5, United States Code, relating to notice and an opportunity for public comment with respect to a final rule promulgated under subparagraph (F) shall be treated as having been met by meeting the requirements of the notice and opportunity for public comment provided under provisions of subparagraphs (B)(iii), (D), and (E).

"(H) NO JUDICIAL REVIEW.—A final rule promulgated under subparagraph (F) shall not be subject to judicial review.".

SEC. 7. REPORT ON THE AMERICAN HEALTH INFORMATION COMMUNITY.

Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the work conducted by the American Health Information Community (in this section referred to as "AHIC"), as established by the Secretary. Such report shall include the following:

(1) A description of the accomplishments of AHIC, with respect to the promotion of the development of a nationwide health information network and the increased adoption of health information technology.

(2) Information identifying the practices that are used to protect health information and to guarantee confidentiality and security of such information.

(3) Information on the progress in—

(A) establishing uniform industry-wide health information technology standards;

(B) achieving an internet-based nationwide health information network;

(C) achieving interoperable electronic health record adoption across health care providers; and

(D) making available technological and other innovations to ensure the security and confidentiality of health information in the promotion of health information technology.

(4) Recommendations for the transition of the AHIC to a permanent entity, including—

(A) a schedule for such transition;

(B) options for structuring the entity as either a public-private or private sector entity;

(C) the collaborative role of the Federal Government in the entity; and

(D) the ongoing responsibilities of the entity, such as providing the leadership and planning in establishing standards, certifying health information technology, and providing long-term governance for health care transformation through technology.

SEC. 8. STRATEGIC PLAN FOR COORDINATING IMPLEMENTATION OF HEALTH INFORMATION TECHNOLOGY.

(a) IN GENERAL.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with public and private entities involved in the area of health information technology, shall develop a strategic plan related to the need for coordination in such area.

(b) COORDINATION OF SPECIFIC IMPLEMENTATION PROCESSES.—The strategic plan under subsection (a) shall address the need for coordination in the implementation of the following:

(1) HEALTH INFORMATION TECHNOLOGY STANDARDS.—Health information technology standards approved under section 271(c)(3)(B)(i) of the Public Health Service Act, as added by section 2.

(2) HIPAA TRANSACTION STANDARDS.—Transaction standards under section 1173(a) of the Social Security Act (42 U.S.C. 1320d–2(d)).

(3) UPDATED ICD CODES.—The International Statistical Classification of Diseases and Related Health Problems, 10th revision, Clinical Modification (ICD–10–CM) and the International Statistical Classification of Diseases and Related Health Problems, 10th revision, Procedure Coding System (ICD–10–PCS) described in section 5.

(c) COORDINATION AMONG SPECIFIC FEDERAL ENTITIES.—The strategic plan under subsection (a) shall address any methods to coordinate, with respect to the electronic exchange of health information, actions taken by the following entities:

(1) The Office of the National Coordinator for Health Information Technology.

(2) The American Health Information Community.

(3) The Office of Electronic Standards and Security of the Centers for Medicare and Medicaid Services.

(4) The National Committee on Vital Health Statistics.

(5) Any other entity involved in the electronic exchange of health information that the Secretary determines appropriate.

SEC. 9. PROMOTION OF TELEHEALTH SERVICES.

(a) FACILITATING THE PROVISION OF TELEHEALTH SERVICES ACROSS STATE LINES.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall, in coordination with representatives of States, physicians, health care practitioners, and patient advocates, encourage and facilitate the adoption of State reciprocity agreements for practitioner licensure in order to expedite the provision across State lines of telehealth services.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the actions taken to carry out paragraph (1).

(3) STATE DEFINED.—In this subsection, the term "State" has the meaning given that term for purposes of title XVIII of the Social Security Act.

(b) USE OF STORE AND FORWARD TECHNOLOGY.—

(1) STUDY.—The Secretary of Health and Human Services, acting through the Director of the Office for the Advancement of Telehealth, shall conduct a study on the use of store and forward technologies (that provide for the asynchronous transmission of health care information in single or multimedia formats) in the provision of telehealth services for which payment may be made under the Medicare program. Such study shall include an assessment of the feasibility, advisability, and the costs of expanding the use of such technologies for use in the diagnosis and treatment of certain conditions.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under paragraph (1) and shall include in such report such recommendations for legislation or administration action as the Secretary determines appropriate.

(c) EXPANSION OF TELEHEALTH SERVICES.—

(1) STUDY.—The Secretary of Health and Human Services, in coordination with the Office for the Advancement of Telehealth, the Agency for Healthcare Research and Quality, and the Centers for Medicare and Medicaid Services, shall conduct a study to determine the feasibility, advisability, and the costs of—

(A) including coverage and payment for home health-related telehealth services as part of home health services under title XVIII of the Social Security Act; and

(B) expanding the list of sites described in paragraph (4)(C)(ii) of section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) to include county mental health clinics or other publicly funded mental health facilities for the purpose of payment under such section for the provision of telehealth services at such clinics or facilities.

(2) SPECIFICS OF STUDY.—Such study shall demonstrate whether the changes described in subparagraphs (A) and (B) of paragraph (1) will result in the following:

(A) Enhanced health outcomes for individuals with one or more chronic conditions.

(B) Health outcomes for individuals furnished telehealth services or home health-related telehealth services that are at least comparable to the health outcomes for individuals furnished similar items and services by a health care provider at the same location of the individual or at the home of the individual, respectively.

(C) Facilitation of communication of more accurate clinical information between health care providers.

(D) Closer monitoring of individuals by health care providers.

(E) Overall reduction in expenditures for health care items and services.

(F) Improved access to health care.

(3) HOME HEALTH-RELATED TELEHEALTH SERVICES DEFINED.—For purposes of this subsection, the term "home health-related telehealth services" means technology-based professional consultations, patient monitoring, patient training services, clinical observation, patient assessment, and any other health services that utilize telecommunications technologies. Such term does not include a telecommunication that consists solely of a telephone audio conversation, facsimile, electronic text mail, or consultation between two health care providers.

(4) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subparagraph (1) and shall include in such report such recommendations for legislation or administration action as the Secretary determines appropriate.

I. INTRODUCTION

A. PURPOSE AND SUMMARY

Broad use of information technology throughout the health care delivery system is essential to improve the quality and efficiency of health care delivery. The adoption of health information technology is increasingly necessary to deliver state of the art care to individuals with chronic illness to promote interoperability between pri-

vate and public providers and payers. Efficiencies gained by the coordinated development of health information technology will accelerate and advance private and public efforts to improve quality of care and reduce health costs.

The purpose of the Health Information Technology Promotion Act of 2006 (H.R. 4157) is to create the Office of the National Coordinator for Health Information Technology to accelerate and oversee the development of interoperability efforts in the public and private health care sectors and to coordinate Federal government activities relating to health information technology (IT). The bill would enable private sources of funding to finance physician adoption of health IT by providing exceptions and safe harbors in the fraud and abuse laws, and would provide for a study of state and federal security and confidentiality laws and regulations to ensure the protection of patient health information as the health system moves to electronic systems. In addition, the bill would direct the Secretary to modernize the procedure and diagnosis coding system, develop procedures to ensure timely updating of standards that enable electronic exchanges, study the use of telemedicine and telemonitoring services, and provide a report on the work conducted by the American Health Information Community and its role in the future. Finally, the bill would direct the Secretary to develop a strategic plan for coordinating implementation of health IT.

Office of the National Coordinator for Health Information Technology.—This bill would codify the Office of the National Coordinator for Health IT (ONCHIT) in statute and clearly delineate its ongoing roles and responsibilities. The duties of the office would include: maintaining and updating the strategic plan to guide the nationwide implementation of interoperable health IT to improve health care quality, reduce medical errors, increase the efficiency of care, and advance the delivery of appropriate evidence-based health care services; and serving as the principal advisor to the Secretary of Health and Human Services (HHS) on the use of health IT.

Duties of this office would also include serving as the coordinator of Federal government activities related to the development and maintenance of standards used in health information exchange and the certification and inspection of health IT products to ensure that such products conform to the standards noted above. Also, duties would include coordinating health IT policies and programs across Federal agencies and providing input and advice to the Office of Management and Budget regarding Federal health IT programs.

Stark/Anti-Kickback Safe Harbors.—This bill would include statutory exceptions and safe harbors in physician self-referral ("Stark" laws) and anti-kickback laws that would allow hospitals, groups practices, and other entities to provide physicians with hardware, software, or IT training and support services that are used for the electronic exchange of health information.

Further, donors of such technology may not impose conditions limiting its use by physicians to individuals who are also patients of the donor entity; nor can donors limit physicians' use of the technology in conjunction with other IT systems that physicians might utilize or condition donations based on the volume or value of referrals or business generated by the physician. This bill would also require written agreements regarding any remuneration, and would

allow this exception to preempt state laws governing self-referral and anti-kickback provisions to ensure that the federal exception can be implemented. Any gift must be for the purpose of better coordination of care, to improve quality or improve efficiency.

Privacy/Security Standards.—This bill would require the Secretary of HHS to conduct a study on the impact of variation between state security and confidentiality laws and federal security and confidentiality standards. The Secretary would report back to Congress within 18 months with recommendations on the extent to which federal standards should be modified to provide greater commonality in order to better protect or strengthen the security and confidentiality when exchanging health information.

If Congress does not enact legislation 18 months after receipt of the study, the Secretary has the authority, but is not required, to modify federal security and confidentiality standards. Any modification in federal standards would supersede State law.

Adoption of Modern Coding System.—This bill would require the Secretary to adopt the updated Health Insurance Portability and Accountability Act (HIPAA) transaction standard ASC X12 5010 (to replace ASC X12 4010) for transactions occurring on or after April 1, 2009. The standard applies to claims transactions.

This bill would also require the Secretary to update the National Council for Prescription Drug Programs (NCPDP) telecommunication standards to the latest version approved by the National Committee on Vital Health Statistics (NCVHS) as of April 1, 2009.

The Secretary is also required to adopt, per the past recommendation of the National Committee on Vital Health Statistics (NCVHS), the ICD–10 coding system for transactions occurring on or after October 1, 2009. The standard applies to coding for diagnosis and procedures, but procedures only in inpatient hospital settings.

Procedures to Ensure Timely Updating of Standards.—This bill would adopt an accelerated process for updating standards in order to keep pace with the development of technology. The Secretary is required to publish a notice in the Federal Register and to receive and to consider comments on proposed additions or modifications developed by a HIPAA standard setting organization and made to the NCVHS and the Designated Standard Maintenance Organization (DSMO). The NCVHS would then submit its recommendation to the Secretary within 120 days. The Secretary would either adopt or reject proposed modifications or additions to existing standards within 90 days if the NCVHS recommends the change.

Report on the American Health Information Community.—This bill would require the Secretary of HHS to report back in one year on the activities of the American Health Information Community (AHIC), with recommendations for the ongoing structure and responsibilities of the entity.

AHIC was formed to provide input and recommendations to HHS on how to make health records digital and interoperable, and assure that the privacy and security of those records are protected.

Strategic Plan for Coordinating Implementation of Health Information Technology.—This bill would require the Secretary to develop a strategic plan to coordinate implementation efforts for health IT standards, HIPAA transaction standards, and new coding systems. This plan will address how activities would be coordinated

between the Office of the National Coordinator for Health IT, the American Health Information Community, the Office of Electronic Standards and Security, and the National Committee for Vital Health Statistics.

Promotion of Telehealth Services.—This bill would require the Secretary to encourage and facilitate the adoption of State licensure agreements in order to provide telehealth services across state lines. The Secretary would also be required to study the use of store and forward technology in the provision of telehealth services under the Medicare program and the expansion of telehealth services provided in home health agencies and county mental health clinics or other publicly funded mental health facilities.

B. Background

It is intended that these provisions would coordinate, advance and speed the development and use of health IT with the goals of improving the quality of care delivered, reducing fraud and abuse and health care costs, and promoting the coordination of care to promote better health outcomes.

C. Legislative History

During the 108th and 109th Congresses, the Subcommittee held a series of four hearings on health care information technology: June 17, 2004; July 22, 2004; July 27, 2005; and April 6, 2006. Subcommittee Chairman Nancy Johnson and Energy and Commerce Health Subcommittee Chairman Deal introduced the "Health Information Technology Promotion Act of 2005" (H.R. 4157) on October 27, 2005. The bill has been referred to the Committee on Ways and Means, and to the Committee on Energy and Commerce, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

On June 17, 2004, the Ways and Means Subcommittee on Health held its first hearing on health care information technology and heard testimony from the National Health Information Technology Coordinator Dr. David Brailer and Dr. Robert Kolodner, Acting Chief Health Informatics Officer, Department of Veterans Affairs. A second panel consisted of Dr. Charles Safran, American Medical Informatics Association; Janet Marchibroda, eHealth Initiative; Dr. Marc Overhage, Indiana University; and Dr. Andrew Wiesenthal, Kaiser Permanente.

The Subcommittee on Health held its second hearing on July 22, 2004, on electronic prescribing and heard testimony from Dave McLean, RxHub; Craig Fuller, National Association of Chain Drug Stores; Dr. Thomas Sullivan, Women's Health Center Cardiology; and Dr. Jonathan Teich, Harvard University.

The Subcommittee on Health held its third hearing on July 27, 2005, on health care information technology and heard testimony from the National Health Information Technology Coordinator, Dr. David Brailer. A second panel consisted of Dr. Don Detmer, American Medical Informatics Association; Linda Kloss, American Health Information Management Association; Dr. Allen Weiss, Naples Community Hospital Healthcare System; Joy Pritts, Health Policy Institute; and Mary Grealy, Healthcare Leadership Council.

The Subcommittee on Health held its final hearing in a series of four hearings on April 6, 2006, and heard testimony from the National Health Information Technology Coordinator, Dr. David Brailer; Lewis Morris, Inspector General, Department of HHS; and Dr. Simon Cohn, National Committee on Vital and Health Statistics. The second panel consisted of Brent Henry, Partners HealthCare System; Dr. Kenneth Kizer, Medsphere Systems Corporation; Joseph Smith, Arkansas Blue Cross Blue Shield; and Gloryanne Bryant, Catholic Healthcare West.

II. EXPLANATION OF PROVISIONS

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS

Current Law

No provision.

Explanation of Provision

The provision specifies the title of the Act as the Health Information Technology Promotion Act of 2006. The provision also includes a brief table of contents, which lists the Act's nine sections.

Effective Date

No provision.

SECTION 2. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

Current Law

There are no existing statutory provisions regarding the current Office of the National Coordinator for Health Information Technology (ONCHIT) within the Department of Health and Human Services (HHS). ONCHIT was created by Executive Order 13335, signed by the President on April 27, 2004. The National Coordinator was instructed to develop, maintain, and direct a strategic plan to guide the nationwide implementation of interoperable health IT in the public and private health care sectors. The National Coordinator was also required, within 90 days, to report to the Secretary on progress towards the strategic plan. On July 21, 2004, the National Coordinator delivered that report, *titled Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care.*

On October 6, 2005, ONCHIT awarded: (1) a $3.3 million contract to the American National Standards Institute to convene a panel of standards development organizations to develop a harmonization process for achieving a widely accepted and useful set of interoperable health IT standards; and (2) a $2.7 million contract to the Certification Commission for Health Information Technology, a nonprofit organization created by three health IT industry associations, to develop a process for certifying electronic health records and the network components through which they interoperate.

Explanation of Provision

The bill would establish within HHS an Office of the National Coordinator for Health Information Technology. The National Coordinator would be appointed by the President and report directly to

the Secretary. The National Coordinator would be required to perform duties consistent with the development of a nationwide interoperable health IT infrastructure that, among other things, improves health care quality, promotes wellness, reduces health care costs, improves health information exchange, and ensures health information privacy and security. Those duties would include: (1) directing and overseeing the continuous improvement of a strategic plan to guide implementation of a nationwide interoperable health IT infrastructure; (2) acting as the principal advisor to the Secretary on health IT and coordinating all health IT programs within the department; (3) coordinating health IT activities across the federal government and, using private entities to the maximum extent possible, providing for the development of health IT standards and the certification of health IT products; and (4) advising the Director of the Office of Management and Budget on federal health IT programs.

The bill would authorize, for each of FY 2006 through FY 2010, such sums as may be necessary to carry out the activities of ONCHIT. Further, the bill would nullify Executive Order 13335. Finally, the bill would provide for the transfer of all functions, personnel, assets, liabilities, administrative actions, and statutory reporting requirements applicable to the existing ONCHIT to the new ONCHIT created under the Act.

Reasons for Change

No statutory position currently exists to coordinate health information technology initiatives for the federal government. The current Office of the National Coordinator for Health Information Technology was created by executive order. Congress should create a statutory position to ensure ongoing attention to health IT issues. This provision would codify the existing Office of the National Coordinator and specify its role in coordinating public/private partnerships to develop technology standards without creating a new government infrastructure to address the issue.

There is also the ongoing effort towards rebuilding the health care system in Louisiana's Gulf Coast region. The Committee believes that the Gulf Coast area providers and payers should increase the use of electronic health records so that patients can receive quality care anywhere, particularly in emergency situations. After the hurricanes in 2005 and as a direct result of the significant loss of paper medical records, the State of Louisiana initiated a series of activities to connect patients to lost information. The State received a $3.7 million grant from the ONCHIT to assist in the development of the Louisiana Health Information Exchange, which has successfully engaged stakeholders in Louisiana to prepare for the next hurricane season by creating a repository for patients' health information. The Committee believes the ONCHIT should continue to work with Louisiana stakeholders to develop a health information technology infrastructure that will allow all participating health care providers to contribute to an electronic patient record that can be accessed by any healthcare provider treating that patient.

Effective Date

Upon enactment.

SECTION 3. SAFE HARBORS FOR THE PROVISION OF HEALTH INFORMATION TECHNOLOGY AND SERVICES TO HEALTH CARE PROFESSIONALS.

Current Law

The federal anti-kickback statute (42 U.S.C. 1320a–7b(b)) prohibits an individual or entity from knowingly or willfully offering or accepting remuneration of any kind to induce a patient referral for, or purchase of, an item or service covered by any federal health care program. Violations of the law are punishable by up to five years in prison, criminal fines up to $25,000, administrative civil money penalties up to $50,000, and exclusion from participation in federal health care programs. HHS issues regulations designating specific safe harbors for various payment and business practices that would otherwise be implicated by the anti-kickback statute and subject to its criminal and civil prosecution.

The Medicare physician self-referral (Stark) law (42 USC 1395nn(e)) prohibits physicians from referring patients to any entity for certain health services if the physician has a financial relationship with the entity, and prohibits entities from billing for any services resulting from such referrals, unless an exception applies. On March 25, 2004, CMS issued an interim final rule creating several new Stark exceptions, including one for health IT items and services furnished by an entity to physicians to enable them to participate in "community-wide health information systems."

The Medicare Modernization Act (MMA; P.L. 108–173, Section 101) instructed the Secretary to establish a safe harbor from penalties under the anti-kickback statute and an exception to the Stark law for the provision of health IT and training services used in electronic prescribing. That would allow, for example, a hospital to provide such technologies and services to its medical staff, and Medicare Advantage plans to provide such technologies and services to pharmacies and prescribing health care providers. Proposed regulations were issued on October 5, 2005. While the proposed safe harbor covers health IT used solely for e-prescribing, as instructed by MMA, the proposed Stark exception would apply more broadly to health IT for electronic health records, provided they include electronic prescribing as one component.

Explanation of Provision

The bill would create a safe harbor from civil monetary penalties under the anti-kickback statute for health IT and related services provided by a hospital or critical access hospital (CAH) to a physician, subject to the following requirements. The provision of health IT and related services must be made pursuant to a written agreement specifying that the primary purpose of the remuneration is for better coordination of care or improvement of health care quality or efficiency, and without a condition that: (1) limits or restricts their use to services provided by the physician to individuals receiving services at the location of the hospital or CAH; (2) limits or restricts their use in conjunction with other health IT; or (3) takes into account the volume or value of referrals (or other business generated) by the physician to the hospital or CAH.

The bill also would create a safe harbor from criminal penalties under the anti-kickback statute for health IT and related services

solicited or received by a physician, subject to the same set of requirements. The provision of health IT and related services must be made pursuant to a written agreement between the physician and the entity providing the technology specifying that the primary purpose of the remuneration is for better coordination of care or improvement of health care quality or efficiency, and without a condition that: (1) limits or restricts their use to services provided by the physician to individuals receiving services at the location of the entity providing such technology; (2) limits or restricts their use in conjunction with other health IT; or (3) takes into account the volume or value of referrals (or other business generated) by the physician to the entity providing such technology.

Finally, the bill would create an exception to the Stark law for health IT and related services provided by an entity to a physician, again subject to the same requirements. The provision of health IT and related services must be made pursuant to a written agreement between the physician and the entity providing the technology specifying that the primary purpose of the remuneration is for better coordination of care or improvement of health care quality or efficiency, and without a condition that: (1) limits or restricts their use to services provided by the physician to individuals receiving services at the location of the entity providing such technology; (2) limits or restricts their use in conjunction with other health IT; or (3) takes into account the volume or value of referrals (or other business generated) by the physician to the entity providing such technology.

For the purposes of this section, health IT includes hardware, software, license, intellectual property, equipment, or other IT or related services used primarily for the electronic creation, maintenance, and exchange of clinical health information.

The bill would require the Secretary, within 180 days of enactment, to promulgate implementing regulations. It also would preempt state laws that would otherwise penalize the provision of health IT and related services as described in this section. In addition, the bill would instruct the Secretary, within three years of enactment, to report to Congress on the impact of each of the safe harbors and the Stark exception on increasing health IT adoption and on the business relationships between providers. The Secretary would be required to include in the report recommendations for changes in the safe harbors and Stark exception, as may be appropriate.

Reasons for Change

Currently, donations of health information technology are subject to the restrictions imposed under the fraud and abuse laws. The penalties for remuneration in the form of health information technology in violation of such laws are severe and include potential exclusion from federal programs. Current law has precluded the broad diffusion of health information technology that would improve care coordination, and the quality and efficiency of health care services. Accordingly, clear and broad exceptions to current law are necessary to promote IT diffusion. This provision would enable health care providers and other entities to donate health information technology without fear of violation.

Effective Date

The amendments made by this section to the anti-kickback statute and the Stark law would take effect 180 days after enactment.

SECTION 4. COMMONALITY AND VARIATION IN HEALTH INFORMATION LAWS AND REGULATIONS

Current Law

Under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA, P.L. 104–191, 42 USC 1320d), Congress set a three-year deadline to enact health information privacy legislation. If, as turned out to be the case, the Congress was unable to enact such legislation before the deadline, the Secretary was instructed to promulgate regulations containing standards to protect the privacy of individually identifiable health information. Under the HIPAA privacy rule (45 CFR Parts 160, 164), which became effective for health care providers and most health plans in April 2003, all applicable state and federal laws must be complied with unless it is impossible to comply with both and if the state law is less protective of medical privacy.

HIPAA also instructed the Secretary to develop security standards to safeguard electronic patient information against unauthorized access, use, and disclosure. The security standards (45 CFR Parts 160, 162, 164), which became effective for health care providers and most health plans in April 2005, preempt contrary state laws, except for exception determinations made by the Secretary. On October 6, 2005, ONCHIT awarded an $11.5 million contract to RTI International in association with the National Governors Association to assess variations in business policies and state laws that affect privacy and security practices that may pose challenges to the secure electronic exchange of health information, and to identify practical solutions for addressing such variation. State solutions and implementation plans are expected to be finalized in early 2007.

Explanation of Provision

The bill would require the Secretary to study the degree of variation and commonality among state and federal (HIPAA) health information privacy and security requirements and examine how such variation may adversely impact the secure, confidential, and timely exchange of health information. The Secretary would have to report to Congress, within 18 months, on whether there is need for greater commonality among state and federal requirements and, if so, how federal standards should be changed to provide the commonality needed to better protect or strengthen the privacy and security of health information that is exchanged.

The bill would give Congress 18 months following receipt of the Secretary's report to enact legislation to implement the report's recommendations, including modifying the HIPAA privacy and security standards. If Congress failed to act within that period, the Secretary could act, by regulation, to modify the HIPAA privacy and security standards based upon the report's recommendations. Such modified HIPAA standards would preempt any related, but contrary state law.

Reasons for Change

There are currently numerous, and often conflicting, State and federal laws and regulations to protect the security and confidentiality of patient information. The lack of commonality makes compliance with laws difficult and limits the ability for patient information to be appropriately shared to ensure the best patient care. Congress needs additional information to determine whether commonality among federal standards and state laws is necessary. This provision would require the Secretary of HHS to conduct a study of the State and federal laws and regulations governing health information exchange and to assess the strengths and weaknesses of those laws and regulations. This study will provide an important opportunity for all interested parties to debate the issues of security and confidentiality that arise when discussing health IT, without mandating any future change to the existing regulatory framework.

Effective Date

Upon enactment.

SECTION 5. IMPLEMENTING MODERN CODING SYSTEM; APPLICATION UNDER PART A OF THE MEDICARE PROGRAM

Current Law

To support the growth of electronic record keeping and claims processing in the nation's health care system, HIPAA's Administrative Simplification provisions instructed the Secretary to adopt electronic format and data standards for several routine administrative transactions between health plans and health care providers (e.g., claims for payment). The Secretary was to rely on the recommendations of the National Committee on Vital and Health Statistics (NCVHS), consult with appropriate federal and state agencies and private organizations, and publish in the Federal Register any NCVHS recommendation regarding the adoption of a standard. Final standards for eight electronic transactions and for code sets to be used in those transactions (45 CFR Parts 160, 162) were issued in August 2000. The transactions standards include several Accredited Standards Committee X12 (ASC X12) version 4010 standards, and the National Council for Prescription Drug Programs (NCPDP) Telecommunications Standards version 5.1. The code sets adopted by the Secretary include the International Statistical Classification of Diseases and Related Health Problems, 9th revision, Clinical Modification (ICD–9–CM).

HIPAA also instructed the Secretary to review and, not more frequently than once a year, modify the Administrative Simplification standards. Again, the Secretary was to rely on the recommendations of the NCVHS and publish in the Federal Register any NCVHS recommendation regarding the modification of a standard. Any such modification must be completed in a manner that minimizes disruption and the cost of compliance. Regarding code sets (e.g., ICD codes), any modification must also include instructions for the conversion or translation of prior encoded data elements so as to preserve the informational value of the data.

Explanation of Provision

The bill would require the Secretary to publish in the Federal Register a notice for the following modification of the HIPAA Administrative Simplification standards: (1) replacement of the ASC X12 version 4010 standards with version 5010; and (2) replacement of the NCPDP Telecommunications Standards version 5.1 with the latest version reviewed by the NCVHS as of April 1, 2008. The replacements would apply to electronic transactions, including those for services provided under Medicare Part A, occurring on or after April 1, 2009. Modification of the NCPDP standards would not be subject to judicial review.

The bill also would require the Secretary to publish in the Federal Register a notice for the following modification of the HIPAA code sets: (1) replacement of ICD–9–CM with both the ICD–10–CM and ICD–10–PCS (Procedure Coding System). The replacement would apply to services furnished on or after October 1, 2009, including under Medicare Part A.

Reasons for Change

The current system for coding health information was developed in the 1970s and it is outdated, inaccurate and running out of codes. A more modern coding system exists and has been adopted by virtually all other first world nations. The new coding system allows providers to more accurately code diagnosis and procedures used in treating patients to ensure better health outcomes, increased efficiency, and higher quality. Updating the coding system is important to realizing the full benefits of health IT. HHS has full authority to require the move to an updated coding system, and this change has been recommended by the National Committee for Vital Health Statistics, but to date HHS has not acted.

Effective Date

Upon enactment.

SECTION 6. PROCEDURES TO ENSURE TIMELY UPDATING OF STANDARDS THAT ENABLE ELECTRONIC EXCHANGES

Current Law

As previously noted, HIPAA instructed the Secretary to review and, not more frequently that once a year, modify the Administrative Simplification standards. Any such modification must be completed in a manner that minimizes disruption and the cost of compliance. Regarding code sets (e.g., ICD codes), any modification must also include instructions for the conversion or translation of prior encoded data elements so as to preserve the informational value of the data.

Explanation of Provision

The bill would amend HIPAA's Administrative Simplification provisions to help expedite the adoption of additions and modifications to the electronic transactions standards, as follows. The Secretary would be required to publish a Federal Register notice within 30 days of receiving a notice from a standard setting organization that: (1) it is initiating the process of developing an addition or modification to an existing standard; (2) has prepared a prelimi-

nary draft of an addition or modification to an existing standard; or (3) has a proposed addition or modification that it intends to submit for review and consideration. In each instance, the published notice would provide the opportunity for public participation and comment. In the case of a proposed addition or modification, the bill would require the standard setting organization, having responded to public comment, to submit its proposal to both the Designated Standard Maintenance Organization (DSMO) and the NCVHS. The DSMO reviews the request with its constituent members (i.e., X12, NCPDP, HL7, NUBC, NUCC, and DeCC) concurrent to review by the NCVHS. The NCVHS would be required within 120 days to conduct a public hearing and submit its recommendation for adopting or rejecting the proposed addition or modification to the Secretary. The Secretary would then have 90 days to accept or reject the recommendation, and a further 30 days to publish a notice of such determination in the Federal Register. If the determination is to accept the NCVHS recommendation, the notice would include the modified standard as a final rule. The final rule would not be subject to judicial review.

Reason for Change

The current HIPAA federal process to adopt updated or modified versions of transaction standards is slow, sometimes taking months or even years. The current process does not allow for the quick implementation of updated versions for HIPAA transactions that have already been adopted. This provision would allow for a more streamlined process to update or modify transaction standards, so as these standards continue to evolve over time, the federal process does not lag behind.

Enactment Date

Upon enactment.

SECTION 7. REPORT ON THE AMERICAN HEALTH INFORMATION COMMUNITY

Current Law

On July 14, 2005, the Secretary announced the formation of the 17-member American Health Information Community (AHIC), a public-private body formed pursuant to the Federal Advisory Committee Act to provide input and recommendations on facilitating the transition to interoperable electronic health records in a market-led way. AHIC's charter terminates after two years, unless the Secretary renews it for a duration of no more than five years. The Secretary intends for AHIC to be succeeded within five years by a private-sector health information community initiative that, among other things, would set additional needed standards, certify new health information technology, and provide long-term governance for health care transformation.

Explanation of Provision

The bill would require the Secretary, within one year of enactment, to report to Congress on the work conducted by AHIC, including: (1) its promotion of the development of a nationwide health information network and the adoption of health IT; and (2)

progress in establishing nationwide health IT standards. The Secretary also would be required to include recommendations for the transition of AHIC to a permanent advisory entity.

Reason for Change

AHIC was formed to provide input and recommendations to HHS on how to make health records digital and interoperable, and ensure that the privacy and security of those records are protected. It is important to understand the role AHIC plays in furthering the adoption of health IT and interoperability to justify the transition of AHIC to a permanent entity.

Effective Date

Upon enactment.

SECTION 8. STRATEGIC PLAN FOR COORDINATING IMPLEMENTATION OF HEALTH INFORMATION TECHNOLOGY

Current Law

Pursuant to Executive Order 13335 (as described earlier), the National Coordinator for health IT, on July 21, 2004, released a strategic plan to guide the nationwide implementation of interoperable health IT in the pubic and private health care sectors.

Explanation of Provision

The bill would require the Secretary, within 180 days of enactment and in coordination with entities involved in health IT, to develop a strategic plan for coordinating the implementation of health IT standards, HIPAA electronic transaction standards, and ICD–10 codes.

Reasons for Change

HHS currently has numerous initiatives and offices involved in health information technology. The efforts of these offices need to be coordinated, and HHS must develop a strategic plan for moving forward in this area.

Effective Date

Upon enactment.

SECTION 9. PROMOTION OF TELEHEALTH SERVICES

Current Law

Nearly a dozen federal agencies support telehealth activities. Within HHS, the Health Resources and Services Administration's Office for the Advancement of Telehealth (OAT) administers telehealth demonstration and evaluation programs, provides technical assistance and promotes best practices, and coordinates telehealth policies and activities across the federal government and with states and private-sector groups. Medicare covers telehealth services provided to beneficiaries at eligible health care facilities. Telehealth services that are eligible for reimbursement include consultations, office visits, individual psychotherapy and pharmacologic management delivered via a telecommunications system. Medicare does not cover home health services provided via a telecommunications system. A home health visit is defined in regula-

tion (42 CFR 409.48(c)) as an episode of personal contact with the beneficiary by staff of the home health agency.

Explanation of Provision

The bill would require the Secretary, in coordination with state representatives and various stakeholders, to: (1) encourage and facilitate the adoption of reciprocal practitioner licensing agreements between states to promote telehealth; and (2) within 18 months, report to Congress on specific actions taken. The bill would further require the Secretary, acting through OAT, to: (1) study the use of store and forward technologies in telehealth services covered under Medicare; and (2) within 18 months, report to Congress with recommendations for legislation. Finally, the bill would require the Secretary, in coordination with OAT, AHRQ and CMS, to study the feasibility, advisability, and costs of: (1) providing coverage for telehealth services as part of home health services, including an evaluation on the equivalency of home health-related telehealth services to an in-person visit for purposes of eligibility and payment under Medicare; and (2) expanding the health care facilities at which Medicare-covered telehealth services are provided to include publicly funded mental health facilities. Within 18 months, the Secretary would be required to report to Congress with recommendations for legislation.

Reasons for Change

Telehealth and telemonitoring services might enhance health outcomes for individuals with one or more chronic conditions, provide for comparable health outcomes to a face-to-face visit, facilitate better communication between providers, provide closer monitoring of patients, reduce overall healthcare costs, and improve access to care. These studies will help determine whether telehealth and telemonitoring services meet these objectives, and if so, would provide recommendations to enhance the provision or coverage of telehealth services under the Medicare program.

Effective Date

Upon enactment.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the vote of the Committee on Ways and Means in its consideration of H.R. 4157, the "Health Information Technology Promotion Act of 2006."

MOTION TO REPORT THE BILL

The bill, H.R. 4157, as amended, was ordered favorably reported by a rollcall vote of 23 yeas to 17 nays (with a quorum being present). The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas	X			Mr. Rangel		X	
Mr. Shaw	X			Mr. Stark		X	
Mrs. Johnson	X			Mr. Levin		X	
Mr. Herger	X			Mr. Cardin		X	

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. McCrery	X			Mr. McDermott		X	
Mr. Camp	X			Mr. Lewis (GA)		X	
Mr. Ramstad	X			Mr. Neal		X	
Mr. Nussle				Mr. McNulty		X	
Mr. Johnson	X			Mr. Jefferson		X	
Mr. English	X			Mr. Tanner		X	
Mr. Hayworth	X			Mr. Becerra		X	
Mr. Weller	X			Mr. Doggett		X	
Mr. Hulshof	X			Mr. Pomeroy		X	
Mr. Lewis (KY)	X			Ms. Tubbs Jonesa		X	
Mr. Foley	X			Mr. Thompson		X	
Mr. Brady	X			Mr. Larson.		X	
Mr. Reynolds	X			Mr. Emanuel		X	
Mr. Ryan	X						
Mr. Cantor	X						
Mr. Linder	X						
Mr. Beauprez	X						
Ms. Hart	X						
Mr. Chocola	X						
Mr. Nunes	X						

VOTES ON AMENDMENTS

A rollcall vote was conducted on the following amendments to the Chairman's Amendment in the Nature of a Substitute.

An amendment by Mr. Stark, which would which would strike section 3 of the Chairman's amendment was defeated by a rollcall vote of 17 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Shaw		X		Mr. Stark	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Herger		X		Mr. Cardin	X		
Mr. McCrery		X		Mr. McDermott	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle				Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Mr. English		X		Mr. Tanner	X		
Mr. Hayworth		X		Mr. Becerra	X		
Mr. Weller		X		Mr. Doggett	X		
Mr. Hulshof		X		Mr. Pomeroy	X		
Mr. Lewis (KY)		X		Ms. Tubbs Jones	X		
Mr. Foley		X		Mr. Thompson	X		
Mr. Brady		X		Mr. Larson	X		
Mr. Reynolds		X		Mr. Emanuel	X		
Mr. Ryan		X					
Mr. Cantor		X					
Mr. Linder		X					
Mr. Beauprez		X					
Ms. Hart		X					
Mr. Chocola		X					
Mr. Nunes		XFe					

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Shaw		X		Mr. Stark	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Herger		X		Mr. Cardin	X		
Mr. McCrery		X		Mr. McDermott	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle				Mr. McNulty	X		

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Shaw		X		Mr. Stark	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Herger		X		Mr. Cardin	X		
Mr. McCrery		X		Mr. McDermott	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle				Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Mr. English		X		Mr. Tanner	X		
Mr. Hayworth		X		Mr. Becerra	X		
Mr. Weller		X		Mr. Doggett	X		
Mr. Hulshof		X		Mr. Pomeroy	X		
Mr. Lewis (KY)		X		Ms. Tubbs Jones	X		
Mr. Foley		X		Mr. Thompson	X		
Mr. Brady		X		Mr. Larson	X		
Mr. Reynolds		X		Mr. Emanuel	X		
Mr. Ryan		X					
Mr. Cantor		X					
Mr. Linder		X					
Mr. Beauprez		X					
Ms. Hart		X					
Mr. Chocola		X					
Mr. Nunes		X					

An amendment by Mr. Thompson which would direct the Secretary of Health and Human Services to establish a mechanism to fund through Medicare acquisition and support of health IT used by providers of health services, was defeated by a rollcall vote of 17 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Shaw		X		Mr. Stark	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Herger		X		Mr. Cardin	X		
Mr. McCrery		X		Mr. McDermott	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle				Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Mr. English		X		Mr. Tanner	X		
Mr. Hayworth		X		Mr. Becerra	X		
Mr. Weller		X		Mr. Doggett	X		
Mr. Hulshof		X		Mr. Pomeroy	X		
Mr. Lewis (KY)		X		Ms. Tubbs Jones	X		
Mr. Foley		X		Mr. Thompson	X		
Mr. Brady		X		Mr. Larson	X		
Mr. Reynolds		X		Mr. Emanuel	X		
Mr. Ryan		X					
Mr. Cantor		X					
Mr. Linder		X					
Mr. Beauprez		X					
Ms. Hart		X					
Mr. Chocola		X					
Mr. Nunes		X					

An amendment by Mr. Stark, which would disallow preemption of certain state laws related to privacy and allow individuals to seek damages from entities that improperly use or disclose identifiable health information, was defeated by a rollcall vote of 17 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Nussle		X		Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Mr. English		X		Mr. Tanner	X		
Mr. Hayworth		X		Mr. Becerra	X		
Mr. Weller		X		Mr. Doggett	X		
Mr. Hulshof		X		Mr. Pomeroy	X		
Mr. Lewis (KY)		X		Ms. Tubbs Jones	X		
Mr. Foley		X		Mr. Thompson	X		
Mr. Brady		X		Mr. Larson	X		
Mr. Reynolds		X		Mr. Emanuel	X		
Mr. Ryan		X					
Mr. Cantor		X					
Mr. Linder		X					
Mr. Beauprez		X					
Ms. Hart		X					
Mr. Chocola		X					
Mr. Nunes		X					

An amendment by Messrs. Emanuel and Doggett, which would strike section 4 of the Chairman's amendment in the nature of a substitute, and replace it with provisions requiring the Secretary of Health and Human Services to modify privacy protections through regulations put forward as a result of the Health Insurance Portability and Accountability Act of 1996, was defeated by a rollcall vote of 17 yeas to 23 nays. The vote was as follows:

Representatives	Yea	Nay	Present	Representative	Yea	Nay	Present
Mr. Thomas		X		Mr. Rangel	X		
Mr. Shaw		X		Mr. Stark	X		
Mrs. Johnson		X		Mr. Levin	X		
Mr. Herger		X		Mr. Cardin	X		
Mr. McCrery		X		Mr. McDermott	X		
Mr. Camp		X		Mr. Lewis (GA)	X		
Mr. Ramstad		X		Mr. Neal	X		
Mr. Nussle				Mr. McNulty	X		
Mr. Johnson		X		Mr. Jefferson	X		
Mr. English		X		Mr. Tanner	X		
Mr. Hayworth		X		Mr. Becerra	X		
Mr. Weller		X		Mr. Doggett	X		
Mr. Hulshof		X		Mr. Pomeroy	X		
Mr. Lewis (KY)		X		Ms. Tubbs Jones	X		
Mr. Foley		X		Mr. Thompson	X		
Mr. Brady		X		Mr. Larson	X		
Mr. Reynolds		X		Mr. Emanuel	X		
Mr. Ryan		X					
Mr. Cantor		X					
Mr. Linder		X					
Mr. Beauprez		X					
Ms. Hart		X					
Mr. Chocola		X					
Mr. Nunes		X					

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

In compliance with clause 3(d)(2) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of this bill, H.R. 4157, as reported: The Committee fundamentally disagrees with the assessment of the Congressional Budget Office (CBO).

The Committee believes H.R. 4157 will result in significantly reduced expenditures in both private and public sector health programs that are not reflected in the CBO estimate. The Committee believes CBO's assumption regarding baseline spending does not reflect the slow rate of adoption of health information technology, nor does it recognize how the legislation will speed the adoption and use of such technology.

Even after the Committee highlighted numerous articles and academic studies on the benefits of health information technology on utilization of services, particularly lab services, CBO continues to believe the bill will result in increased utilization. Despite the bill's clear requirement that entities must enter into written agreements to improve the quality of care, to reduce medical errors and duplicative services, to promote quality or to enhance efficiency, CBO continues to believe volume of services would increase. In addition, the bill makes it illegal to condition gifts of donated technology on the value or volume of services. Legal experts and the Inspector General of the Department of Health and Human Services look at inappropriate indirect referral arrangements. CBO, however, believes such indirect arrangements will occur despite the legal prohibition in the legislation, and irrespective of the significant penalties under the Stark and anti-kickback statutes. CBO thus believes the provision will increase costs. The Committee fundamentally disagrees with this assessment and believes CBO has not provided any credible or material evidence to justify its claims.

B. Statement Regarding New Budget Authority and Tax Expenditures

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee states that enactment of H.R. 4157 would provide new budget authority for the newly created Office of the National Coordinator for Health Information Technology. The Committee states the bill would not effect tax expenditures.

C. Cost Estimate Prepared by the Congressional Budget Office

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following report prepared by the CBO is provided.

U.S. Congress,
Congressional Budget Office,
Washington, DC, July 25, 2006.

Hon. William "Bill" M. Thomas,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4157, the Better Health Information System Act of 2006.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Tom Bradley.

Sincerely,

Donald B. Marron,
Acting Director.

Enclosure.

H.R. 4157—Health Information Technology Promotion Act of 2006

Summary: H.R. 4157 would amend the Public Health Service Act (PHSA) to codify the establishment and responsibilities of the Office of the National Coordinator for Health Information Technology (ONCHIT). In addition, the bill would modify the Social Security Act to:

- Establish "safe harbors" that would permit gifts of health information technology that might otherwise be subject to civil monetary penalties, criminal penalties, or sanctions for violating the prohibitions against certain types of inducements for physician referrals; and
- Specify procedures for adopting updated standards for the electronic exchange of health data, and require that certain updated standards for coding medical services be implemented in 2009.

The amendments to the PHSA and the deadline for updated standards for coding medical services would affect spending subject to appropriation. Assuming appropriation of the necessary amounts, CBO estimates that implementing the bill would increase discretionary spending by $658 million over the 2007–2011 period and reduce such spending by $150 million over the succeeding five years.

Enacting the deadline for updated standards for coding medical services and the safe-harbor provisions would affect direct spending. CBO estimates those provisions would increase direct spending by $180 million over the 2007–2011 period and by $80 million during the following five years.

CBO estimates that enacting the deadline for updated standards for coding medical services would reduce federal revenues by $26 million over the 2007–2011 period, and would increase federal revenues by $84 million over the succeeding five years. Social Security payroll taxes, which are off-budget, account for about one-third of those amounts.

H.R. 4157 would preempt, in some circumstances, certain state laws that govern the security and confidentiality of health information as well as laws that establish civil or criminal penalties for exchanging health information technology. Because those preemptions would limit the application of state laws, they would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the costs of the mandates to states would be minimal and would not exceed the threshold established in UMRA ($64 million in 2006, adjusted annually for inflation).

Other provisions of the bill, notably new coding requirements and the safe-harbor provisions—for gifts of information technology, would affect states' spending, adding about $200 million to their costs over the 2007–2011 period. However, those provisions would not be intergovernmental mandates as defined in UMRA.

The bill would impose private-sector mandates on health plans, providers, and clearing-houses by requiring them to adopt updated coding and transaction standards by specified future dates. CBO estimates that the direct cost of these provisions would exceed the threshold specified in UMRA for private-sector mandates ($128

million in 2006, adjusted annually for inflation) in the first three years following enactment of the bill.

Estimated cost to the Federal Government: The estimated cost of H.R. 4157 is shown in the following table. The costs of this legislation fall within budget functions 550 (health) and 570 (Medicare).

ESTIMATED BUDGETARY EFFECTS OF H.R. 4157

	By fiscal year, in millions of dollars—											
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2007–2011	2007–2016
CHANGES IN SPENDING SUBJECT TO APPROPRIATION												
ONCHIT:												
Estimated Authorization Level	116	119	122	125	0	0	0	0	0	0	482	482
Estimated Outlays	58	94	114	121	61	24	5	1	0	0	448	478
Medicare:												
Estimated Authorization Level	0	200	25	25	−200	−20	0	0	0	0	50	30
Estimated Outlays	0	50	75	75	10	−70	−70	−40	0	0	210	30
Total, Changes in Discretionary Spending:												
Estimated Authorization Level	116	319	147	150	−200	−20	0	0	0	0	532	512
Estimated Outlays	58	144	189	196	71	−46	−65	−39	0	0	658	508
CHANGES IN DIRECT SPENDING												
Medicaid, Safe Harbors	10	15	15	15	20	20	20	25	25	25	75	190
Medicare, Safe Harbors	15	15	15	15	15	15	20	20	20	20	75	170
Subtotal, Safe Harbors	25	30	30	30	35	35	40	45	45	45	150	360
Medicaid, ICD–10	5	20	25	5	−25	−40	−30	−25	−20	−15	30	−100
Total, Changes in Direct Spending (Budget Authority and Outlays)	30	50	55	35	10	−5	10	20	25	30	180	260
CHANGES IN REVENUE												
Income and HI Payroll Taxes (on budget)	−2	−10	−14	−2	12	19	13	10	7	6	−16	39
Social Security Payroll Taxes (off-budget)	−1	−6	−8	−1	6	10	7	5	4	3	−10	19
Total, Changes in Revenue	−3	−16	−22	−3	18	29	20	15	11	9	−26	58

* = Increase or decrease of less than $500,000.

Notes: ICD–10 = 10th revision of the International Classification of Diseases; HI = Hospital Insurance (Part A of Medicare); ONCHIT = Office of the National Coordinator for Health Information Technology.

Basis of estimate: H.R. 4157 would amend the Public Health Service Act to codify the establishment and responsibilities of the Office of the National Coordinator for Health Information Technology, establish safe harbors for gifts of health information technology, and specify procedures and establish deadlines for adopting updated standards for the electronic exchange of health data.

HEALTH INFORMATION TECHNOLOGY AND QUALITY

On April 27, 2004, the President issued Executive Order 13335, which established within the Office of the Secretary of Health and Human Services the position of National Coordinator of Health Information Technology, The Secretary subsequently established the Office of the National Coordinator of Health Information Technology to support the adoption of interoperable health information technology. Funding for ONCHIT totaled $62 million for 2006: $43 million was appropriated to the office, and $19 million was reprogrammed from other activities. The President requested $116 million for ONCHIT for 2007.

The National Coordinator for Health Information Technology serves as the senior advisor to the President and the Secretary of Health and Human Services on all health information technology programs and initiatives, and is responsible for:

- Developing and maintaining a strategic plan to guide the nationwide implementation of electronic health records in both the public and private health care sectors;
- Coordinating spending by federal agencies for health information technology programs and initiatives; and
- Coordinating outreach activities to the private sector on health information technology matters.

H.R. 4157 would codify the establishment and responsibilities of ONCHIT. The bill would require the Secretary to prepare reports on certain activities initiated pursuant to the executive order to promote the development of a nationwide health information network and on issues related to the development, operation, and implementation of state, regional, and community organizations that share and coordinate the deployment and use of health information technology (so-called health information exchanges).

The bill would authorize the appropriation for 2006 through 2010 of such sums as are necessary to conduct ONCHIT's activities. Based on information provided by the Department of Health and Human Services (HHS), CBO estimates that funding the authorized activities would require the appropriation of about $116 million in 2007 and that funding requirements would grow with inflation in subsequent years. Assuming appropriation of those amounts, CBO estimates that ONCHIT's activities would cost $58 million in 2007, $448 million over the 2007–2011 period, and $478 million over the 2007–2016 period.

SAFE HARBORS FOR GIFTS OF HEALTH INFORMATION TECHNOLOGY

H.R. 4157 would establish "safe harbors" for donations of health information technology that might otherwise be subject to civil monetary penalties, criminal penalties, or sanctions for violating the prohibitions on certain physician referrals. The bill would permit any entity to provide health information technology (hardware, software, or related services) to physicians. CBO estimates that

provision would increase direct spending by $25 million in 2007, $150 million over the 2007–2011 period, and $360 million over the 2007–2016 period; federal spending for Medicaid and Medicare would each account for about half of those increases.

The Administration has identified the current application of those penalties and sanctions as an impediment to the success of efforts to promote the widespread adoption of interoperable health information technology. Accordingly, the HHS Office of the Inspector General and the Centers for Medicare & Medicaid Services (CMS), under authority existing in current law, are engaged in a rule-making process to establish safe harbors for gifts of health information technology that would balance enforcement of program-integrity rules with promotion of the adoption of interoperable health information technology. In the preliminary stage of the rule-making process, those offices described a framework that would limit:

- Entities eligible for the safe harbor (a hospital may donate to members of its medical staff; a group practice may donate to physicians who are members of the group practice; and Medicare Advantage plans and prescription drug plans may donate to their prescribing physicians), and
- Eligible donations (software and related training).

It is likely that the final rules will specify a somewhat broader set of eligible entities and donations than the preliminary guidelines. In particular, we anticipate that hospitals and group practices will be allowed to donate to a broader set of physicians and that the eligible gifts will include some equipment.

However, CBO expects that, based on concerns about program integrity, the final rules will establish a set of eligible entities that is narrower than those specified in the bill. Thus, clinical laboratories, imaging centers, suppliers of durable medical equipment, pharmaceutical manufacturers, and other entities that probably will not be eligible for the safe harbor under current law would qualify under the bill. Although the legislation would prohibit the contract between the donor and the physician from including a condition that links the gift of technology to the volume or value of referrals to the donor, CBO expects that, in some cases, that condition would be implicit (or would be perceived by the physician as being implicit). To the extent that a gift might lead to a shift of business from one provider to another, such a development would not affect the cost of the government's health care programs. But CBO estimates that, in aggregate, such donations by entities other than hospitals, group practices, Medicare Advantage plans, and prescription drug plans would lead to an increase in the volume of services that Medicare and state Medicaid programs pay for, thus increasing costs.

Information furnished by CMS, the HHS Inspector General, and the Department of Justice indicates that some physicians who receive gifts of value from suppliers substantially increase the volume of services they order. CBO's estimate assumes that the number of physicians inclined to do so is quite small—less than 1 percent of practicing physicians. Moreover, CBO expects that many of those physicians would not receive donations of technology from donors who would be covered by the safe harbors under H.R. 4157 but not covered under current law. Accordingly, CBO's estimate

ofthe additional direct spending for Medicare and Medicaid represents an increase in spending for services furnished by the newly-protected categories of donors of less than one-tenth of a percent. (Total federal spending for such services in those two programs is estimated to total about $55 billion in 2006.)

BUDGETARY EFFECTS OF HEALTH INFORMATION TECHNOLOGY

CBO expects that the use of information technology in the health care sector will continue to grow under current law, and that expanded use of such technology will likely produce improvements in the quality of the health care provided to U.S. residents. In some cases, that improvement in the quality of health care might mean less use of medical services; in other cases, it might mean an increase in utilization.

Under current law, CBO also expects that the expanded use of health information technology will likely result in increased efficiency in the health care system. That is, the use of information technology will result in more health benefits per dollar of spending than would otherwise be realized.

Experts caution, however, that the evidence is mixed concerning whether those improvements in quality and efficiency will also result in lower spending for health care, either in the private sector or for government programs.[1] In her recent testimony to the Senate Subcommittee on Technology, Innovation, and Competitiveness, Dr. Carolyn Clancy (Director of the Agency for Health Research and Quality) noted that, if poorly designed or implemented, health information technology will not bring those benefits, and in some cases may even lead to new medical errors and potential costs. She also noted that achieving improvements in health care and realizing potential cost savings will require real process change and will not result from simply acquiring and deploying hardware and software.

To the extent that health information technology will result in lower spending for health care, much of those savings would not be passed through as a reduction in direct spending for federal programs—particularly Medicare—under current law. For example, two areas account for much of the potential savings reported in the literature: reductions in the cost of care during a hospital stay, and administrative savings for providers and claims processors. Under current law, Medicare's payment rates for hospital inpatient services are updated each year to reflect changes in general inflation rates, and do not reflect changes in the costs that hospitals incur (either for administrative activities or for providing health care services). Medicare might realize savings in the cost of processing claims. However, funding for Medicare's claims-processing activi-

[1]See, for example:

Testimony of Carolyn Clancy, MD to the Subcommittee on Technology, Innovation and Competitiveness of the Senate Committee on Commerce, Science, and Transportation, June 21, 2006. (http://commerce.senate.gov/public/**XX**—files/Clancy062106. pdf)

Clifford Goodman, "Savings In Electronic Medical Record Systems? Do It For The Quality", Health Affairs, Sept/Oct. 2005. (http://content.healthaffairs.org/cgi/content/full/24/5/1124)

Paul B. Ginsburg, Ph.D., "Controlling Health Care Costs", New England Journal of Medicine, Oct 14, 2004. (*http://content.nejm.org/cgi/content/full/351/16/1591*)

Jaan Sidorov, "It Ain't Necessarily So: The Electronic Health Record And The Unlikely Prospect Of Reducing Health Care Costs", Health Affairs, July/August 2006. (http://content.healthaffairs.org/cgi/reprint/25/4/1079)

James Walker, "Electronic Medical Records And Health Care Transformation", Health Affairs, Sept./Oct 2005. (http://content.healthaffairs.org/cgi/content/full/24/5/1118)

ties is subject to appropriation, so such savings could only be realized through the appropriations process.

In preparing an estimate of the budgetary effect of legislation involving health information technology, CBO focuses on the extent to which the bill would change the rate at which the use of health technology will grow or how well that technology will be designed and implemented under current law. CBO then evaluates the extent to which those changes, in conjunction with other provisions in current law and in the proposed legislation, would affect direct spending.

CBO estimates that enacting H.R. 4157 would not significantly affect either the rate at which the use of health technology will grow or how well that technology will be designed and implemented. Therefore, with the exception of the effects on spending described above, CBO estimates enacting the bill would have no effect on spending by the federal government.

STANDARDS FOR THE ELECTRONIC EXCHANGE OF HEALTH DATA

H.R. 4157 would require the Secretary of HHS to establish expedited procedures for adopting updates to standards that enable the electronic exchange of health data.

The bill would require that two sets of standards apply to certain health information transactions by April 1, 2009: the "X12" standards developed by the Accredited Standards Committee for electronic data interchange, and the updated telecommunication standards adopted by the National Council for Prescription Drug Programs. CBO estimates that implementing those provisions would not have a significant effect on federal spending.

In addition, the bill would require health plans, providers, and clearinghouses to adopt the 10th revision of the International Classification of Diseases (ICD–10) by October 1, 2009, for all services currently submitted for payment using codes specified in the 9th revision (ICD–9). Under current law, CBO expects that the ICD–10 standard will be adopted by the end of fiscal year 2012.

Providers and health plans will incur costs for moving to ICD–10 no matter when the transition occurs. Many providers and health plans will purchase or upgrade computer hardware and software to handle the new codes, which are longer and contain alphanumeric characters. In addition, there will be costs to train people to use the new codes, and reductions in productivity while they become familiar with the new system.

There also will be benefits of moving to ICD–10, although they are more difficult to estimate and are subject to greater uncertainty. The increased specificity and clinical detail of the new set of codes will reduce providers' and plans' costs. For example, the more accurate coding will lower processing costs through a reduction in the number of rejected claims that must be resubmitted. Also, the more detailed information included in the new codes may discourage improper or fraudulent claims, which would lower plans' costs. However, those savings will be relatively low in the first few years because error rates will be higher during an initial period of unfamiliarity with the new system, and new algorithms will need to be developed for detecting improper claims under the new system.

Other changes could occur under the ICD–10 system that might be beneficial to patients and result in better health outcomes, but would not necessarily lower (and might even raise) health care costs. For example, more accurate payments for new procedures that would be possible under the new coding system might result in newer and more appropriate procedures being performed than under the old system. Health plans' costs would decrease to the extent that less costly procedures were performed, but would increase to the extent that more or more costly procedures were performed.

CBO expects that implementing the ICD–10 system will result in costs to providers and health plans in the first few years, with benefits beginning later. The shift to an earlier implementation date under the bill would thus result in increased costs in the near term and subsequent savings that would be realized earlier than under current law. In addition, the reduced amount of time that providers and plans would have to adopt ICD–10 under the bill, combined with the transition to updated standards for claims and transactions that also will be occurring during that same time period, would increase costs as providers and health plans would have to compete for scarce resources such as programmers and consultants.

Estimated Effect on Federal Revenues. CBO estimates that the net effect of accelerating implementation of the ICD–10 system would be to increase the cost of private health care benefits and health insurance premiums in the near term, and decrease such costs in later years, compared to current law. The changes would be small—an increase of 0.03 percent in 2008, followed by an even smaller decrease in later years. Because health care benefits generally are excluded from taxable incomes, H.R. 4157 would reduce federal tax revenues in the near term by increasing the share of employee compensation furnished as tax-excluded health benefits rather than as taxable wages and salaries. That pattern would be reversed in subsequent years. CBO estimates that enacting H.R. 4157 would reduce federal revenues by $3 million in 2007 and by $26 million over the 2007–2011 period; it would increase revenues by $58 million over the 2007–2016 period. Social Security payroll taxes, which are off budget, account for about one-third of those amounts.

Estimated Effect on Direct Spending. The Medicaid program would be subject to a similar pattern of acceleration of both the costs of implementing the ICD–10 coding system and the subsequent realization of savings for health benefits. CBO estimates that provision would increase Medicaid spending by $30 million over the 2007–2011 period, and would reduce spending for Medicaid by $100 million over the 2007–2016 period.

CBO expects that accelerating the implementation of the ICD–10 coding system would not have a significant effect on direct spending for Medicare for two reasons. First, Medicare funding for processing claims—including the implementation and maintenance of claims-processing systems—is subject to appropriation. Second, under current law, the Medicare program recalibrates payment rates each year to ensure that coding changes are implemented on a budget-neutral basis.

Estimated Effect on Spending Subject to Appropriation. Medicare's spending to implement, operate, and maintain claims—processing systems—including the cost of transition to the ICD–10 sys-

tem—is subject to appropriation. In general, accelerating implementation of the ICD–10 system would shift implementation costs from the 2012–2016 period into the 2008–2011 period. Assuming appropriation of the necessary amounts, CBO estimates that the cost to Medicare of implementing the ICD–10 system in 2009 would be $210 million over the 2007–2011 period and $30 million over the 2007–2016 period.

Estimated impact on state, local, and tribal governments: H.R. 4157 would preempt, in some circumstances, certain state laws that govern the security and confidentiality of health information as well as laws that establish civil or criminal penalties for exchanging health information technology. Although those preemptions would be intergovernmental mandates as defined in UMRA, CBO estimates that the costs of the mandates would be small and thus would not exceed the threshold established in UMRA ($64 million in 2006, adjusted annually for inflation).

The bill would direct the Secretary of HHS to conduct a study of the variation in state security and confidentiality laws, compare the range of those laws with existing federal standards, and make recommendations to the Congress for establishing greater commonality among laws. If the Congress takes no action within 18 months after receiving the recommendations, they would become regulations with the force of law. The regulations would supersede any state security or confidentiality laws that relate to but are different from those standards. CBO estimates that this preemption would not significantly affect the budgets of state, local, or tribal governments because it would impose no duty on those governments that would result in additional spending or a loss of revenues.

The bill also would change safe-harbor guidelines for the exchange of health information technology, and it would preempt state laws that would assess civil or criminal penalties on exchanges of information that the bill would allow. Although this preemption could affect the ability of states to assess penalties and collect revenues, CBO estimates that such losses would be small.

OTHER IMPACTS

The bill would require health plans, providers, and clearing houses to adopt revisions to medical coding requirements by 2009. State, local, and tribal governments are excluded from the definitions of those entities in ERISA, and thus would not be directly subject to the required changes if they operate their own health plans for employees. However, from a practical perspective, they would have to comply in order for their health plans to be able to communicate information to providers, hospitals, other health plans, and clearing houses. CBO estimates that employee health plans of those governments would incur additional expenses of about $125 million over the 2007–2011 period in order to meet the 2009 deadline.

Those five-year costs are net of savings that would begin to accrue to governments in 2011. In that year, savings are estimated to total about $20 million.

The Medicaid program also would be subject to the new deadline, but because states have significant flexibility in that program to alter their programmatic and financial responsibilities to meet the

new requirement, the change would not be an intergovernmental mandate as defined in UMRA. CBO estimates that state spending would increase by about $20 million over the 2007–2011 period in order to meet the new coding deadline for Medicaid programs. Again, those five-year costs are net of savings that would begin to accrue in 2011.

The safe-harbor provisions would result in additional spending by states for Medicaid totaling about $55 million over the 2007–2011 period, CBO estimates.

Estimated impact on the private sector: The bill would impose private-sector mandates on health plans, providers, and clearing houses by requiring them to adopt updated coding and transaction standards by specified future dates. CBO estimates that the direct cost of these mandates would exceed the threshold specified in UMRA ($128 million in 2006, adjusted annually for inflation) in each of the first three years following enactment of the bill.

First, the bill would require the adoption of the 10th revision of the International Classification of Diseases (ICD–10) by October 1, 2009. Under current law, CBO expects that those updated standards will be adopted by the end of fiscal year 2012. CBO estimates the direct cost to the mandated entities would be $320 million in 2007, $470 million in 2008, $490 million in 2009, and $70 million in 2010. The new requirement would result in direct savings of $330 million in 2011 (and additional amounts in later years) because a significant part of the adoption costs would be shifted to the earlier years under the bill.

Second, the bill would require the adoption of updated standards for claims transactions by April 1, 2009. Specifically, health plans, providers, and clearing houses would be required to adopt updated versions of the Accredited Standards Committee X12 standards and the National Council for Prescription Drug Programs Telecommunication Standards. CBO expects that the deadline specified in the bill would be met under current law. Thus, the mandate would impose no additional costs on the mandated entities.

Estimate Prepared by: Federal Costs: Tom Bradley, Jeanne De Sa, and Camile Williams; Impact on state, local and tribal governments: Leo Lex; Impact on the private sector: Stuart Hagen and Julie Lee.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee, based on public hearing testimony and information from the Administration, concluded that it is appropriate and timely to consider the bill as reported.

B. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

With respect to clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the Committee advises that the bill H.R. 4157 makes *de minimis* authorization of funding.

C. CONSTITUTIONAL AUTHORITY STATEMENT

With respect to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, relating to Constitutional Authority, the Committee states that the Committee's action in reporting the bill is derived from Article 1 of the Constitution, Section 8 ('The Congress shall have power to lay and collect taxes, duties, imposts and excises, to pay the debts and to provide for * * * the general Welfare of the United States.')

D. INFORMATION RELATING TO UNFUNDED MANDATES

This information is provided in accordance with section 423 of the Unfunded Mandate Act of 1995 (P.L. 104–4). The Committee has determined that the bill does not contain Federal mandates on the private sector. The Committee has determined that the bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

VI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

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

PUBLIC HEALTH SERVICE ACT

* * * * * * *

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

* * * * * * *

PART D—HEALTH INFORMATION TECHNOLOGY

SEC. 271. OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY.

(a) ESTABLISHMENT.—There is established within the Department of Health and Human Services an Office of the National Coordinator for Health Information Technology that shall be headed by the National Coordinator for Health Information Technology (referred to in this section as the "National Coordinator"). The National Coordinator shall be appointed by the President and shall report directly to the Secretary. The National Coordinator shall be paid at a rate equal to the rate of basic pay for level IV of the Executive Schedule.

(b) GOALS OF NATIONWIDE INTEROPERABLE HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The National Coordinator shall

perform the duties under subsection (c) in a manner consistent with the development of a nationwide interoperable health information technology infrastructure that—

(1) improves health care quality, reduces medical errors, increases the efficiency of care, and advances the delivery of appropriate, evidence-based health care services;

(2) promotes wellness, disease prevention, and management of chronic illnesses by increasing the availability and transparency of information related to the health care needs of an individual for such individual;

(3) ensures that appropriate information necessary to make medical decisions is available in a usable form at the time and in the location that the medical service involved is provided;

(4) produces greater value for health care expenditures by reducing health care costs that result from inefficiency, medical errors, inappropriate care, and incomplete information;

(5) promotes a more effective marketplace, greater competition, greater systems analysis, increased choice, enhanced quality, and improved outcomes in health care services;

(6) improves the coordination of information and the provision of such services through an effective infrastructure for the secure and authorized exchange and use of health care information; and

(7) ensures that the confidentiality of individually identifiable health information of a patient is secure and protected.

(c) DUTIES OF NATIONAL COORDINATOR.—

(1) STRATEGIC PLANNER FOR INTEROPERABLE HEALTH INFORMATION TECHNOLOGY.—The National Coordinator shall maintain, direct, and oversee the continuous improvement of a strategic plan to guide the nationwide implementation of interoperable health information technology in both the public and private health care sectors consistent with subsection (b).

(2) PRINCIPAL ADVISOR TO HHS.—The National Coordinator shall serve as the principal advisor of the Secretary on the development, application, and use of health information technology, and coordinate the health information technology programs of the Department of Health and Human Services.

(3) COORDINATOR OF FEDERAL GOVERNMENT ACTIVITIES.—

(A) IN GENERAL.—The National Coordinator shall serve as the coordinator of Federal Government activities relating to health information technology.

(B) SPECIFIC COORDINATION FUNCTIONS.—In carrying out subparagraph (A), the National Coordinator shall provide for—

(i) the development and approval of standards used in the electronic creation, maintenance, or exchange of health information; and

(ii) the certification and inspection of health information technology products, exchanges, and architectures to ensure that such products, exchanges, and architectures conform to the applicable standards approved under clause (i).

(C) USE OF PRIVATE ENTITIES.—The National Coordinator shall, to the maximum extent possible, contract with

or recognize private entities in carrying out subparagraph (B).

(D) UNIFORM APPLICATION OF STANDARDS.—A standard approved under subparagraph (B)(i) for use in the electronic creation, maintenance, or exchange of health information shall preempt a standard adopted under State law, regulation, or rule for such a use.

(4) INTRAGOVERNMENTAL COORDINATOR.—The National Coordinator shall ensure that health information technology policies and programs of the Department of Health and Human Services are coordinated with those of relevant executive branch agencies and departments with a goal to avoid duplication of effort and to ensure that each agency or department conducts programs within the areas of its greatest expertise and its mission in order to create a national interoperable health information system capable of meeting national public health needs effectively and efficiently.

(5) ADVISOR TO OMB.—The National Coordinator shall provide to the Director of the Office of Management and Budget comments and advice with respect to specific Federal health information technology programs.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section for each of fiscal years 2006 through 2010.

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SOCIAL SECURITY ACT

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

PART A—GENERAL PROVISIONS

* * * * * * *

CIVIL MONETARY PENALTIES

SEC. 1128A. (a) * * *
(b)(1) * * *

* * * * * * *

(4)(A) For purposes of this subsection, a payment described in paragraph (1) does not include any nonmonetary remuneration (in the form of health information technology and related services) made on or after the HIT effective date (as defined in subparagraph (B)(ii)) by a hospital or critical access hospital to a physician if the following requirements are met:

(i) The provision of such remuneration is made without a condition that—

(I) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the location of the hospital or critical access hospital providing such technology;

(II) limits or restricts the use of the health information technology in conjunction with other health information technology; or

(III) takes into account the volume or value of referrals (or other business generated) by the physician to the hospital or critical access hospital.

(ii) Such remuneration is arranged for in a written agreement that is signed by a representative of the hospital or critical access hospital and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.

(B) For purposes of subparagraph (A) and sections 1128B(b)(3)(J) and 1877(e)(9)—

(i) the term "health information technology" means hardware, software, license, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) or related services used for the electronic creation, maintenance, and exchange of clinical health information; and

(ii) the term "HIT effective date" means the date that is 180 days after the date of the enactment of this paragraph.

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CRIMINAL PENALTIES FOR ACTS INVOLVING FEDERAL HEALTH CARE PROGRAMS

SEC. 1128B. (a) * * *

(b)(1) * * *

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(3) Paragraphs (1) and (2) shall not apply to—

(A) * * *

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(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section); **[**and**]**

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4)**[**.**]***;*

[(H)**]** *(I)* any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or en-

hance the quality, of services provided to a medically underserved population served by the health center entity**[.]***; and*

(J) any nonmonetary remuneration (in the form of health information technology, as defined in section 1128A(b)(4)(B)(i), and related services) solicited or received by a person on or after the HIT effective date (as defined in section 1128A(b)(4)(B)(ii)) (or offered or paid to a person on or after such date) if—

(i) such remuneration is solicited or received (or offered or paid) without a condition that—

(I) limits or restricts the use of the health information technology to services provided by the person to individuals receiving services at the location of the entity providing such technology;

(II) limits or restricts the use of the health information technology in conjunction with other health information technology; or

(III) takes into account the volume or value of referrals (or other business generated) by the person to the entity providing such technology; and

(ii) such remuneration is arranged for in a written agreement that is signed by a representative of the entity and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.

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PART C—ADMINISTRATIVE SIMPLIFICATION

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TIMETABLES FOR ADOPTION OF STANDARDS

SEC. 1174. (a) * * *

(b) ADDITIONS AND MODIFICATIONS TO STANDARDS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months *and in accordance with paragraph (3)*. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance. *For purposes of this subsection and section 1173(c)(2), the term "modification" includes a new version or a version upgrade.*

* * * * * * *

(3) EXPEDITED PROCEDURES FOR ADOPTION OF ADDITIONS AND MODIFICATIONS TO STANDARDS.—

(A) IN GENERAL.—For purposes of paragraph (1), the Secretary shall provide for an expedited upgrade program (in this paragraph referred to as the "upgrade program"), in accordance with this paragraph, to develop and approve additions and modifications to the standards adopted under section 1173(a) to improve the quality of such stand-

ards or to extend the functionality of such standards to meet evolving requirements in health care.

(B) PUBLICATION OF NOTICES.—Under the upgrade program:

(i) VOLUNTARY NOTICE OF INITIATION OF PROCESS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization is initiating a process to develop an addition or modification to a standard adopted under section 1173, the Secretary shall publish a notice in the Federal Register that—

(I) identifies the subject matter of the addition or modification;

(II) provides a description of how persons may participate in the development process; and

(III) invites public participation in such process.

(ii) VOLUNTARY NOTICE OF PRELIMINARY DRAFT OF ADDITIONS OR MODIFICATIONS TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has prepared a preliminary draft of an addition or modification to a standard adopted by section 1173, the Secretary shall publish a notice in the Federal Register that—

(I) identifies the subject matter of (and summarizes) the draft;

(II) specifies the procedure for obtaining documentation for the draft;

(III) provides a description of how persons may submit comments in writing and at any public hearing or meeting held by the organization on the draft; and

(IV) invites submission of such comments and participation in such hearing or meeting.

(iii) NOTICE OF PROPOSED ADDITION OR MODIFICATION TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has a proposed addition or modification to a standard adopted under section 1173 that the organization intends to submit under subparagraph (D)(iii), the Secretary shall publish a notice in the Federal Register that contains, with respect to the proposed addition or modification, the information required in the notice under clause (ii) with respect to a preliminary draft of an addition or modification.

(iv) CONSTRUCTION.—Nothing in this paragraph shall be construed as requiring a standard setting organization to request the notices described in clauses (i) and (ii) with respect to an addition or modification to a standard in order to qualify for an expedited determination under subparagraph (C) with respect to a proposal submitted to the Secretary for adoption of such addition or modification.

(C) PROVISION OF EXPEDITED DETERMINATION.—Under the upgrade program and with respect to a proposal by a standard setting organization for an addition or modification to a standard adopted under section 1173, if the Secretary determines that the standard setting organization developed such addition or modification in accordance with the requirements of subparagraph (D) and the National Committee on Vital and Health Statistics recommends approval of such addition or modification under subparagraph (E), the Secretary shall provide for expedited treatment of such proposal in accordance with subparagraph (F).

(D) REQUIREMENTS.—The requirements under this subparagraph with respect to a proposed addition or modification to a standard by a standard setting organization are the following:

(i) REQUEST FOR PUBLICATION OF NOTICE.—The standard setting organization submits to the Secretary a request for publication in the Federal Register of a notice described in subparagraph (B)(iii) for the proposed addition or modification.

(ii) PROCESS FOR RECEIPT AND CONSIDERATION OF PUBLIC COMMENT.—The standard setting organization provides for a process through which, after the publication of the notice referred to under clause (i), the organization—

(I) receives and responds to public comments submitted on a timely basis on the proposed addition or modification before submitting such proposed addition or modification to the National Committee on Vital and Health Statistics under clause (iii); and

(II) makes publicly available a written explanation for its response in the proposed addition or modification to comments submitted on a timely basis.

(iii) SUBMITTAL OF FINAL PROPOSED ADDITION OR MODIFICATION TO NCVHS.—After completion of the process under clause (ii), the standard setting organization submits the proposed addition or modification to the National Committee on Vital and Health Statistics for review and consideration under subparagraph (E). Such submission shall include information on the organization's compliance with the notice and comment requirements (and responses to those comments) under clause (ii).

(E) HEARING AND RECOMMENDATIONS BY NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.—Under the upgrade program, upon receipt of a proposal submitted by a standard setting organization under subparagraph (D)(iii) for the adoption of an addition or modification to a standard, the National Committee on Vital and Health Statistics shall provide notice to the public and a reasonable opportunity for public testimony at a hearing on such addition or modification. The Secretary may participate in such

hearing in such capacity (including presiding ex officio) as the Secretary shall determine appropriate. Not later than 120 days after the date of receipt of the proposal, the Committee shall submit to the Secretary its recommendation to adopt (or not adopt) the proposed addition or modification.

(F) DETERMINATION BY SECRETARY TO ACCEPT OR REJECT NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS RECOMMENDATION.—

(i) TIMELY DETERMINATION.—Under the upgrade program, if the National Committee on Vital and Health Statistics submits to the Secretary a recommendation under subparagraph (E) to adopt a proposed addition or modification, not later than 90 days after the date of receipt of such recommendation the Secretary shall make a determination to accept or reject the recommendation and shall publish notice of such determination in the Federal Register not later than 30 days after the date of the determination.

(ii) CONTENTS OF NOTICE.—If the determination is to reject the recommendation, such notice shall include the reasons for the rejection. If the determination is to accept the recommendation, as part of such notice the Secretary shall promulgate the modified standard (including the accepted proposed addition or modification accepted) as a final rule under this subsection without any further notice or public comment period.

(iii) LIMITATION ON CONSIDERATION.—The Secretary shall not consider a proposal under this subparagraph unless the Secretary determines that the requirements of subparagraph (D) (including publication of notice and opportunity for public comment) have been met with respect to the proposal.

(G) TREATMENT AS SATISFYING REQUIREMENTS FOR NOTICE-AND-COMMENT.—Any requirements under section 553 of title 5, United States Code, relating to notice and an opportunity for public comment with respect to a final rule promulgated under subparagraph (F) shall be treated as having been met by meeting the requirements of the notice and opportunity for public comment provided under provisions of subparagraphs (B)(iii), (D), and (E).

(H) NO JUDICIAL REVIEW.—A final rule promulgated under subparagraph (F) shall not be subject to judicial review.

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EFFECT ON STATE LAW

SEC. 1178. (a) GENERAL EFFECT.—*Subject to section 4(b) of the Health Information Technology Promotion Act of 2006—*

(1) * * *

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * * * *

PROVISIONS RELATING TO THE ADMINISTRATION OF PART A

SEC. 1816. (a) * * *

(b) With respect to—

(1) transactions under this part occurring on or after April 1, 2009, all providers of services shall use ASC X12 version 5010 with respect to services provided under this part in compliance with section 5(a) of the Health Information Technology Promotion Act of 2006; and

(2) services furnished on or after October 1, 2009—

(A) all providers of services shall use ICD–10–CM codes with respect to services provided under this part in compliance with section 5(b) of such Act; and

(B) hospitals shall use ICD–10–PCS codes (as well as ICD–10–CM codes) with respect to inpatient hospital services provided under this part in compliance with such section.

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PART E—MISCELLANEOUS PROVISIONS

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LIMITATION ON CERTAIN PHYSICIAN REFERRALS

SEC. 1877. (a) * * *

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(e) EXCEPTIONS RELATING TO OTHER COMPENSATION ARRANGEMENTS.—The following shall not be considered to be a compensation arrangement described in subsection (a)(2)(B):

(1) * * *

* * * * * * *

(9) INFORMATION TECHNOLOGY AND SERVICES.—Any nonmonetary remuneration (in the form of health information technology, as defined in section 1128A(b)(4)(B)(i), and related services) made on or after the HIT effective date (as defined in section 1128A(b)(4)(B)(ii)) by an entity to a physician if the following requirements are met:

(A) The provision of such remuneration is made without a condition that—

(i) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the location of the entity providing such technology;

(ii) limits or restricts the use of the health information technology in conjunction with other health information technology; or

(iii) takes into account the volume or value of referrals (or other business generated) by the physician to the entity providing such technology.

(B) Such remuneration is arranged for in a written agreement that is signed by a representative of the entity and by the physician and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health care quality or efficiency.

* * * * * * *

SECTION 264 OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

SEC. 264. RECOMMENDATIONS WITH RESPECT TO PRIVACY OF CERTAIN HEALTH INFORMATION.

(a) * * *

* * * * * * *

(c) REGULATIONS.—

(1) * * *

(2) PREEMPTION.—[A regulation] *Subject to section 4(b) of the Health Information Technology Promotion Act of 2006, a regulation* promulgated under paragraph (1) shall not supercede a contrary provision of State law, if the provision of State law imposes requirements, standards, or implementation specifications that are more stringent than the requirements, standards, or implementation specifications imposed under the regulation.

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VII. VIEWS

DISSENTING VIEWS ON H.R. 4157—"HEALTH INFORMATION TECHNOLOGY PROMOTION ACT OF 2006"

The promise of expanding the use of interoperable health information technology (IT) systems has been widely documented. Information technology applications in the field of health care are expected to yield greater efficiencies and save lives. Total system-wide savings from widespread adoption of health information technology are estimated to range from $81 billion to $160 billion per year when fully implemented.

Unfortunately, H.R. 4157, as reported by the Committee on Ways and Means, will not advance the goal of a nationwide interoperable health information technology system. In fact, this legislation actually causes greater harm by squandering an important opportunity to establish a clear pathway to achieve interoperability standards and assure widespread adoption. Moreover, the bill will foster fraud, waste, and abuse in the Medicare program, and sets in motion a process to preempt state laws and regulations that protect the privacy and confidentiality of individually identifiable health information.

A number of organizations representing consumers, providers and others wrote to express concerns with the Chairman's Mark

and support for several of the Democratic amendments discussed below. Those letters have been inserted in the Record.

PRIVACY PROTECTIONS ARE ERODED

H.R. 4157, as reported, undermines patients' right to privacy with respect to individually identifiable health information. While the legislation reported out of the Subcommittee on Health contained troubling provisions on privacy, the Chairman's Mark amended the reported bill with a provision that would ultimately clearly preempt state privacy laws that are stronger than the federal law. This is unacceptable.

The federal privacy regulations that resulted from the Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a minimum level of protection at the federal level, while allowing continued application of more protective state laws. As required under the law, the Clinton Administration issued final regulations in 2000, after Congress was unable to agree on privacy legislation in the three years following the passage of HIPAA. The Bush Administration then suspended the rules after taking office in 2001, and proposed modifications and finalized new rules in 2002.

HIPAA applies directly to only providers, insurers, and "health care clearinghouses," though others who use information from these "covered entities" are vicariously subject to HIPAA as "business associates" of the covered entities. Regulatory changes made by the Bush Administration in 2002 authorize the use and disclosure without consent of virtually *all* identifiable health information in routine situations—e.g., for treatment, payment, or health care operations (e.g., quality improvement activities; underwriting; business planning and administration, certain fundraising for the benefit of the covered entity, etc.).

Even with these weakened standards, enforcement is passive and virtually non-existent, relying almost exclusively on complaints to trigger investigations. According to the Administration, the Department of Health and Human Services (HHS) has been enforcing the privacy rule since April 2003, which is the date by which most entities were required to be in compliance, but no penalties have been levied. Plus, even if enforcement were more aggressive, the penalties apply only in narrow, egregious situations and only to covered entities, not to business associates or to individual employees who have actually engaged in the misconduct.

HHS may impose civil money penalties on a covered entity of $1.00 per failure to comply, not to exceed $25,000 per year. However, HHS may not impose a fine if the violation did not involve willful neglect and the covered entity corrected the violation within 30 days of when it knew or should have known of the violation. In addition, criminal penalties are theoretically available. A covered entity who knowingly obtains or discloses protected health information could be fined $50,000 and face up to one year in prison; higher penalties and longer terms are available if the case involves false pretenses or the intent to sell, transfer, or use the information for commercial advantage, personal gain, or malicious harm. Regardless, it is important to note that available remedies under federal law, if applied, are provided to the government, not the individual whose information was disclosed or misused.

Efforts to move toward an electronic environment need to enhance—not erode—confidentiality of individually identifiable health information and improve enforcement. Electronic systems make it easier, not harder, to accommodate different laws. Vendors or other software developers can build the various laws into the system, and update as needed. More uniformity may be desirable but would only be acceptable if it leads to an improvement for all, not an erosion for many.

HIPAA was consciously designed as a floor upon which states could build. As such, its provisions are inadequate in many ways. States have a variety of laws that provide additional protections for certain sensitive information. Some states even provide for a right of action that allows individuals to pursue remedies when information is improperly used or disclosed. Careful consideration and public debate should occur before a weak federal standard is used to preempt stronger state laws. That has not occurred in this Committee.

LACKS A TIMELINE FOR STANDARDS DEVELOPMENT AND ADOPTION

To assure progress on the development of interoperability standards for health information technology, Congress needs to provide leadership and schedule a timeline for action. For more than a decade, adoption of standards has been stalled to protect proprietary interests. In such circumstances, it is necessary for the government to step in to assert the public's interest. Without uniform standards, systems are unable to communicate with one another and the potential benefits of expanding the use of technology in clinical practice remain out of reach.

Although many standards have already been developed, few have been adopted because there is no incentive for providers or venders to adhere to particular standards. As a result, patients and taxpayers have been forced to wait to enjoy the benefits of an interoperable health information technology system. As it stands, HR 4157 does not establish a deadline or even a timeframe for adoption of standards. Accordingly, the legislation fails to lay the fundamental groundwork needed to move forward. The first step toward the vision of an interoperable system is to set a deadline by which standards have to be designated.

LACK OF FUNDING

To spur adoption among providers, Congress should fund acquisition, support, and maintenance of information technology systems that meet the designated standards. At the same time, Congress should ensure that Medicare patients receive the full benefit of health information technology systems by requiring Medicare providers to use such systems. In addition, relevant technology purchased by the federal government and its contractors should also comply with the standards. The system-wide savings expected from the more efficient health system will more than offset the initial investments.

Unfortunately, HR 4157 fails to take these needed steps. There is nothing in the legislation that assures meaningful use of interoperable health technology. Absent widespread or near universal adoption, the potential savings and clinical benefits will never be fully realized. Even more alarming, because the legislation lacks

funding and encourages providers to invest in technology that does not meet standards, HR 4157 could actually undermine the goal of widespread adoption by creating perverse incentives for investment in non-interoperable products just prior to the designation of needed standards. This could lead to further entrenchment and commitment to systems that may soon be rendered obsolete.

INCREASES WASTE, FRAUD AND ABUSE

Rather than provide funding for acquisition and support of health information technology, the Chairman's bill presumes that providers themselves will supply equipment and services to other providers. In order to accommodate these relationships, section 3 of the bill creates several exceptions to Medicare's anti-fraud and abuse statutes. These provisions will increase Medicare's vulnerability to waste, fraud, and abuse, and will not result in the level of investment needed to materially advance the adoption of health information technology among hospitals and physician offices.

Most hospitals do not have the capital resources necessary to purchase health information technology for physicians, and many physicians do not want to be beholden to hospitals or other entities for the provision of IT. Poor and rural communities will likely be left behind with this strategy, exacerbating health disparities in under-served populations.

In testimony before the Subcommittee, a large health system that has been a prime advocate for the exception to limitations in the self-referral law admitted that the exception would only benefit a handful of providers that met very specific conditions. Other providers have privately admitted that they want to use information technology to tighten relationships with certain doctors or gain a competitive edge over other hospitals in the market.

At the same time, physicians with privileges at multiple hospitals do not want to be locked into one hospital in their community, particularly when a hospital that has extra resources to purchase information technology is likely to already be more dominant. Conversely, forcing doctors to maneuver between multiple information technology systems to accommodate various hospitals in their community is inefficient, undesirable and not feasible. Furthermore, hospital-level systems may be inappropriate for physician practices, and physicians are rightfully concerned about hospitals "owning" their patients' data.

Creating safe harbors that encourage purchase of information technology prior to the adoption and certification of standards, as this legislation would do, will exacerbate current problems relating to multiple systems that are not interoperable. It will also undermine interest in moving forward with compliant systems when standards are in place. Promoting immediate investment in and subsequent adoption of systems that are not interoperable or do not meet standards will only impede future progress by encouraging stove-piping, waste, and "buy-in" to old systems.

The Centers for Medicare and Medicaid Services (CMS) and the HHS Office of the Inspector General (OIG) are predicted to issue a final rule by the end of this year that would create tightly-crafted safe harbors enabling these transactions. It is difficult to draft safe harbors that balance the need to maintain program integrity while permitting previously impermissible activities; involvement of

CMS, OIG and the Department of Justice is critical, yet this does not appear to have happened in the drafting of HR 4157.

Finally, the Congressional Budget Office has sent a letter, as seen in the Record, indicating that section 3 will increase Medicare spending because of the induced services and other increased waste, fraud, and abuse expected as a result of these provisions. A precise estimate is not available at this time.

DEMOCRATIC AMENDMENTS

Mr. Emanuel and Mr. Doggett offered an amendment, which was defeated on a party-line vote, to strengthen current HIPAA protections. This amendment would have replaced section 4 with provisions to improve and preserve privacy, confidentiality and security protections for individually identifiable health information in the new electronic environment. The amendment included provisions that would have—

(1) created a consent requirement;

(2) required breach notification to affected individual(s) and the Secretary;

(3) extended the application of rules and protections to all entities;

(4) established safeguard requirements; and

(5) provided access to damages and other relief for individuals whose information is inappropriately disclosed or used.

In addition, Mr. Stark offered an amendment to protect from preemption state laws that provide greater protection of information relating to mental health, substance abuse, rape, incest and other domestic violence, family planning, HIV, sexually transmitted diseases, screening for and presence of genes or genetic markers, and other sensitive areas as designated by the Secretary, or permit individuals to pursue legal action against an entity that improperly uses or discloses identifiable health information. This amendment was also defeated on a party-line vote.

Two additional amendments would have addressed timeline and funding concerns. The first, offered by Mr. Emanuel, would have established a process for the Secretary to develop and approve interoperability standards within 24 months of enactment if the process set forth in section 2 of the bill did not produce standards within 18 months of enactment. The amendment also directed the Secretary of HHS to establish a Medicare payment to finance the purchase of health information technology that meets specified standards. Finally, the amendment would have required Medicare providers—including Medicare Advantage and Part D plans—to use electronic health records with the core functionalities identified by the Institute of Medicine in their correspondence to HHS, "Key Capabilities of an electronic Health Record System" (July 31, 2003).

An amendment offered by Mr. Thompson proposed to give Medicare providers the financial assistance necessary to purchase, support, and maintain health information technology systems. Recognizing that the cost of such systems is still unknown, the amendment gave broad authority for the Secretary of HHS to determine the appropriate amount and manner of distributing these funds. Funding would be available to all providers, including integrated delivery systems whose systems needed to be conformed to meet the new standards. However, given the current payment structure

for Medicare Advantage plans, most plans would have been ineligible for additional funding under this provision.

Although it is widely acknowledged that direct financing is an essential component for widespread adoption of health information technology, these two amendments were defeated on party-line votes.

Finally, Mr. Stark offered an amendment to strike section 3. It was also defeated on a party-line vote.

CONCLUSION

Democrats want to see widespread adoption of inter-operable health information technology systems be a reality. That's why amendments were offered to ensure progress on this critical front.

Lack of ready access to critical information in a patient's medical record has resulted in massive inefficiencies, sub-optimal quality of care, and even death. The longer the Congress waits to provide the leadership necessary to progress toward a fully interoperable health information technology system, the more damage that is done. Unfortunately, HR 4157 as reported by the Committee misses the mark. Even worse, if passed in its current form, this bill may hinder the development of interoperable medical records for years to come.

The promotion of health information technology should not be a partisan undertaking. However, the Committee leadership has made it so every step of the way: rejecting our suggestions and potential compromise positions to early drafts of the bill, not seeking input from the minority in constructing a manager's amendment, and defeating each of our amendments on party-line votes.

In contrast, the Senate unanimously passed a bill (S 1418) to establish standards and certification processes for interoperability within a year of enactment, and to provide funding to help health care providers acquire and support the expanded use of information technology in their practices. Although S 1418 does not go as far as we would like, it is significantly better than the bill the Committee recommended.

We look forward to correcting the deficiencies in HR 4157 prior to final passage by the House in order to send into conference with the Senate a strong bill with timelines for action, clear guidance for advancement, financial support, and improved patient privacy protections.

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