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REPT. 109–601
Part 1

BETTER HEALTH INFORMATION SYSTEM 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. BARTON of Texas, from the Committee on Energy and Commerce, 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 Energy and Commerce, 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 amendments and recommend that the bill as amended do pass.

CONTENTS

	Page
Amendment	2
Purpose and Summary	13
Background and Need for Legislation	14
Hearings	22
Committee Consideration	23
Committee Votes	23
Committee Oversight Findings	32
Statement of General Performance Goals and Objectives	32
New Budget Authority, Entitlement Authority, and Tax Expenditures	32
Committee Cost Estimate	32
Congressional Budget Office Estimate	32
Federal Mandates Statement	37
Advisory Committee Statement	37
Constitutional Authority Statement	37
Applicability to Legislative Branch	38
Section-by-Section Analysis of the Legislation	38
Changes in Existing Law Made by the Bill, as Reported	40

49–006

Dissenting Views 54

AMENDMENT

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 "Better Health Information System 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. Preserving privacy and security laws.

TITLE I—COORDINATION FOR, PLANNING FOR, AND INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY

Sec. 101. Office of the National Coordinator for Health Information Technology.
Sec. 102. Report on the American Health Information Community.
Sec. 103. Interoperability planning process; Federal information collection activities.
Sec. 104. Ensuring health care providers may maintain health information in electronic form.
Sec. 105. Study and report on State, regional, and community health information exchanges.
Sec. 106. Grants to integrated health systems to promote health information technologies to improve coordination of care for the uninsured, underinsured, and medically underserved.
Sec. 107. Demonstration program.

TITLE II—EXPEDITED MODIFICATION PROCEDURES FOR AND ADOPTION OF TRANSACTIONAL STANDARDS AND CODES

Sec. 201. Procedures to ensure timely updating of standards that enable electronic exchanges.
Sec. 202. Upgrading ASC X12 and NCPDP standards.
Sec. 203. Coding and documentation of non-medical information.

TITLE III—PROMOTING THE USE OF HEALTH INFORMATION TECHNOLOGY TO BETTER COORDINATE HEALTH CARE

Sec. 301. Safe harbors to antikickback civil penalties and criminal penalties for provision of health information technology and training services.
Sec. 302. Exception to limitation on certain physician referrals (under Stark) for provision of health information technology and training services to health care professionals.

SEC. 2. PRESERVING PRIVACY AND SECURITY LAWS.

Nothing in this Act (or the amendments made by this Act) shall be construed to affect the scope, substance, or applicability of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 and any regulation issued pursuant to such section.

TITLE I—COORDINATION FOR, PLANNING FOR, AND INTEROPERABILITY OF HEALTH INFORMATION TECHNOLOGY

SEC. 101. 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 part as the 'National Coordinator'). The National Coordinator shall be appointed by and 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, promotes data accuracy, 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) promotes the availability of appropriate and accurate information necessary to make medical decisions 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 or inaccurate information;

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

"(6) with respect to health information of consumers, advances the portability of such information and the ability of such consumers to share and use such information to assist in the management of their health care;

"(7) 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;

"(8) is consistent with legally applicable requirements with respect to securing and protecting the confidentiality of individually identifiable health information of a patient;

"(9) promotes the creation and maintenance of transportable, secure, Internet-based personal health records, including promoting the efforts of health care payers and health plan administrators for a health plan, such as Federal agencies, private health plans, and third party administrators, to provide for such records on behalf of members of such a plan;

"(10) promotes access to and review of the electronic health record of a patient by such patient;

"(11) promotes health research and health care quality research and assessment; and

"(12) promotes the efficient and streamlined development, submission, and maintenance of electronic health care clinical trial data.

"(c) DUTIES OF THE NATIONAL COORDINATOR.—

"(1) STRATEGIC PLANNER FOR INTEROPERABLE HEALTH INFORMATION TECHNOLOGY.—The National Coordinator shall provide for a strategic plan for 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 THE SECRETARY.—The National Coordinator shall serve as the principal advisor to the Secretary on the development, application, and use of health information technology, and shall coordinate the policies and programs of the Department of Health and Human Services for promoting the use of health information technology.

"(3) 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, to align the health information architecture of each agency or department toward a common approach, 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, and to assist Federal agencies and departments in security programs, policies, and protections to prevent unauthorized access to individually identifiable health information created, maintained, or in the temporary possession of that agency or department. The coordination authority provided to the National Coordinator under the previous sentence shall supercede any such authority otherwise provided to any other official of the Department of Health and Human Services. For the purposes of this paragraph, the term 'unauthorized access' means access that is not authorized by that agency or department including unauthorized employee access.

"(4) 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.

"(5) PROMOTER OF HEALTH INFORMATION TECHNOLOGY IN MEDICALLY UNDERSERVED COMMUNITIES.—The National Coordinator shall—

"(A) identify sources of funds that will be made available to promote and support the planning and adoption of health information technology in

medically underserved communities, including in urban and rural areas, either through grants or technical assistance;

"(B) coordinate with the funding sources to help such communities connect to identified funding; and

"(C) collaborate with the Agency for Healthcare Research and Quality and the Health Services Resources Administration and other Federal agencies to support technical assistance, knowledge dissemination, and resource development, to medically underserved communities seeking to plan for and adopt technology and establish electronic health information networks across providers.".

(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) RULE OF CONSTRUCTION.— Nothing in this section or the amendment made by this section shall be construed as requiring the duplication of Federal efforts with respect to the establishment of the Office of the National Coordinator for Health Information Technology, regardless of whether such efforts are carried out before or after the date of the enactment of this Act.

(3) 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 Secretary of Health and Human Services may appoint the old National Coordinator as the new National Coordinator.

(4) 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. 102. 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 national guidelines, the development of a nationwide health information network, and the increased adoption of health information technology.

(2) Information on how model privacy and security policies may be used to protect confidentiality of health information, and an assessment of how existing policies compare to such model policies.

(3) Information on the progress in—

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

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

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

(4) Recommendations for the transition of AHIC to a longer-term advisory and facilitation 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 role of the Federal Government in the entity;

(D) steps for—

(i) continued leadership in the facilitation of guidelines or standards;

(ii) the alignment of financial incentives; and

(iii) the long-term plan for health care transformation through information technology; and

(E) the elimination or revision of the functions of AHIC during the development of the nationwide health information network.

SEC. 103. INTEROPERABILITY PLANNING PROCESS; FEDERAL INFORMATION COLLECTION ACTIVITIES.

Part D of title II of the Public Health Service Act, as added by section 101, is amended by adding at the end the following new section:

"SEC. 272. INTEROPERABILITY PLANNING PROCESS; FEDERAL INFORMATION COLLECTION ACTIVITIES.

"(a) STRATEGIC INTEROPERABILITY PLANNING PROCESS.—

"(1) ASSESSMENT AND ENDORSEMENT OF CORE STRATEGIC GUIDELINES.—

"(A) IN GENERAL.—Not later than December 31, 2006, the National Coordinator shall publish a strategic plan, including a schedule, for the assessment and the endorsement of core interoperability guidelines for significant use cases consistent with this subsection. The National Coordinator may update such plan from time to time.

"(B) ENDORSEMENT.—

"(i) IN GENERAL.—Consistent with the schedule under this paragraph and not later than one year after the publication of such schedule, the National Coordinator shall endorse a subset of core interoperability guidelines for significant use cases. The National Coordinator shall continue to endorse subsets of core interoperability guidelines for significant use cases annually consistent with the schedule published pursuant to this paragraph, with endorsement of all such guidelines completed not later than August 31, 2009.

"(ii) CONSULTATION.—All such endorsements shall be in consultation with the American Health Information Community and other appropriate entities.

"(iii) VOLUNTARY COMPLIANCE.—Compliance with such guidelines shall be voluntary, subject to subsection (b)(1).

"(C) CONSULTATION WITH OTHER PARTIES.—The National Coordinator shall develop and implement such strategic plan in consultation with the American Health Information Community and other appropriate entities.

"(D) DEFINITIONS.—For purposes of this section:

"(i) INTEROPERABILITY GUIDELINE.—The term 'interoperability guideline' means a guideline to improve and promote the interoperability of health information technology for purposes of electronically accessing and exchanging health information. Such term includes named standards, architectures, software schemes for identification, authentication, and security, and other information needed to ensure the reproducible development of common solutions across disparate entities.

"(ii) CORE INTEROPERABILITY GUIDELINE.—The term 'core interoperability guideline' means an interoperability guideline that the National Coordinator determines is essential and necessary for purposes described in clause (i).

"(iii) SIGNIFICANT USE CASE.—The term 'significant use case' means a category (as specified by the National Coordinator) that identifies a significant use or purpose for the interoperability of health information technology, such as for the exchange of laboratory information, drug prescribing, clinical research, and electronic health records.

"(2) NATIONAL SURVEY.—

"(A) IN GENERAL.—Not later than August 31, 2008, the National Coordinator shall conduct one or more surveys designed to measure the capability of entities (including Federal agencies, State and local government agencies, and private sector entities) to exchange electronic health information by appropriate significant use case. Such surveys shall identify the extent to which the type of health information, the use for such information, or any other appropriate characterization of such information may relate to the capability of such entities to exchange health information in a manner that is consistent with methods to improve the interoperability of health information and with core interoperability guidelines.

"(B) DISSEMINATION OF SURVEY RESULTS.—The National Coordinator shall disseminate the results of such surveys in a manner so as to—

"(i) inform the public on the capabilities of entities to exchange electronic health information;

"(ii) assist in establishing a more interoperable information architecture; and

"(iii) identify the status of health information systems used in Federal agencies and the status of such systems with respect to interoperability guidelines.

"(b) FEDERAL HEALTH INFORMATION COLLECTION ACTIVITIES.—

"(1) REQUIREMENTS.—With respect to a core interoperability guideline endorsed under subsection (a)(1)(B) for a significant use case, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such guideline within three years after the date of such endorsement.

"(2) PROMOTING USE OF NON-IDENTIFIABLE HEALTH INFORMATION TO IMPROVE HEALTH RESEARCH AND HEALTH CARE QUALITY.—

"(A) IN GENERAL.—Where feasible, and consistent with applicable privacy or security or other laws, the President, in consultation with the Secretary, shall take measures to allow timely access to useful categories of non-identifiable health information in records maintained by the Federal government, or maintained by entities under contract with the Federal government, to advance health care quality and health research where such information is in a form that can be used in such research. The President shall consult with appropriate Federal agencies, and solicit public comment, on useful categories of information, and appropriate measures to take. The President may consider the administrative burden and the potential for improvements in health care quality in determining such appropriate measures. In addition, the President, in consultation with the Secretary, shall encourage voluntary private and public sector efforts to allow access to such useful categories of non-identifiable health information to advance health care quality and health research.

"(B) NON-IDENTIFIABLE HEALTH INFORMATION DEFINED.—For purposes of this paragraph, the term 'non-identifiable health information' means information that is not individually identifiable health information as defined in rules promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note), and includes information that has been de-identified so that it is no longer individually identifiable health information, as defined in such rules.

"(3) ANNUAL REVIEW AND REPORT.—For each year during the five-year period following the date of the enactment of this section, the National Coordinator shall review the operation of health information collection by and submission to the Federal government and the purchases (and planned purchases) of health information technology by the Federal government. For each such year and based on the review for such year, the National Coordinator shall submit to the President and Congress recommendations on methods to—

"(A) streamline (and eliminate redundancy in) Federal systems used for the collection and submission of health information;

"(B) improve efficiency in such collection and submission;

"(C) increase the ability to assess health care quality; and

"(D) reduce health care costs.".

SEC. 104. ENSURING HEALTH CARE PROVIDERS MAY MAINTAIN HEALTH INFORMATION IN ELECTRONIC FORM.

Part D of title II of the Public Health Service Act, as added by section 101(a) and amended by section 103, is amended by adding at the end the following new section:

"SEC. 273. ENSURING HEALTH CARE PROVIDERS MAY MAINTAIN HEALTH INFORMATION IN ELECTRONIC FORM.

"(a) IN GENERAL.—Any health care provider that participates in a health care program that receives Federal funds shall be deemed as meeting any requirement for the maintenance of data in paper form under such program (whether or not for purposes of management, billing, reporting, reimbursement, or otherwise) if the required data is maintained in an electronic form.

"(b) RELATION TO STATE LAWS.—Beginning on the date that is one year after the date of the enactment of this section, subsection (a) shall supersede any contrary provision of State law.

"(c) CONSTRUCTION.—Nothing in this section shall be construed as—

"(1) requiring health care providers to maintain or submit data in electronic form;

"(2) preventing a State from permitting health care providers to maintain or submit data in paper form; or

"(3) preventing a State from requiring health care providers to maintain or submit data in electronic form.".

SEC. 105. STUDY AND REPORT ON STATE, REGIONAL, AND COMMUNITY HEALTH INFORMATION EXCHANGES.

(a) STUDY.—The Secretary of Health and Human Services shall conduct a study on issues related to the development, operation, and implementation of State, regional, and community health information exchanges. Such study shall include the following, with respect to such health information exchanges:

(1) Profiles detailing the current stages of such health information exchanges with respect to the progression of the development, operation, implementation, organization, and governance of such exchanges.

(2) The impact of such exchanges on healthcare quality, safety, and efficiency, including—

(A) any impact on the coordination of health information and services across healthcare providers and other organizations relevant to health care;

(B) any impact on the availability of health information at the point-of-care to make timely medical decisions;

(C) any benefits with respect to the promotion of wellness, disease prevention, and chronic disease management;

(D) any improvement with respect to public health preparedness and response;

(E) any impact on the widespread adoption of interoperable health information technology, including electronic health records;

(F) any contributions to achieving an Internet-based national health information network;

(G) any contribution of health information exchanges to consumer access and to consumers' use of their health information; and

(H) any impact on the operation of—

(i) the Medicaid program;

(ii) the State Children's Health Insurance Program (SCHIP);

(iii) disproportionate share hospitals described in section 1923 of the Social Security Act;

(iv) Federally-qualified health centers; or

(v) managed care plans, if a significant number of the plan's enrollees are beneficiaries in the Medicaid program or SCHIP.

(3) Best practice models for financing, incentivizing, and sustaining such health information exchanges.

(4) Information identifying the common principles, policies, tools, and standards used (or proposed) in the public and private sectors to support the development, operation, and implementation of such health information exchanges.

(5) A description of any areas in which Federal government leadership is needed to support growth and sustainability of such health information exchanges.

(b) REPORT.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the study described in subsection (a), including such recommendations as the Secretary determines appropriate to facilitate the development, operation, and implementation of health information exchanges.

SEC. 106. GRANTS TO INTEGRATED HEALTH SYSTEMS TO PROMOTE HEALTH INFORMATION TECHNOLOGIES TO IMPROVE COORDINATION OF CARE FOR THE UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED.

Subpart I of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

"SEC. 330M. GRANTS FOR IMPROVEMENT OF THE COORDINATION OF CARE FOR THE UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED.

"(a) IN GENERAL.—The Secretary may make grants to integrated health care systems, in accordance with this section, for projects to better coordinate the provision of health care through the adoption of new health information technology, or the significant improvement of existing health information technology, to improve the provision of health care to uninsured, underinsured, and medically underserved individuals (including in urban and rural areas) through health-related information about such individuals, throughout such a system and at the point of service.

"(b) ELIGIBILITY.—

"(1) APPLICATION.—To be eligible to receive a grant under this section, an integrated health care system shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

"(A) a description of the project that the system will carry out using the funds provided under the grant;

"(B) a description of the manner in which the project funded under the grant will advance the goal specified in subsection (a); and

"(C) a description of the populations to be served by the adoption or improvement of health information technology.

"(2) OPTIONAL REPORTING CONDITION.—The Secretary may also condition the provision of a grant to an integrated health care system under this section for a project on the submission by such system to the Secretary of a report on the impact of the health information technology adopted (or improved) under such project on the delivery of health care and the quality of care (in accordance with applicable measures of such quality). Such report shall be at such time and in such form and manner as specified by the Secretary.

"(c) INTEGRATED HEALTH CARE SYSTEM DEFINED.—For purposes of this section, the term 'integrated health care system' means a system of health care providers that is organized to provide care in a coordinated fashion and has a demonstrated commitment to provide uninsured, underinsured, and medically underserved individuals with access to such care.

"(d) PRIORITIES.—In making grants under this section, the Secretary shall give priority to an integrated health care system—

"(1) that can demonstrate past successful community-wide efforts to improve the quality of care provided and the coordination of care for the uninsured, underinsured, and medically underserved; or

"(2) if the project to be funded through such a grant—

"(A) will improve the delivery of health care and the quality of care provided; and

"(B) will demonstrate savings for State or Federal health care benefits programs or entities legally obligated under Federal law to provide health care from the reduction of duplicative health care services, administrative costs, and medical errors.

"(e) LIMITATION, MATCHING REQUIREMENT, AND CONDITIONS.—

"(1) LIMITATION ON USE OF FUNDS.—None of the funds provided under a grant made under this section may be used for a project providing for the adoption or improvement of health information technology that is used exclusively for financial record keeping, billing, or other non-clinical applications.

"(2) MATCHING REQUIREMENT.—To be eligible for a grant under this section an integrated health care system shall contribute non-Federal contributions to the costs of carrying out the project for which the grant is awarded in an amount equal to $1 for each $5 of Federal funds provided under the grant.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2007 and 2008.".

SEC. 107. DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a demonstration program under which the Secretary makes grants to small physician practices (including such practices that furnish services to individuals with chronic illnesses) that are located in rural areas or medically underserved urban areas for the purchase and support of health information technology.

(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an applicant shall prepare and submit to the Secretary of Health and Human Services an application, at such time, in such manner, and containing such information, as the Secretary may require.

(c) REPORTING.—

(1) REQUIRED REPORTS BY SMALL PHYSICIAN PRACTICES.—A small physician practice receiving a grant under subsection (a) shall submit to the Secretary of Health and Human Services an evaluation on the health information technology funded by such grant. Such evaluation shall include information on—

(A) barriers to the adoption of health information technology by the small physician practice;

(B) issues for such practice in the use of health information technology;

(C) the effect health information technology will have on the quality of health care furnished by such practice; and

(D) the effect of the rules under sections 1128A, 1128B, and 1877 of the Social Security Act and any medical liability rules on such practice.

(2) REPORT TO CONGRESS.—Not later than January 1, 2009, the Secretary of Health and Human Services shall submit to Congress a report on the results of the demonstration program under this section.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2007 and 2008.

TITLE II—EXPEDITED MODIFICATION PROCEDURES FOR AND ADOPTION OF TRANSACTIONAL STANDARDS AND CODES

SEC. 201. 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(a), 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 of 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(a), the Secretary shall publish a notice in the Federal Register that—

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

"(II) specifies the procedure for obtaining 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 addition or modification; and

"(IV) invites submission of such comments and participation in such hearing or meeting without requiring the public to pay a fee to participate.

"(iii) NOTICE OF PROPOSED ADDITION OR MODIFICATION TO STANDARDS.—Not later than 30 days after the date of 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(a) 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 the 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(a), 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);

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

"(III) makes public comments received under clause (I) available, or provides access to such comments, to the Secretary.

"(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 90 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).

"(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) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to a final rule promulgated under subparagraph (F).".

SEC. 202. UPGRADING ASC X12 AND NCPDP STANDARDS.

The Secretary of Health and Human Services shall provide by notice published in the Federal Register for the following replacements of standards to apply to transactions occurring on or after April 1, 2009:

(1) 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.

(2) 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 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, 2007.

SEC. 203. CODING AND DOCUMENTATION OF NON-MEDICAL INFORMATION.

In any regulation or other action implementing the International Classification of Diseases, 10th revision, Clinical Modification (ICD–10–CM), the International Classification of Diseases, 10th revision, Procedure Coding System (ICD–10–PCS), or other version of the International Classification of Diseases, 10th revision, the Secretary of Health and Human Services shall ensure that no health care provider is required to code to a level of specificity that would require documentation of non-medical information on the external cause of any given type of injury.

TITLE III—PROMOTING THE USE OF HEALTH INFORMATION TECHNOLOGY TO BETTER COORDINATE HEALTH CARE

SEC. 301. SAFE HARBORS TO ANTIKICKBACK CIVIL PENALTIES AND CRIMINAL PENALTIES FOR PROVISION OF HEALTH INFORMATION TECHNOLOGY AND TRAINING SERVICES.

(a) FOR CIVIL PENALTIES.—Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a) is amended—

(1) in subsection (b), by adding at the end the following new paragraph:

"(4) For purposes of this subsection, inducements to reduce or limit services described in paragraph (1) shall not include the practical or other advantages resulting from health information technology or related installation, maintenance, support, or training services."; and

(2) in subsection (i), by adding at the end the following new paragraph:

"(8) The term 'health information technology' means hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.".

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

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

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

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

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

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

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

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

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

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

"(J) any nonmonetary remuneration (in the form of health information technology, as defined in section 1128A(i)(8), or related installation, maintenance, support or training services) made to a person by an entity that is a hospital, group practice, prescription drug plan sponsor, or Medicare Advantage organization if—

"(i) the provision of such remuneration is without an agreement between the parties or legal 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 entity;

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

"(III) conditions the provision of such remuneration on the referral of patients or business to the entity;

"(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) and that specifies the remuneration solicited or received (or offered or paid) and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health quality, efficiency, or research; and

"(iii) the entity providing the remuneration (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability.".

(c) EFFECTIVE DATE AND EFFECT ON STATE LAWS.—

(1) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect on the date that is 120 days after the date of the enactment of this Act.

(2) PREEMPTION OF STATE LAWS.—No State (as defined in section 1101(a) of the Social Security Act (42 U.S.C. 1301(a)) for purposes of title XI of such Act) shall have in effect a State law that imposes a criminal or civil penalty for a transaction described in section 1128A(b)(4) or section 1128B(b)(3)(J) of such Act, as added by subsections (a)(1) and (b), respectively, if the conditions described in the respective provision, with respect to such transaction, are met.

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

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

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

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

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

(D) The impact of the adoption of health information technology on health care quality, cost, and access under each safe harbor.

(2) REPORT.—Not later than three years after the effective date described in subsection (c)(1), the Secretary of Health and Human Services shall submit to Congress a report on the study under paragraph (1).

(3) SAFE HARBORS DESCRIBED.—For purposes of paragraphs (1) and (2), the safe harbors described in this paragraph are—

(A) the safe harbor under section 1128A(b)(4) of such Act (42 U.S.C. 1320a-7a(b)(4)), as added by subsection (a)(1); and

(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).

SEC. 302. EXCEPTION TO LIMITATION ON CERTAIN PHYSICIAN REFERRALS (UNDER STARK) FOR PROVISION OF HEALTH INFORMATION TECHNOLOGY AND TRAINING SERVICES TO HEALTH CARE PROFESSIONALS.

(a) IN GENERAL.—Section 1877(b) of the Social Security Act (42 U.S.C. 1395nn(b)) is amended by adding at the end the following new paragraph:

"(6) INFORMATION TECHNOLOGY AND TRAINING SERVICES.—

"(A) IN GENERAL.—Any nonmonetary remuneration (in the form of health information technology or related installation, maintenance, support or training services) made by an entity that is a hospital, group practice, prescription drug plan sponsor, or a Medicare Advantage organization to a physician if—

"(i) the provision of such remuneration is without an agreement between the parties or legal 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 entity;

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

"(III) conditions the provision of such remuneration on the referral of patients or business to the entity;

"(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) 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 quality, efficiency, or research; and

"(iii) the entity (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability.

"(B) HEALTH INFORMATION TECHNOLOGY DEFINED.—For purposes of subparagraph (A), the term 'health information technology' means hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.".

(b) EFFECTIVE DATE AND EFFECT ON STATE LAWS.—

(1) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 120 days after the date of the enactment of this Act.

(2) PREEMPTION OF STATE LAWS.—No State (as defined in section 1101(a) of the Social Security Act (42 U.S.C. 1301(a)) for purposes of title XI of such Act) shall have in effect a State law that imposes a criminal or civil penalty for a transaction described in section 1877(b)(6) of such Act, as added by subsection (a), if the conditions described in such section, with respect to such transaction, are met.

(c) STUDY AND REPORT TO ASSESS EFFECT OF EXCEPTION ON HEALTH SYSTEM.—

(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct a study to determine the impact of the exception under section 1877(b)(6) of such Act (42 U.S.C. 1395nn(b)(6)), as added by subsection (a). In particular, the study shall examine the following:

(A) The effectiveness of the exception in increasing the adoption of health information technology.

(B) The types of health information technology provided under the exception.

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

(D) The impact of the adoption of health information technology on health care quality, cost, and access under the exception.

(2) REPORT.—Not later than three years after the effective date described in subsection (b)(1), the Secretary of Health and Human Services shall submit to Congress a report on the study under paragraph (1).

Amend the title so as to read:

A bill to promote a better health information system.

PURPOSE AND SUMMARY

The purpose of H.R. 4157, "Better Health Information System Act of 2006," is to promote a better health information system. Broad use of information technology throughout the health care system is essential to improve the quality and efficiency of health care delivery. Adoption of health information technology (health IT) is increasingly necessary to deliver state-of-the-art care to individuals with chronic illness and to promote interoperability between providers, both private and public, and payers. Efficiencies gained by the coordinated development of health IT will accelerate and advance private and public efforts to improve quality, lower costs, reduce fraud and abuse, and promote the coordination of care to achieve better health outcomes.

Title I codifies and expands the authorities and duties of the National Coordinator for Health Information Technology (National Coordinator) at the Department of Health and Human Services (HHS). This includes a number of responsibilities such as endorsing interoperability guidelines under a schedule, conducting a National survey on the information exchange capabilities of certain entities, and reviewing Federal information systems and security practices. Title I requires that certain Federal health information collection systems be capable of receiving information in a form consistent with any guidelines endorsed by the National Coordinator within three years of endorsement. Title I also provides that the President take steps to promote the use of nonidentifiable electronic health information for health and health care research. In addition, Title I provides for a report on the work conducted by the American Health Information Community (Community) and its role in the future as well as a report on financing incentives. In addition, Title I provides grants to help integrated health systems relay health information and better coordinate the delivery of care for uninsured, underinsured and medically underserved populations. Finally, Title I contains a demonstration program to promote adoption of health IT in the small physician setting.

Title II makes revisions to Section 1173 of the Social Security Act and streamlines the process for updating additions and modifications to the Health Insurance Portability and Accountability Act (HIPPA) electronic financial and administrative healthcare transaction standards. Title II also sets deadlines for upgrading certain other electronic transaction standards. The bill as reported doesn't maintain provisions which would have mandated by 2009 a transition from the current 9th version of the International Classification of Diseases (ICD–9) to the 10th version for diseases and procedures (ICD–10 CM and ICD–10–PCS) for purposes of billing and transactions that were originally in H.R. 4157 as introduced. Upon adoption of the 10th version, however, the bill as reported prohibits requiring providers to code to a level of specificity that necessitates documentation of non-medical external causes of injury.

Lastly, Title III creates safe harbors for providing certain health IT or related services under both Section 1128B of the Social Security Act (anti-kickback law) and Section 1877 of the Social Security Act (the physician referral law), contingent on a number of conditions in such safe harbors.

BACKGROUND AND NEED FOR LEGISLATION

Today's health IT provides substantial opportunity to improve health and health care. At the simplest level, an e-mail with attachments transmitted through a broadband connection increases the speed of exchanging health information among providers. Much larger advantages come from placing health information into formats which allow software to sort or aggregate such information for multiple purposes. These purposes include greater data sharing, intelligent support to physicians for patient care, remote patient monitoring, use of nonidentifiable patient information for studies, quality measure reporting, pricing transparency, bio-surveillance, and provision of personal health records to involve patients in their own care.

Changing the way health records are created, stored, maintained, and transferred across the health care industry is not easy. Many observers, however, believe adoption of more sophisticated health IT and practices has been slower than has occurred in other industries. Moreover, greater functionality of electronic health information systems depends on integration in a manner that allows for the interoperable exchange of such information.

The primary engine for advancing a better health information system is and will continue to be the private sector. Software and technology vendors are making products with increasing value and function. Participants in the health care industry are improving quality of care and efficiency by adopting new technologies, which provide a good return on investments.

The policies and programs in the Better Health Information System Act of 2006 are by no means exhaustive. Moreover, the legislation reflects a subset of efforts already underway through the leadership of the President, the Secretary of HHS, and others.

CERTAIN INITIATIVES AT THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

On April 27, 2004, the President signed Executive Order 13335 (EO) announcing his commitment to the promotion of health IT to lower costs, reduce medical errors, improve quality of care, and provide better information for patients and physicians. In particular, the President called for widespread adoption of electronic health records (EHRs) within 10 years so that health information will follow patients throughout their care in a seamless and secure manner. Toward that vision, the EO directed the Secretary of HHS to establish within the Office of the Secretary the position of National Coordinator for Health Information Technology (National Coordinator) with responsibilities for coordinating Federal health IT programs with those of relevant executive branch agencies as well as coordinating with the private sector on their health IT efforts.

On July 21, 2004, during the Department's Health IT Summit, the Administration published the "Strategic Framework: The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care" (The Framework). The Framework outlined an approach toward nationwide implementation of interoperable EHRs and identified four major goals. These goals are: (1) inform clinical practice by accelerating the use of EHRs; (2) interconnect clinicians so that they can exchange health information using advanced and secure electronic communication; (3) personalize care with consumer-based health records and better information for consumers; and (4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research.

On July 14, 2005, Secretary Leavitt formally announced the formation of a national collaboration, the American Health Information Community (the Community), a public-private body formed pursuant to the Federal Advisory Committee Act to help transition the Nation to EHRs in a smooth, market-led way. The Community will provide input and recommendations to the Secretary on the use of common standards and on achievement of interoperability among EHRs while assuring that the privacy and security of those records are protected.

HHS is providing contracts in a number of areas. Those include a process to harmonize and make refinements to industry wide standards; create a process to specify criteria for certain EHR products; development of models for health information exchange; and evaluation of variation of State laws around privacy and security that may pose challenges for health information exchange.

HHS is doing a number of things to assist in the development of a national interoperable health IT infrastructure including: evaluation of health care providers in small practices to determine their EHR adoption rates; setting standards to support electronic prescriptions for Medicare; and proposing exceptions to the physician self referral and anti kickback statutes.

The bill reported out of Committee is intended to enhance these efforts.

INTEROPERABILITY

The Commission on Systemic Interoperability, authorized by the MMA, held its first meeting on January 10, 2005. Interoperability focuses on the need for healthcare information to be connected so information is accessible whenever and wherever it is needed and authorized. Interoperability issues often become exceedingly technical, focusing on the rules for how information is created, stored, and moved among computer systems. The Commission recommended among other items that HHS, advised by the American Health Information Community (AHIC) and in consultation with the National Committee for Vital and Health Statistics (NCVHS), should ensure broad acceptance, effective implementation, and ongoing maintenance of a complete set of interoperable, non-overlapping data standards that function to assure data in one part of the health system, when authorized, is available and meaningful across the complete range of clinical, administrative, payment system, public health, and research settings. Additionally, AHIC should build upon HIPAA to develop national standards for authentication, authorization, and security that will permit the necessary infrastructure for consumers' confident adoption of health IT. Standardizing data at the point of its creation will accelerate greatly the creation of an interoperable healthcare information network. HHS should work with manufacturers of drugs, devices, and test kits to achieve standardized identifiers and vocabulary in labels and packaging as well as in all data outputs of devices and test kits.

The bill as reported provides for (1) the National Coordinator to develop a schedule for the endorsement of guidelines for interoperability for significant use cases which may include the exchange of laboratory data, drug prescribing data, clinical research and electronic health records; (2) the National Coordinator to endorse interoperability guidelines under a schedule it develops on a yearly basis but consistent with the schedule; (2) conduct of a national survey on the information exchange capabilities of certain entities; and (3) a review of Federal information systems and security practices. Title I also requires that certain Federal health information collection systems be capable of receiving information in a form consistent with any guidelines endorsed by the National Coordinator within three years of endorsement.

The Committee believes issues surrounding interoperability can be very complicated. Moreover, there is no single clear definition of

interoperability. It is important that the endorsements and requirements on Federal information collection systems be practical, not pose unnecessary administrative or cost burdens, and not disrupt or take away from the delivery of health care. Interoperability can be achieved on systems in many ways, including through the addition of software that converts information to a more interoperable format. Accordingly, measuring interoperability at the point of purchasing or donating products may not be pragmatic. A device or software can be placed into one information system in a manner that operates to meet interoperability guidelines. Yet, the same device or software can be placed into another system that may not meet interoperability guidelines. The Committee believes the National Coordinator and others will need to address the complexity of these issues in an ongoing process and that policies related to interoperability guidelines will need to be considered carefully.

INCENTIVES

Generally, health information technology and related expenses qualify as business expenses that could either be depreciated or deducted under Federal tax laws.

There are some existing Federal programs and initiatives underway to provide funding and other assistance for the adoption of health IT. Some of these initiatives include:

Medicaid Transformation Grants within the Deficit Reduction Act of 2005 (Public Law 109–171) provide for payments to States for the adoption of innovative methods to improve the effectiveness and efficiency in providing medical assistance under Medicaid. These include methods for reducing patient error rates through the implementation and use of EHRs, electronic clinical decision support tools and e-prescribing programs. These grants were funded at $75 million in each of fiscal years 2007 and 2008.

The MMA authorizes the Secretary of HHS to make grants to assist physicians in implementing electronic prescription drug programs. The MMA also established a Medicare Care Management Performance Demonstration which provides payment to each physician who exceeds quality and outcome measures and who uses health IT to manage care. $500 million was authorized for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009. The MMA also extends for four years, and increases funding to $60 million, a telemedicine demonstration project that involves health care provider telemedicine networks that use high-capacity computer systems and medical informatics to improve primary care and prevent health complications in Medicare beneficiaries with diabetes.

Within the Agency for Healthcare Research and Quality (AHRQ), there are numerous initiatives involving funding for health IT. AHRQ's $166 million in health IT investments support diffusion of health IT to 41 States. Many AHRQ health IT projects also receive funding from private charitable foundations, local communities, and State governments. They have awarded over 100 three-year grants that focus on specific applications of health IT to problem areas in healthcare delivery. They have also awarded six 5-year State contracts to support the development of statewide health information exchange (HIE). Additionally, AHRQ's National Resource Center for Health IT (NRC) has invested over $20 million over 5

years in nationwide resource and assistance for organizations implementing health IT and has provided access to national experts with experience in health IT implementation.

The Centers for Medicare and Medicaid Services (CMS) is providing technical assistance to physician offices on how to adopt health IT tools to improve quality through the Doctor's Office Quality Information Technology (DOQ–IT) project. Additionally, the President's fiscal year 2007 budget request includes $169 million, an increase of $58 million over fiscal year 2006, to continue efforts toward achieving the President's goal for most Americans to have electronic health records by 2014.

The bill as reported adds to these incentives. Title I provides $30 million in grants over two years to help integrated health systems relay health information and better coordinate the delivery of care for uninsured, underinsured and medically underserved populations. Title I also contains a demonstration program to promote adoption of health IT in the small physician setting through a $10 million grant over two years. Importantly, as discussed below, Title III removes barriers to economically viable arrangements to better coordinate care through the use of information technology. This will increase adoption and improve return on investment for such expenditures.

SAFE HARBORS

Section 1128B(b) of the Social Security Act (the anti-kickback statute) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any of the Federal health care programs, as defined in Section 1128B(f) of the Act. The offense is classified as a felony and is punishable by fines of up to $25,000 and imprisonment for up to five years. Violations of the anti-kickback statute may also result in the imposition of civil money penalties. As a result of the statute's broad reach, however, concern was expressed that some relatively innocuous commercial arrangements were covered by the statute and, therefore, potentially subject to criminal prosecution. In response, Congress required the development and promulgation of regulations, the so-called "safe harbor" provisions, that would specify various payment and business practices that would not be treated as criminal offenses under the anti-kickback statute. Since July 29, 1991, the HHS Office of Inspector General (OIG) has published a series of final regulations establishing "safe harbors" in various areas.

Section 1877 of the Social Security Act (the physician self-referral law): (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies. The statute establishes a number of exceptions and grants the Secretary of HHS authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

Section 101 of the MMA added a new Section 1860D to the Social Security Act establishing a prescription drug benefit in the Medicare program. As part of the new legislation, Congress directed the Secretary to adopt standards for electronic prescribing with the objective of improving patient safety, quality of care, and efficiency in the delivery of care. The MMA directs the Secretary, in consultation with the Attorney General, to create an exception to the physician self-referral prohibition and a safe harbor under the anti-kickback statute to protect certain arrangements involving the provision of non-monetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) that is necessary and used solely to receive and transmit electronic prescription drug information in accordance with electronic prescribing standards published by the Secretary.

Fear of self-referral and anti-kickback laws often stands in the way of diffusion and use of health information technology and better coordination of care. Today, nothing prevents a physician from purchasing his own system under his own license, performing his own maintenance, or conducting his own training and upkeep. Yet obtaining these items through a proven system in a hospital or from another health care entity can reduce risk and allow for economies of scale. One of the most significant risks to a physician's office is an unproven and unused system. Connecting to an existing system can reduce this risk premium.

There are numerous reasons for a health care entity to provide software, training, licensing agreements, etc. that do not involve an agreement for referrals. First, connecting providers creates faster and cheaper information flow between parties. Second, such information flow improves coordination of care which leads to better follow-up care for patients. This translates into improved outcomes and less complication. Third, better outcomes reduce liability expenses for health care entities such as hospitals. Fourth, better coordination of care means less duplicative tests and procedures.

EHRs can not only aggregate data but also keep track through an audit trail of each time a record has been accessed, who opened the record, and what data was entered. This should be a valuable tool for identifying fraud including kickbacks and fraud during billing. Just the fact that an EHR can perform this function will be a deterrent. Moreover, fraud can be detected and reduced through a variety of information technology capabilities, including abnormal pattern recognition, powerful system audits, practice pattern monitoring, and tracking of controlled substances.

Title III provides for limited safe harbors for hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations providing certain health information technology or related services under both Section 1128B of the Social Security Act (the anti- kickback statute) and Section 1877 of the Social Security Act (the physician self-referral law). These have been crafted with the above considerations in mind. However, the Committee does not support agreements between parties that are conditioned on referrals.

PRIVACY AND SECURITY

H.R. 4157 as introduced would provide for a study regarding Federal and State privacy and security standards and a new pre-

emption scheme that would fully preempt State standards within a certain timeframe. The purpose of this provision was to reduce barriers to an interstate electronic health information system. Several parties objected to such a change. Other parties have argued for additional and substantial changes to the current Federal privacy rules. HHS is currently assessing variations in State laws and organization level business policies around privacy and security practices, including variations in implementation of HIPAA privacy and security requirements that may pose challenges to automated health information exchange and interoperability.

The bill reported out of Committee preserves the existing Federal-State relationship and does not rewrite the current privacy rules. As discussed below, these rules are the product of a great deal of process and debate and are very extensive in nature. Several privacy and security laws are currently under review by the Committee.

HIPAA Sections 261 through 264 requires the Secretary of HHS to publicize standards for the electronic exchange, privacy, and security of health information. Collectively, these are known as the Administrative Simplification provisions. HIPAA Section 264 provides that if Congress fails to enact legislation governing the privacy of individually identifiable health information within 3 years (of 1996), HHS is to promulgate regulations containing such standards. Section 264 of HIPAA also provides that such regulations do not preempt contrary state law if the provision of state law imposes requirements, standards, or implementation specifications that are more stringent than those imposed by the federal regulations.

Because Congress was unable to enact health privacy legislation within the 3-year deadline, HHS developed proposed Standards for Privacy of Individually Identifiable Health Information, known as the "Privacy Rule," and released it for public comment on November 3, 1999. The Department received over 52,000 public comments. The final Privacy Rule (described below) was published December 28, 2000. In March 2002, the Department proposed and released for public comment modifications to the Privacy Rule. The Department received over 11,000 comments. The final modifications were published in final form on August 14, 2002.

The Privacy Rule establishes a set of national standards for the protection of certain health information. The Privacy Rule standards address the use and disclosure of individually identifiable health information (protected health information) by organizations directly subject to the rule called "covered entities." These include most healthcare providers, health plans, and health care clearinghouses. Other groups called "business associates" of a covered entity may need to follow certain contractual requirements as required by HIPAA but are not themselves subject to the same enforcement authorities under HIPAA. The Rule also sets standards governing an individuals' privacy rights to understand and control how their health information is used. Within HHS, the Office for Civil Rights (OC) has responsibility for implementing and enforcing the Privacy Rule with respect to voluntary compliance activities and civil money penalties.

A covered entity is permitted to use and disclose protected health information fairly freely without an individual's authorization to the individual and for treatment, payment, and health care oper-

ations. In addition, no authorization is needed for disclosing health information for "public interest" purposes (including, but not limited to, research, public health, law enforcement and disclosures required by law) so long as the covered entity meets the specific requirements imposed by the Rule.

For a number of purposes, (such as including information in facility directories and dealing with family and friends involved in a patient's care) a covered entity may use and disclose protected health information without an individual's written authorization so long as they give the individual the opportunity to object.

A central aspect of the Privacy Rule is the principle of "minimum necessary". A covered entity must develop and implement policies and procedures to reasonably limit uses and disclosures of protected health information to the minimum necessary needed to accomplish the intended purpose of the use, disclosure, or request. A key exception to the minimum necessary rule is made for treatment: the minimum necessary rule does not apply when a provider asks for or discloses health information for treatment purposes.

A covered entity must develop and implement written privacy policies and procedures that are consistent with the Privacy Rule. A covered entity must designate a privacy official responsible for developing and implementing its privacy policies and procedures as well as a contact person or contact office responsible for receiving complaints and providing individuals with information on the covered entity's privacy practices. A covered entity must train all workforce members on its privacy policies and procedures as necessary and appropriate for them to carry out their functions. A covered entity must have and apply appropriate sanctions against workforce members who violate its privacy policies and procedures or the Privacy Rule. Also, a covered entity must mitigate, to the extent practicable, any harmful effect it learns was caused by use or disclosure of protected health information by its workforce or its business associates in violation of its privacy policies and procedures or the Privacy Rule.

A covered entity must maintain reasonable and appropriate administrative, technical, and physical safeguards to prevent intentional or unintentional use or disclosure of protected health information in violation of the Privacy Rule and to limit its incidental use and disclosure pursuant to otherwise permitted or required use or disclosure. For example, such safeguards could include shredding documents containing protected health information before discarding them, securing medical records with lock and key or passcode, and limiting access to keys or pass codes.

The HIPAA Privacy Rule preempts provisions of state law that are contrary to the Federal standard. In accordance with Section 264 of HIPAA, the Privacy Rule provides exceptions from this preemption for contrary State laws that: (1) relate to the privacy of individually identifiable health information and provide greater privacy protections or privacy rights with respect to such information; (2) provide for the reporting of disease or injury, child abuse, birth or death, or for public health surveillance, investigation, or intervention; or (3) require certain health plan reporting such as for management or financial audits.

The final rule adopting HIPAA standards for security was published in the Federal Register on February 20, 2003. This final rule

specifies a series of administrative, technical, and physical security procedures for covered entities to assure the confidentiality of electronic protected health information. The security standards define administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The standards require covered entities to implement basic safeguards to protect electronic protected health information from unauthorized access, alteration, deletion, and transmission.

HHS may impose civil money penalties on a covered entity of $100 per failure to comply with a requirement. That penalty may not exceed $25,000 per year for multiple violations of the same Privacy Rule requirement in a calendar year. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA faces a fine of $50,000 and up to one year in prison. The criminal penalties increase to $100,000 and up to five years imprisonment if the wrongful conduct involves false pretenses and to $250,000 and up to ten years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. The United States Department of Justice, the department responsible for criminal enforcement of the Privacy Rule, has taken the position that these criminal penalties may only be applied to the "covered entity" and may not be imposed on employees or certain others.

The Privacy Act of 1974, as amended at 5 U.S.C. 552a, applies to Federal agencies and protects records that can be retrieved by personal identifiers such as a name, social security number, or other identifying number or symbol. The Privacy Act prohibits disclosure of these records without individual written consent unless one of the twelve disclosure exceptions enumerated in the Act applies. These records are held in Privacy Act systems of records, and a notice of any such system is published in the Federal Register. These notices identify the legal authority for collecting and storing the records, a description of whose records will be collected, the type of information to be collected, and how such records will be used.

The bill reported out of Committee maintains all of the above protections while preserving the existing Federal-State relationships among laws. Regulations must balance the need to get the right information at the right time with privacy and security concerns. This will be a subject of ongoing review for the Committee. Title I does provide a role for the National Coordinator in assisting other Federal Departments and agencies in security issues.

HEARINGS

On March 16, 2006, the Subcommittee on Health held a hearing entitled "Legislative Proposals to Promote Electronic Health Records and a Smarter Health Information System." The Subcommittee received testimony from: Mr. Ivo Nelson, Healthcare Industry Leader, Global Americas, IBM; Dr. William Braithwaite, MD, PhD, Chief Clinical Officer, eHealth Initiative and Foundation for eHealth Initiative; Mr. Alan Mertz, President, American Clinical Laboratory Association; Mr. Bill Vaughan, Senior Policy Analyst, Consumers Union; Mr. Mark Neaman, President and CEO,

Evanston Northwestern Healthcare; Mr. James Pyles, Attorney Member, Powers, Pyles, Sutter, and Verville, P.C.; and Dr. Don Detmer; President and CEO, American Medical Informatics Association.

COMMITTEE CONSIDERATION

On Thursday, June 8, 2006, the Subcommittee on Health met in open markup session and approved H.R. 4157 for Full Committee consideration, amended, by a voice vote, a quorum being present.

On Thursday, June 15, 2006, the Full Committee met in open markup session and ordered H.R. 4157 favorably reported to the House, amended, by a record vote of 28 yeas and 14 nays, a quorum being present.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. The following are the recorded votes taken on amendments offered to the measure, including the names of those Members voting for and against. A motion by Mr. Barton to order H.R. 4157 reported to the House, amended, was agreed to by a record vote of 28 yeas and 14 nays.

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 120

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Mr. Markey, No. 2, to require the Secretary of HHS to provide for privacy an security standards for health information technology, in addition to those that exist under the curren Federal privacy and security rules. The amendment would require such new standards to (1) provide fo patient consent requirements including, but not limited to treatment and payment, to share their healt information electronically and allows patients greater rights to control access to their electroni information; (2) apply the standards to anyone who has the health information; (3) allow individuals t enforce protections and get redress when there is a violation; (4) require notification to a person if the information has been violated; and (5) require security safeguards.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 20 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman			
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns		X		Mr. Towns	X		
Mr Gillmor		X		Mr. Pallone	X		
Mr Deal		X		Mr. Brown	X		
Mr. Whitfield				Mr. Gordon	X		
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson				Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette			
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. Allen	X		
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis			
Mr. Terry		X		Mr. Gonzalez			
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn		X					

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 121

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment in the nature of a substitute by Mr. Pallone, No. 4, to (1) codify the Office of the National Coordinator of Heal Information Technology, and the public-private American Health Information Collaborative; (2) requires the development o standards on interoperability; (3) prohibit any Federal agency from expending Federal funds to purchase any new healt information technology that is inconsistent with adopted standards one year after standards adoption; (4) require all Feder agencies collecting health data as determined appropriate by the Secretary to comply with the adopted standards within thre years; (5) establishes a voluntary certification program for health IT products to determine if they meet standards o interoperability (6) permit the Secretary to award grants to: (a) providers to facilitate the purchase and enhance the utilization o qualified health information technology systems; (b) implement regional or local health information plans; and (c) to States develop loan programs leveraging private funding; (7) carry out demonstration projects to develop academic curricu integrating qualified health information technology systems in the clinical education of health professionals; and (8) require the Secretary to establish standards for Federal security and privacy protections in health information technology.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 19 yeas to 22 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall				Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus		X		Mr. Stupak			
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering				Mr. Green	X		
Mr Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle			
Mr Bass		X		Mr. Allen	X		
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis			
Mr. Terry		X		Mr. Gonzalez	X		
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn							

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 122

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Mr. Pallone, No. 6, to (1) require the Secretary to provide a Medicare add-o payment for health IT and services to each health care provider that furnishes items or service under Medicare Part B; (2) provide grants to healthcare providers to facilitate the widesprea adoption of interoperable health information technology, and grants to States for th development of State loan programs, which may include private contributions, for loans t health care providers to facilitate the purchase and enhance the utilization of qualified healt information technology; and (3) strike Title III relating to safe harbors under Stark self referra and Anti-kickback fraud and abuse laws.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 19 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr Hall				Mr. Waxman			
Mr Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr Stearns				Mr. Towns	X		
Mr Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield				Mr. Gordon			
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle			
Mr. Bass		X		Mr. Allen			
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez	X		
Mr. Ferguson		X		Mr. Inslee	X		
Mr. Rogers		X		Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy		X					
Mr. Burgess		X					
Ms. Blackburn							

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 123

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Mr. Brown, No. 8, to (1) require the Secretary of HHS to provide a Medicar add-on payment for health IT and services to each health care provider that furnishes items c services under Medicare Part B; (2) provide grants to healthcare providers to facilitate th widespread adoption of interoperable health information technology; (3) and provide grants t States for the development of State loan programs, which may include private contributions, fc loans to health care providers to facilitate the purchase and enhance the utilization of qualifie health information technology.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 22 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall				Mr. Waxman			
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns				Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson		X		Mr. Engel			
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle			
Mr. Bass		X		Mr. Allen			
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky	X		
Mr. Walden		X		Ms. Solis	X		
Mr. Terry		X		Mr. Gonzalez	X		
Mr. Ferguson				Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy							
Mr. Burgess		X					
Ms Blackburn		X					

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 124

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Mr. Stupak, No. 9, to (1) provide grants for rural providers for the purchase adoption, implementation and maintenance of Health IT, and (2) provide grants to States t establish revolving loan funds, which may include private contributions, for the adoption implementation and maintenance of health IT.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 18 yeas to 22 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman	X		
Mr. Bilirakis		X		Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns		X		Mr. Towns			
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield		X		Mr. Gordon			
Mr. Norwood		X		Mr. Rush	X		
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson		X		Mr. Engel			
Mr. Shadegg		X		Mr. Wynn	X		
Mr. Pickering		X		Mr. Green			
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps			
Mr. Radanovich		X		Mr. Doyle			
Mr. Bass		X		Mr. Allen			
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky			
Mr. Walden	X			Ms. Solis	X		
Mr. Terry	X			Mr. Gonzalez	X		
Mr. Ferguson				Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy							
Mr. Burgess		X					
Ms. Blackburn		X					

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 125

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Ms. Eshoo, No. 10, to (1) require that not later than 18 months after the dat of enactment, the National Coordinator shall adopt core interoperability guidelines for healt information technology and develop a system for the voluntary certification of healt information technology products; and (2) provide that not later than one year after the adoptio of such guidelines, no Federal funds may be expended for the purchase of any new healt information technology that is not consistent with applicable interoperability guidelines.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 17 yeas to 22 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall		X		Mr. Waxman			
Mr. Bilirakis				Mr. Markey	X		
Mr. Upton		X		Mr. Boucher			
Mr. Stearns		X		Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield		X		Mr. Gordon	X		
Mr. Norwood		X		Mr. Rush			
Ms. Cubin				Ms. Eshoo	X		
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg				Mr. Wynn	X		
Mr. Pickering		X		Mr. Green			
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps			
Mr. Radanovich				Mr. Doyle			
Mr. Bass		X		Mr. Allen			
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky			
Mr. Walden		X		Ms. Solis	X		
Mr. Terry		X		Mr Gonzalez	X		
Mr. Ferguson				Mr Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy							
Mr. Burgess		X					
Ms. Blackburn		X					

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 126

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

AMENDMENT: An amendment by Mr. Stupak, No. 11, to reauthorize HRSA's Telehealth program b extending the telehealth network and telehealth resource centers grant programs for another years at the current authorization levels.

DISPOSITION: **NOT AGREED TO**, by a roll call vote of 13 yeas to 21 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton		X		Mr. Dingell	X		
Mr. Hall				Mr. Waxman			
Mr. Bilirakis		X		Mr. Markey			
Mr. Upton		X		Mr. Boucher			
Mr. Stearns		X		Mr. Towns	X		
Mr. Gillmor		X		Mr. Pallone	X		
Mr. Deal		X		Mr. Brown	X		
Mr. Whitfield		X		Mr. Gordon	X		
Mr. Norwood		X		Mr. Rush			
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus		X		Mr. Stupak	X		
Ms. Wilson		X		Mr. Engel	X		
Mr. Shadegg				Mr. Wynn	X		
Mr. Pickering		X		Mr. Green			
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps			
Mr. Radanovich				Mr. Doyle			
Mr. Bass		X		Mr. Allen			
Mr. Pitts		X		Mr. Davis			
Ms. Bono		X		Ms. Schakowsky			
Mr. Walden		X		Ms. Solis			
Mr. Terry		X		Mr. Gonzalez	X		
Mr. Ferguson				Mr. Inslee	X		
Mr. Rogers				Ms. Baldwin	X		
Mr. Otter				Mr. Ross	X		
Ms. Myrick		X					
Mr. Sullivan							
Mr. Murphy							
Mr. Burgess		X					
Ms. Blackburn		X					

6/15/2006

COMMITTEE ON ENERGY AND COMMERCE -- 109TH CONGRESS
ROLL CALL VOTE # 127

Bill: H.R. 4157, Health Information Technology Promotion Act of 2005

MOTION: Motion by Mr. Barton to order H.R. 4157 reported to the House, amended.

DISPOSITION: **AGREED TO**, by a roll call vote of 28 yeas to14 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Barton	X			Mr. Dingell		X	
Mr. Hall	X			Mr. Waxman			
Mr. Bilirakis	X			Mr. Markey		X	
Mr. Upton	X			Mr. Boucher			
Mr. Stearns	X			Mr. Towns			
Mr. Gillmor	X			Mr. Pallone		X	
Mr. Deal	X			Mr. Brown			
Mr. Whitfield	X			Mr. Gordon			
Mr. Norwood	X			Mr. Rush			
Ms. Cubin				Ms. Eshoo			
Mr. Shimkus	X			Mr. Stupak		X	
Ms. Wilson	X			Mr. Engel		X	
Mr. Shadegg	X			Mr. Wynn		X	
Mr. Pickering	X			Mr. Green		X	
Mr. Fossella				Mr. Strickland		X	
Mr. Blunt				Ms. DeGette		X	
Mr. Buyer	X			Ms. Capps			
Mr. Radanovich	X			Mr. Doyle		X	
Mr. Bass	X			Mr. Allen		X	
Mr. Pitts	X			Mr. Davis			
Ms. Bono	X			Ms. Schakowsky		X	
Mr. Walden	X			Ms. Solis			
Mr. Terry	X			Mr. Gonzalez	X		
Mr. Ferguson	X			Mr. Inslee	X		
Mr. Rogers	X			Ms. Baldwin		X	
Mr. Otter				Mr. Ross		X	
Ms. Myrick	X						
Mr. Sullivan							
Mr. Murphy	X						
Mr. Burgess	X						
Ms. Blackburn	X						

6/15/2006

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held an oversight hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The purpose of H.R. 4157, the Better Health Information System Act of 2006, is to provide for a better health information system.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 4157, the Better Health Information System Act of 2006, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

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

CONGRESSIONAL BUDGET OFFICE ESTIMATE

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

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 5, 2006.

Hon. JOE BARTON,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 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—Better Health Information System Act of 2006

Summary: CBO estimates that implementing H.R. 4157 would cost $4 million in 2007 and $38 million over the 2007–2011 period, assuming appropriation of the authorized amounts. Enacting the bill would have no effect on direct spending or revenues.

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. The bill

also would require the Secretary to conduct several studies on programs to promote the development and adoption of health information technology, and would authorize the appropriation of $20 million a year for 2007 and 2008 for grants to facilitate the adoption of certain health information technology.

In addition, H.R. 4157 would modify the Social Security Act to:

- Specify procedures for adopting updated standards for the electronic exchange of health data, and require that certain updated standards be implemented in 2009; and
- 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.

H.R. 4157 would preempt, in some circumstances, state laws that govern record-keeping requirements and that establish civil or criminal penalties for the exchange of 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, however, that the costs of the mandates to states would be small and, thus, would not exceed the threshold established in UMRA ($64 million in 2006, adjusted annually for inflation).

The bill would impose a private-sector mandate on health plans, providers, and clearing houses by requiring them to adopt updated standards for claims transactions by 2009. CBO assumes that this deadline would be met under current law, however, so the mandate would impose no additional cost on those private-sector entities.

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 function 550 (health).

	By fiscal year, in millions of dollars—				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Authorization level	20	20	0	0	0
Estimated outlays	4	14	14	5	1

Basis of estimate

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

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, specify procedures for adopting updated standards for the electronic exchange of health data, and establish safe harbors for donations of health information technology.

For this estimate, CBO assumes that H.R. 4157 will be enacted near the end of fiscal year 2006, that the authorized amounts will be appropriated each year, and that outlays will follow historical patterns for similar activities of the Department of Health and Human Services.

Health Information Technology and Quality

The National Coordinator for Health Information Technology serves as the senior advisor to the Secretary of HHS and the President 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 the Office of the National Coordinator for Health Information Technology. The bill would require the Secretary of HHS 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). CBO estimates that implementing those provisions would not change the cost of ONCHIT's activities.

The bill also would authorize the appropriation of $15 million a year for 2007 and 2008 for grants to integrated health systems to promote the adoption and use of health information technology for the purpose of improving coordination of care for uninsured and underserved populations. In addition, it would authorize the appropriation of $5 million a year for 2007 and 2008 for grants to small physician practices located in rural or medically underserved areas for the purchase and support of health information technology. Based on spending patterns for similar programs that provide grants to health care providers, CBO estimates that implementing those grant programs would cost $4 million in 2007 and $38 million over the 2007–2011 period, assuming appropriation of the specified amounts.

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 also 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.

Safe Harbors for Donations 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 certain entities (hospitals, group practices, Medicare Advantage plans, and prescription drug plans) to donate health information technology (hardware; software; or related maintenance, support, or training services) to physicians.

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, under authority existing in current law, are engaged in a rule-making process to establish safe harbors for donations 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).

CBO anticipates that the final rules will establish a set of eligible entities and donations similar to those specified in the bill. Therefore, CBO estimates that enacting the safe-harbor provisions in H.R. 4157 would not have a significant effect on federal spending.

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

[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/—files/Clancy062106.pdf)

Continued

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

In preparing an estimate of the budgetary effect of enacting this bill—or other 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, CBO estimates enacting the bill would have no effect on spending by the federal government, other than the specific appropriations it would authorize.

Estimated impact on state, local, and tribal governments: H.R. 4157 would preempt, in some circumstances, state laws that govern record-keeping requirements and that establish civil or criminal penalties for the exchange of health information technology. While those preemptions would be intergovernmental mandates as defined in UMRA, CBO estimates that the costs of the mandates to states would be small and, thus, would not exceed the thresholds established in UMRA ($64 million in 2006, adjusted annually for inflation).

The bill would preempt state laws that require providers to maintain data in paper form, if those providers receive federal funds and maintains the data electronically. In most cases, such a

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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", NEJM, Oct 14, 2004. (http://content.nejm.org/cgi/content/full/351/16/1591)

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

preemption would be a condition of aid and thus not an intergovernmental mandate, as most federal assistance to health care providers comes through state governments as part of agreements with the federal government. However, some federal assistance goes directly to providers, independent of federal agreements with state governments, and in those cases the preemption of state laws requiring paper documentation would be an intergovernmental mandate. CBO estimates, however, that the 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. While this preemption could affect the ability of states to assess penalties and collect revenues, CBO estimates that any such losses would be small.

Estimated impact on the private sector: The bill would impose a private-sector mandate on health plans, providers, and clearing houses by requiring them to adopt updated standards for claims transactions by April 1, 2009. The bill would require them to move from version 4010 to version 5010 of the Accredited Standards Committee X12 standards. It would also require them to move from version 5.1 of the National Council for Prescription Drug Programs Telecommunication Standards to the most recent version approved as of April 1, 2008.

CBO assumes that this deadline would be met under current law. Thus, this mandate would impose no additional costs on private-sector 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: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

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

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

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

APPLICABILITY TO LEGISLATIVE BRANCH

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

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title and table of contents

This Act may be cited as the "Better Health Information System Act of 2006."

Section 2. Preserving privacy and security laws

Section 2 states that nothing in this Act affects the scope, substance, or applicability of privacy and security regulations pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA; Public Law 104–191).

Section 101. Office of the National Coordinator for Health Information Technology

Section 101 codifies the Office of National Coordinator for Health Information Technology (National Coordinator) including National goals and duties. This would include work with other agencies regarding the security of health information.

Section 102. Report on the American Health Information Community

Section 102 requires a report to Congress within one year on the work of the American Health Information Community (Community) along with recommendations for the transition of the Community to a longer-term advisory and facilitation entity.

Section 103. Interoperability planning process; Federal information collection activities

Section 103 provides that the National Coordinator shall conduct by August 31, 2008 a national survey to measure the capabilities of entities to exchange electronic health information.

This section requires that not later than December 31, 2006, the National Coordinator to publish a strategic plan, including a schedule, for the assessment and endorsement of core interoperability guidelines for significant use cases. The National Coordinator has substantial flexibility in how to administer this section and to interpret the terms "core," "interoperability," and "significant use cases." Moreover, the scope and meaning of those terms may change as technology adoption, software, and health care practices evolve.

The National Coordinator shall endorse a subset of core interoperability guidelines not later than one year after the publication of the schedule, and annually thereafter, with endorsement of all such guidelines consistent with the schedule by August 31, 2009.

Section 103 requires the President to assure that activities involving the broad collection and submission of health information allow for submissions consistent with core interoperability guidelines within three years of endorsement of such guidelines by the National Coordinator.

Further, the section requires the President to take measures to allow access to useful categories of non-identifiable health information in records maintained by the Federal government or entities under contract with the Federal government to advance health care quality and health research.

Section 103 also requires, for five years following the date of enactment of this Act, the National Coordinator to review and make recommendations regarding the operation of health information collection and exchange in the Federal government and the proposed purchasing plans of Federal agencies.

Section 104. Ensuring health care providers may maintain health information in electronic form

Section 104 assures that any health care provider may maintain records in electronic form for Federally-funded programs.

Section 105. Study and report on state, regional, and community health information exchanges

Section 105 requires the Secretary of HHS to conduct a study on issues related to the development, operation, and implementation of State, regional, and community health information exchanges.

Section 106. Grants to integrated health systems to promote health information technologies to improve coordination of care for the uninsured, underinsured, and medically underserved.

Section 106 authorizes the Secretary to make grants to integrated health care systems for projects to bettor coordinate the provision of healthcare through the adoption of new health information technology or the significant improvement of existing health information technology.

Section 107. Demonstration program

Section 107 requires the Secretary to establish a demonstration program under which grants are awarded to small physician practices that are located in rural areas or medically underserved urban areas for the purchase and support of health information technology.

Section 201. Procedures to ensure timely updating of standards that enable electronic exchanges

Section 201 streamlines the current procedures under Section 1173(a) of the Social Security Act for updating standards that enable electronic exchanges.

Section 202. Upgrade ASC X12 and NCPDP standards

Section 202 requires upgrading to the Accredited Standards Committee X12 (ASC X12) version 5010. This section also requires upgrading the National Council for Prescription Drug Programs (NCPDP) telecommunications standards to the latest version as approved by the Council and reviewed by the National Committee on Vital Health Statistics (NCVHS) as of April 1, 2007. Both of these standards would be applied to transactions occurring on or after April 1, 2009.

Section 203. Coding and documentation of non-medical information

Section 203 specifies that in any regulation or other action implementing the International Classification of Diseases, 10th revision, Clinical Modification (ICD–10–CM) or the International Classification of Diseases, 10th revision, Procedure Coding System (ICD–10–PCS), the Secretary of HHS shall ensure that no health care provider is required to code to a level of specificity that would require documentation of non-medical information on the external cause of any given type of injury.

Section 301. Safe harbors to antikickback civil penalties and criminal penalties for provision of health information technology and training services

Section 301 creates a safe harbor from current anti-kickback laws for providing certain health information technology or training and related services. The safe harbor requires that any such provision of technology, training, or related services not be pursuant to an agreement limiting its use by entity, limiting its connection to other technology, or conditioned on the referral of patients.

Section 302. Exception to limitation on certain physician referrals (under Stark) for provision of health information technology and training services to health care professionals

Section 302 creates a safe harbor from current physician self-referral rules for providing certain health information technology or training and related services. The safe harbor requires that any such provision of technology, training or related services not be pursuant to an agreement limiting its use by entity, limiting its connection to other technology, or conditioned on the referral of patients.

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

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TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

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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 (re-

ferred to in this part as the "National Coordinator"). The National Coordinator shall be appointed by and 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, promotes data accuracy, 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) promotes the availability of appropriate and accurate information necessary to make medical decisions 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 or inaccurate information;

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

(6) with respect to health information of consumers, advances the portability of such information and the ability of such consumers to share and use such information to assist in the management of their health care;

(7) 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;

(8) is consistent with legally applicable requirements with respect to securing and protecting the confidentiality of individually identifiable health information of a patient;

(9) promotes the creation and maintenance of transportable, secure, Internet-based personal health records, including promoting the efforts of health care payers and health plan administrators for a health plan, such as Federal agencies, private health plans, and third party administrators, to provide for such records on behalf of members of such a plan;

(10) promotes access to and review of the electronic health record of a patient by such patient;

(11) promotes health research and health care quality research and assessment; and

(12) promotes the efficient and streamlined development, submission, and maintenance of electronic health care clinical trial data.

(c) DUTIES OF THE NATIONAL COORDINATOR.—

(1) STRATEGIC PLANNER FOR INTEROPERABLE HEALTH INFORMATION TECHNOLOGY.—The National Coordinator shall provide

for a strategic plan for 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 THE SECRETARY.—The National Coordinator shall serve as the principal advisor to the Secretary on the development, application, and use of health information technology, and shall coordinate the policies and programs of the Department of Health and Human Services for promoting the use of health information technology.

(3) 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, to align the health information architecture of each agency or department toward a common approach, 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, and to assist Federal agencies and departments in security programs, policies, and protections to prevent unauthorized access to individually identifiable health information created, maintained, or in the temporary possession of that agency or department. The coordination authority provided to the National Coordinator under the previous sentence shall supercede any such authority otherwise provided to any other official of the Department of Health and Human Services. For the purposes of this paragraph, the term "unauthorized access" means access that is not authorized by that agency or department including unauthorized employee access.

(4) 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.

(5) PROMOTER OF HEALTH INFORMATION TECHNOLOGY IN MEDICALLY UNDERSERVED COMMUNITIES.—The National Coordinator shall—

(A) identify sources of funds that will be made available to promote and support the planning and adoption of health information technology in medically underserved communities, including in urban and rural areas, either through grants or technical assistance;

(B) coordinate with the funding sources to help such communities connect to identified funding; and

(C) collaborate with the Agency for Healthcare Research and Quality and the Health Services Resources Administration and other Federal agencies to support technical assistance, knowledge dissemination, and resource development, to medically underserved communities seeking to plan for and adopt technology and establish electronic health information networks across providers.

SEC. 272. INTEROPERABILITY PLANNING PROCESS; FEDERAL INFORMATION COLLECTION ACTIVITIES.

(a) STRATEGIC INTEROPERABILITY PLANNING PROCESS.—

(1) ASSESSMENT AND ENDORSEMENT OF CORE STRATEGIC GUIDELINES.—

(A) IN GENERAL.—Not later than December 31, 2006, the National Coordinator shall publish a strategic plan, including a schedule, for the assessment and the endorsement of core interoperability guidelines for significant use cases consistent with this subsection. The National Coordinator may update such plan from time to time.

(B) ENDORSEMENT.—

(i) IN GENERAL.—Consistent with the schedule under this paragraph and not later than one year after the publication of such schedule, the National Coordinator shall endorse a subset of core interoperability guidelines for significant use cases. The National Coordinator shall continue to endorse subsets of core interoperability guidelines for significant use cases annually consistent with the schedule published pursuant to this paragraph, with endorsement of all such guidelines completed not later than August 31, 2009.

(ii) CONSULTATION.—All such endorsements shall be in consultation with the American Health Information Community and other appropriate entities.

(iii) VOLUNTARY COMPLIANCE.—Compliance with such guidelines shall be voluntary, subject to subsection (b)(1).

(C) CONSULTATION WITH OTHER PARTIES.—The National Coordinator shall develop and implement such strategic plan in consultation with the American Health Information Community and other appropriate entities.

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

(i) INTEROPERABILITY GUIDELINE.—The term "interoperability guideline" means a guideline to improve and promote the interoperability of health information technology for purposes of electronically accessing and exchanging health information. Such term includes named standards, architectures, software schemes for identification, authentication, and security, and other information needed to ensure the reproducible development of common solutions across disparate entities.

(ii) CORE INTEROPERABILITY GUIDELINE.—The term "core interoperability guideline" means an interoperability guideline that the National Coordinator determines is essential and necessary for purposes described in clause (i).

(iii) SIGNIFICANT USE CASE.—The term "significant use case" means a category (as specified by the National Coordinator) that identifies a significant use or purpose for the interoperability of health information technology, such as for the exchange of laboratory information, drug prescribing, clinical research, and electronic health records.

(2) NATIONAL SURVEY.—

(A) IN GENERAL.—Not later than August 31, 2008, the National Coordinator shall conduct one or more surveys designed to measure the capability of entities (including Fed-

eral agencies, State and local government agencies, and private sector entities) to exchange electronic health information by appropriate significant use case. Such surveys shall identify the extent to which the type of health information, the use for such information, or any other appropriate characterization of such information may relate to the capability of such entities to exchange health information in a manner that is consistent with methods to improve the interoperability of health information and with core interoperability guidelines.

(B) DISSEMINATION OF SURVEY RESULTS.—The National Coordinator shall disseminate the results of such surveys in a manner so as to—

(i) inform the public on the capabilities of entities to exchange electronic health information;

(ii) assist in establishing a more interoperable information architecture; and

(iii) identify the status of health information systems used in Federal agencies and the status of such systems with respect to interoperability guidelines.

(b) FEDERAL HEALTH INFORMATION COLLECTION ACTIVITIES.—

(1) REQUIREMENTS.—With respect to a core interoperability guideline endorsed under subsection (a)(1)(B) for a significant use case, the President shall take measures to ensure that Federal activities involving the broad collection and submission of health information are consistent with such guideline within three years after the date of such endorsement.

(2) PROMOTING USE OF NON-IDENTIFIABLE HEALTH INFORMATION TO IMPROVE HEALTH RESEARCH AND HEALTH CARE QUALITY.—

(A) IN GENERAL.—Where feasible, and consistent with applicable privacy or security or other laws, the President, in consultation with the Secretary, shall take measures to allow timely access to useful categories of non-identifiable health information in records maintained by the Federal government, or maintained by entities under contract with the Federal government, to advance health care quality and health research where such information is in a form that can be used in such research. The President shall consult with appropriate Federal agencies, and solicit public comment, on useful categories of information, and appropriate measures to take. The President may consider the administrative burden and the potential for improvements in health care quality in determining such appropriate measures. In addition, the President, in consultation with the Secretary, shall encourage voluntary private and public sector efforts to allow access to such useful categories of non-identifiable health information to advance health care quality and health research.

(B) NON-IDENTIFIABLE HEALTH INFORMATION DEFINED.—For purposes of this paragraph, the term "non-identifiable health information" means information that is not individually identifiable health information as defined in rules promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C.

1320d-2 note), and includes information that has been de-identified so that it is no longer individually identifiable health information, as defined in such rules.

(3) ANNUAL REVIEW AND REPORT.—For each year during the five-year period following the date of the enactment of this section, the National Coordinator shall review the operation of health information collection by and submission to the Federal government and the purchases (and planned purchases) of health information technology by the Federal government. For each such year and based on the review for such year, the National Coordinator shall submit to the President and Congress recommendations on methods to—

(A) streamline (and eliminate redundancy in) Federal systems used for the collection and submission of health information;

(B) improve efficiency in such collection and submission;

(C) increase the ability to assess health care quality; and

(D) reduce health care costs.

SEC. 273. ENSURING HEALTH CARE PROVIDERS MAY MAINTAIN HEALTH INFORMATION IN ELECTRONIC FORM.

(a) IN GENERAL.—Any health care provider that participates in a health care program that receives Federal funds shall be deemed as meeting any requirement for the maintenance of data in paper form under such program (whether or not for purposes of management, billing, reporting, reimbursement, or otherwise) if the required data is maintained in an electronic form.

(b) RELATION TO STATE LAWS.—Beginning on the date that is one year after the date of the enactment of this section, subsection (a) shall supersede any contrary provision of State law.

(c) CONSTRUCTION.—Nothing in this section shall be construed as—

(1) requiring health care providers to maintain or submit data in electronic form;

(2) preventing a State from permitting health care providers to maintain or submit data in paper form; or

(3) preventing a State from requiring health care providers to maintain or submit data in electronic form.

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

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SEC. 330M. GRANTS FOR IMPROVEMENT OF THE COORDINATION OF CARE FOR THE UNINSURED, UNDERINSURED, AND MEDICALLY UNDERSERVED.

(a) IN GENERAL.—The Secretary may make grants to integrated health care systems, in accordance with this section, for projects to better coordinate the provision of health care through the adoption of new health information technology, or the significant improvement of existing health information technology, to improve the pro-

vision of health care to uninsured, underinsured, and medically underserved individuals (including in urban and rural areas) through health-related information about such individuals, throughout such a system and at the point of service.

(b) ELIGIBILITY.—

(1) APPLICATION.—To be eligible to receive a grant under this section, an integrated health care system shall prepare and submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, including—

(A) a description of the project that the system will carry out using the funds provided under the grant;

(B) a description of the manner in which the project funded under the grant will advance the goal specified in subsection (a); and

(C) a description of the populations to be served by the adoption or improvement of health information technology.

(2) OPTIONAL REPORTING CONDITION.—The Secretary may also condition the provision of a grant to an integrated health care system under this section for a project on the submission by such system to the Secretary of a report on the impact of the health information technology adopted (or improved) under such project on the delivery of health care and the quality of care (in accordance with applicable measures of such quality). Such report shall be at such time and in such form and manner as specified by the Secretary.

(c) INTEGRATED HEALTH CARE SYSTEM DEFINED.—For purposes of this section, the term "integrated health care system" means a system of health care providers that is organized to provide care in a coordinated fashion and has a demonstrated commitment to provide uninsured, underinsured, and medically underserved individuals with access to such care.

(d) PRIORITIES.—In making grants under this section, the Secretary shall give priority to an integrated health care system—

(1) that can demonstrate past successful community-wide efforts to improve the quality of care provided and the coordination of care for the uninsured, underinsured, and medically underserved; or

(2) if the project to be funded through such a grant—

(A) will improve the delivery of health care and the quality of care provided; and

(B) will demonstrate savings for State or Federal health care benefits programs or entities legally obligated under Federal law to provide health care from the reduction of duplicative health care services, administrative costs, and medical errors.

(e) LIMITATION, MATCHING REQUIREMENT, AND CONDITIONS.—

(1) LIMITATION ON USE OF FUNDS.—None of the funds provided under a grant made under this section may be used for a project providing for the adoption or improvement of health information technology that is used exclusively for financial record keeping, billing, or other non-clinical applications.

(2) MATCHING REQUIREMENT.—To be eligible for a grant under this section an integrated health care system shall contribute non-Federal contributions to the costs of carrying out the

project for which the grant is awarded in an amount equal to $1 for each $5 of Federal funds provided under the grant.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $15,000,000 for each of fiscal years 2007 and 2008.

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SOCIAL SECURITY ACT

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

PART A—GENERAL PROVISIONS

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CIVIL MONETARY PENALTIES

SEC. 1128A. (a) * * *

(b)(1) * * *

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(4) For purposes of this subsection, inducements to reduce or limit services described in paragraph (1) shall not include the practical or other advantages resulting from health information technology or related installation, maintenance, support, or training services.

* * * * * * *

(i) For the purposes of this section:

(1) * * *

* * * * * * *

(8) The term "health information technology" means hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.

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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 enhance 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(i)(8), or related installation, maintenance, support or training services) made to a person by an entity that is a hospital, group practice, prescription drug plan sponsor, or Medicare Advantage organization if—

(i) the provision of such remuneration is without an agreement between the parties or legal 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 entity;

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

(III) conditions the provision of such remuneration on the referral of patients or business to the entity;

(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) and that specifies the remuneration solicited or received (or offered or paid) and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health quality, efficiency, or research; and

(iii) the entity providing the remuneration (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability.

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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 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(a), 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 of 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(a), the Secretary shall publish a notice in the Federal Register that—

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

(II) specifies the procedure for obtaining 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 addition or modification; and

(IV) invites submission of such comments and participation in such hearing or meeting without requiring the public to pay a fee to participate.

(iii) NOTICE OF PROPOSED ADDITION OR MODIFICATION TO STANDARDS.—Not later than 30 days after the date of 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(a) 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 the 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(a), 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);

(II) makes publicly available a written explanation for its response in the proposed addition or

modification to comments submitted on a timely basis; and

(III) makes public comments received under clause (I) available, or provides access to such comments, to the Secretary.

(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 90 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).

(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) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to a final rule promulgated under subparagraph (F).

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART E—MISCELLANEOUS PROVISIONS

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LIMITATION ON CERTAIN PHYSICIAN REFERRALS

SEC. 1877. (a) * * *

(b) GENERAL EXCEPTIONS TO BOTH OWNERSHIP AND COMPENSATION ARRANGEMENT PROHIBITIONS.—Subsection (a)(1) shall not apply in the following cases:

(1) * * *

* * * * * * *

(6) INFORMATION TECHNOLOGY AND TRAINING SERVICES.—

(A) IN GENERAL.—Any nonmonetary remuneration (in the form of health information technology or related installation, maintenance, support or training services) made by an entity that is a hospital, group practice, prescription drug plan sponsor, or a Medicare Advantage organization to a physician if—

(i) the provision of such remuneration is without an agreement between the parties or legal 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 entity;

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

(III) conditions the provision of such remuneration on the referral of patients or business to the entity;

(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) 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 quality, efficiency, or research; and

(iii) the entity (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability.

(B) HEALTH INFORMATION TECHNOLOGY DEFINED.—For purposes of subparagraph (A), the term "health information technology" means hardware, software, license, right, intellectual property, equipment, or other information tech-

nology (including new versions, upgrades, and connectivity) designed primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.

* * * * * * *

DISSENTING VIEWS

SUMMARY

H.R. 4157, as amended and reported by the Committee on Energy and Commerce, is inadequate to effectively move the U.S. healthcare system into an electronic age and adopt health information technology, such as electronic health records, that will enable providers to communicate with each other to achieve administrative efficiencies and improve care. The bill does not include sufficient funding to enable providers to adopt and implement systems in their offices. Instead, it undermines existing fraud and abuse laws in the name of spreading health information technology. And, even though moving to an electronic age for healthcare records will make personal information more vulnerable to breach and theft, the bill fails to protect the privacy of patient medical information.

The Minority offered a number of amendments in an effort to (1) provide funding for healthcare providers to purchase and adopt health information technology without undermining protective fraud and abuse laws; (2) improve the quality of care, care coordination, and patient access to information; (3) allow providers, labs, and others in the healthcare system to communicate electronically with each other ("interoperability"), and (4) protect the privacy of patient's information in a new world where information will be maintained electronically. These amendments were rejected on party-line votes.

It is particularly disappointing that a bipartisan Senate bill on health information technology that passed the Senate unanimously on November 18, 2005, has been ignored by the Committee as a starting point for discussions. Instead, Republican colleagues chose to consider a highly partisan bill, greatly reducing the likelihood of enactment of health IT legislation this Congress.

DEMOCRATS OFFERED A SUBSTITUTE CONSISTING OF THE BIPARTISAN SENATE LEGISLATION ALONG WITH PRIVACY PROTECTIONS

Representatives Pallone and Gonzalez offered a substitute that included the text of the Senate bill, S. 1418, a bipartisan bill that passed the Senate unanimously on November 18, 2005, along with protections to ensure privacy of patient medical records. Unlike the Committee bill, the Democratic substitute would have ensured the rapid adoption of interoperable health information technology without exposing Federal health programs to fraud. Its stronger standards and guaranteed funding would more rapidly move the U.S. healthcare system to the electronic age.

The Democratic substitute codifies the Office of the National Coordinator for Health Information Technology and assigns it duties, including the adoption of interoperability standards allowing for electronic communication between providers, plans, and others. It

requires that the Federal Government purchase health information technology that meets interoperability standards. It also includes funding in the form of grants and loans for providers and regional collaboratives to buy and implement health information technology. The technology must meet standards of interoperability, as well. It requires the creation of a voluntary certification process for technology sold by vendors allowing providers to identify whether a product meets their needs and the needs of their patients before purchasing it. It does not make exceptions to the Stark self-referral and anti-kickback fraud and abuse laws, but instead leverages private dollars for a revolving loan fund that would not create a conflict of interest between providers. The substitute also includes privacy and security protections offered by Representative Markey in his privacy amendment described below. It was defeated on a party-line vote.

THE LEGISLATION FAILS TO PROTECT THE PRIVACY OF MEDICAL RECORDS

H.R. 4157 does not include adequate protections to ensure the privacy of patient personal medical information. The expanded adoption and use of technology to enable electronic exchange of information places larger amounts of personally-sensitive data at risk of disclosure or breach. For the successful adoption of health information technology, patients will need assurances their medical records are secure. President Bush has acknowledged this need, noting,

> "One thing is the federal government has got to make sure the privacy rules are strong. You're going to hear us talk about medical—electronic medical records. And that's exciting. But it's not so exciting if you're a patient who thinks somebody could snoop on your records, to put it bluntly . . . for those people—there's a lot of people in America who say, good, I want there to be good information technology in the health care field, I just don't want somebody looking at my records unless I give them permission to do so. And I fully understand that. And your records are private, if that's the way you want them to be." [1]

The bill, however, fails to include adequate protections for privacy, merely affirming the limited protections in the current law, the Health Insurance Portability and Accountability Act (HIPAA).

The HIPAA privacy rule, however, is not comprehensive and does not include provisions to adequately protect privacy in an electronic healthcare world. For example, the existing Federal law now only directly applies to some providers, health plans, and health information clearinghouses, but does not apply to anyone else who could receive sensitive health information, such as anyone the provider contracts with, or electronic health records companies. HIPAA also does not require consent for the use or disclosure of health information for treatment, payment, or healthcare operations. This means,

[1] President Bush Touts Benefits of Health Care Information Technology; Department of Veterans Affairs Medical Center, Baltimore, Maryland, April 27, 2004. (www.whitehouse.gov/news/releases/2004/04/20040427–5.html)

for example, that companies could use sensitive, individual information for fundraising.

Current law privacy rules under HIPAA, which would be maintained under the bill, do not require that the person be notified if there is a breach of data where individually-identifiable health information is lost, stolen, or used for an unauthorized purpose. This can include the accidental or erroneous disclosure of individually identifiable health information or the purposeful breach (hacking, theft) of a computer system to access information. And, while HIPAA allows for civil and criminal penalties to be assessed on violators by the Government, despite 19,420 grievances filed so far, not one entity has been assessed civil penalties; only two criminal cases have been prosecuted.

Moreover, HIPAA does not allow an individual who has been harmed to pursue enforcement or seek damages; only the Government is permitted to do that. And because the privacy rule applies only to groups that misuse or disclose health information, such as providers, health plans, and health information clearinghouses, there can be no direct penalties assessed against anyone other than these groups. HIPAA does permit States to have more protective privacy laws and a number of States have laws that address these concerns.

Representatives Markey and Capps offered an amendment to address these privacy and security concerns. Their amendment (1) requires patient consent to share personal health information electronically and allows patients to control access to their sensitive electronic health information; (2) applies protections to any individual in possession of personal health information; (3) allows individuals to get redress when their privacy is breached; (4) requires notification to individuals if their information is violated; (5) requires reasonable safeguards, such as encryption of data; and (6) does not preempt more protective State laws. The Markey-Capps amendment was defeated on a party-line vote.

THE LEGISLATION FAILS TO PROVIDE ADEQUATE RESOURCES TO ACQUIRE HEALTH INFORMATION TECHNOLOGY

H.R. 4157, as amended and reported by the Committee, provides an extremely limited amount of the funding necessary to encourage physicians, hospitals, and other providers to invest in technology. The bill authorizes $40 million over 2007 and 2008 for integrated healthcare systems serving uninsured, under-insured, and medically under-served individuals, and also to small physician practices. By contrast, S. 1418, which passed the Senate unanimously, authorized $652 million over the 2006–2010 period for health information technology.

The lack of sufficient funding to enable providers to adopt health information technology is a critical flaw in the legislation and will make it unlikely that this bill will initiate a large-scale movement to electronic provider communication and improved quality and more coordinated care. A number of Democratic amendments were offered that would have provided substantial funding for IT in order to encourage faster and more comprehensive adoption of such systems. Representatives Brown and Gonzalez offered an amendment that would ensure all providers would be eligible for grants,

Medicare add-on payments, and low-interest loans; Representative Stupak offered an amendment focused on rural providers; and Representatives Wynn, Rush, Solis, Schakowsky, and Engel offered an amendment to address the needs of safety net providers. The amendments were all defeated along largely party-line votes.

THE LEGISLATION OPENS NEW OPPORTUNITIES FOR FRAUD AND ABUSE

Instead of assisting the funding of health information technology, H.R. 4157 loosens current fraud and abuse laws to allow hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage organizations to give free health information technology, maintenance, service, training, and more to other providers.

These existing anti-fraud laws, known as the Stark self-referral and anti-kickback laws, protect Medicare and Medicaid, as well as patients against biased decision-making by doctors, and ensure that doctors are not referring patients to a specific hospital or other provider because of free gifts they are receiving. While it is important to leverage private sector dollars for the adoption of health information technology, it can be done without increasing the possibility of fraud and abuse. H.R. 4157, on the other hand, provides the broad waivers to the law, which present particular problems:

First, allowing a provider to give valuable free goods and services to another may influence decision-making in favor of the donor. In fact, the Congressional Budget Office noted in their analysis of the fraud loopholes in the Committee on Ways and Means legislation that while the language prohibits explicit *quid pro quo*, in many instances it would be implicit and assumed, resulting in fraudulent behavior.[2]

Second, the exemption does not require that the donated technology meet interoperability standards. Because a hospital can provide a physician with free technology that only works with the hospital's own technology, this allows the creation of technology silos across the country—areas where a physician may only be able to electronically communicate with the hospital that gave the physician the free technology, and no one else, including other hospitals or the Government. This runs directly contrary to promoting technology that will allow providers across the country to communicate with each other.

Third, there is no sunset on the provision, meaning that even when technology becomes very inexpensive, as most technology eventually does, the exemption and potential for abuse would still exist because hospitals will still be allowed to influence other providers with support and maintenance services.

Fourth, although the exemptions do not permit a hospital to condition the donation of technology to a doctor on the receipt of referrals, a hospital is allowed to take into account the volume and value of referrals a physician provides to the hospital in determining to whom to donate technology. This means the hospital could choose to reward the physicians that give the hospital its most valuable referrals, such as those with a high percentage of insured patients, and thus implicitly punish the others.

[2] Congressional Budget Office letter to Committee on Ways and Means Ranking Member Charles B. Rangel on H.R. 4157, June 15, 2006.

Fifth, the technology a hospital may give a physician may not be the best choice or fit for the physician, but without other incentives or funding to help the doctor, the doctor may have no choice but to accept the technology that is offered or remain a paper-based practice.

Sixth, the definition of health information technology and services is broad, making the potential for fraud and abuse greater.

Representative Pallone offered an amendment to provide direct funding to providers through grants and loans that leverage private sector dollars while reinstating the current law fraud and abuse provisions. The amendment was defeated on a party-line vote.

THE LEGISLATION FAILS TO ACHIEVE INTEROPERABILITY OF HEALTH INFORMATION SYSTEMS

H.R. 4157, as amended and reported by the Committee, requires the National Coordinator to endorse standards for electronic communications that would allow providers, health plans, and others to communicate with each other by August 2009, or earlier if required under the schedule the National Coordinator establishes. The bill, however, does not require the adoption of standards in the key areas of laboratory information, drug prescribing, clinical research, and ambulatory and inpatient electronic health records, and thus fails to guarantee national standards in these critical areas. Instead, the bill leaves the National Coordinator full discretion as to what standards to adopt.

The bill also does not require the Federal Government to provide a leadership role by incorporating the standards of interoperability in its use of health information technology or purchases of health information technology. Similarly, no other providers or health plans are required to incorporate the use of the standards, nor are incentives included to encourage the use of the standards. The bill merely requires the Federal Government to receive information electronically in a format that meets the standards. Therefore, the Government would not need to implement or use all the standards for electronic communication, therefore allowing fiefdoms where only a handful of providers can communicate with each other electronically.

Representative Eshoo offered an amendment to require the adoption of standards for key areas of health information including, at a minimum, laboratory information, drug prescribing, clinical research, and ambulatory and inpatient electronic health records within 18 months of the enactment of this act. This amendment also requires the Secretary of Health and Human Services to ensure that any purchases of health information technology or systems by Federal health programs meet the national standards of interoperability developed by the Government national task force. Finally, it requires the Federal Government to develop a voluntary certification process allowing buyers of health information technology to know about the system they are purchasing and whether it meets standards of interoperability. This would have encouraged an informed marketplace where providers and others purchasing hardware and software could assess more fairly and easily which

technology best met their needs. This amendment failed on a party-line vote.

CONCLUSION

The reported bill fails to (1) ensure providers have sufficient resources and incentives to acquire health information technology; (2) require the development of standards to allow electronic communication among providers in the key areas of lab data, prescription drug data, research, and ambulatory and inpatient data in a timely fashion; (3) protect patients and the taxpayers against fraud and improper kickbacks; and (4) protect patient privacy in this new electronic world being promoted in the bill. For those reasons, we oppose H.R. 4157, as reported.

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