114TH CONGRESS
2D SESSION

S. _____

To improve Federal requirements relating to the development and use of electronic health records technology.

IN THE SENATE OF THE UNITED STATES

_____

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To improve Federal requirements relating to the development and use of electronic health records technology.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "_____ Act of _____".

SEC. 2. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING THE QUALITY OF CARE FOR PATIENTS.

(a) IN GENERAL.—Part 1 of subtitle A of title XIII of the Health Information Technology for Economic and

Clinical Health Act (Public Law 111-5) is amended by adding at the end the following:

"SEC. 13103. ASSISTING DOCTORS AND HOSPITALS IN IMPROVING THE QUALITY OF CARE FOR PATIENTS.

''(a) REDUCTION IN BURDENS GOAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), in consultation with providers of health services, health care suppliers of services, health care payers, health professional societies, health information technology developers, health care quality organizations, health care accreditation organizations, public health entities, States, and other appropriate entities, shall, in accordance with subsection (b)—

''(1) establish a goal with respect to the reduction of regulatory or administrative burdens (such as documentation requirements) relating to the use of electronic health records;

''(2) develop a strategy for meeting the goal established under paragraph (1); and

''(3) develop recommendations for meeting the goal established under paragraph (1).

''(b) STRATEGY AND RECOMMENDATIONS.—

''(1) IN GENERAL.—To achieve the goals established under subsection (a)(1), the Secretary, in con-

sultation with the entities described in such subsection, shall, not later than 12 months after the date of enactment of this section, develop a strategy and recommendations to meet the goals in accordance with this subsection.

''(2) STRATEGY.—The strategy developed under paragraph (1) shall address the regulatory and administration burdens (such as documentation requirements) relating to the use of electronic health records. Such strategy shall include broad public comment and shall prioritize burdens related to—

''(A) the incentive programs for the Meaningful Use of certified EHR technology, the Merit-based Incentive Payment System, the Alternative Payment Models, the Hospital Value-Based Purchasing Program, and other value-based payment program determined appropriate by the Secretary;

''(B) health information technology certification programs;

''(C) standards, and implementation specifications, as appropriate;

''(D) activities that provide individuals access to their electronic health information;

"(E) activities related to protecting the privacy of electronic health information;

"(F) activities related to protecting the security of electronic health information;

"(G) activities related to facilitating health and clinical research;

"(H) activities related to public health;

"(I) activities related to aligning and simplifying quality measures across Federal programs and other payers;

"(J) activities related to reporting clinical data for administrative purposes; and

"(K) other areas determined appropriate by the Secretary;

"(3) RECOMMENDATIONS.—The recommendations developed under paragraph (1) shall address—

"(A) actions that improve the clinical documentation experience;

"(B) actions that improve patient care;

"(C) actions to be taken by the Secretary and by other entities; and

"(D) other areas determined appropriate by the Secretary to reduce the reporting burden required of health care providers.

"(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—Notwithstanding any other provision of law, clinical documentation requirements that are imposed upon health care providers by Department of Health and Human Service regulations may be delegated to non-physician members of the care team as permitted by State licensure and State medical and health professional board regulations, except as may be required for program integrity, including the prevention of fraud, waste, or abuse.".

(b) CERTIFICATION OF HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11(c)(5)) is amended by adding at the end the following:

"(C) HEALTH INFORMATION TECHNOLOGY FOR MEDICAL SPECIALTIES.—

"(i) IN GENERAL.—The National Coordinator shall encourage, keep, or recognize, through existing authorities, the voluntary certification of health information technology under the program developed under subparagraph (A) for use in medical specialties for which no such technology is available or where more technological advancement or integration is needed.

"(ii) SPECIFIC MEDICAL SPECIALTIES.—The HIT Advisory Committee shall make recommendations on specific medical specialties, in addition to those described in clause (iii), applicable under this paragraph.

"(iii) CERTIFIED HEALTH INFORMATION TECHNOLOGY FOR PEDIATRICS.—Not later than 18 months after the date of enactment of this subparagraph, the HIT Advisory Committee, in consultation with relevant stakeholders, shall make recommendations for the voluntary certification of health information technology for use by pediatric health providers to support the health care of children. Not later than 24 months after the date of enactment of this subparagraph, the Secretary shall adopt certification criteria (under section 3004) to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.".

SEC. 3. TRANSPARENT RATINGS ON USABILITY AND SECURITY TO TRANSFORM INFORMATION TECHNOLOGY.

(a) ENHANCEMENTS TO CERTIFICATION.—Section 3001(c)(5) of the Public Health Service Act (42 U.S.C. 300jj–11), as amended by section 2(b), is further amended—

(1) in subparagraph (A)—

(A) by striking ''The National Coordinator'' and inserting the following:

''(i) VOLUNTARY CERTIFICATION PROGRAM.—The National Coordinator''; and

(B) by adding at the end the following:

''(ii) TRANSPARENCY OF PROGRAM.—

''(I) IN GENERAL.—To enhance transparency in the compliance of health information technology with certification criteria and other requirements adopted under this subtitle, the National Coordinator, in coordination with authorized certification bodies, may make information demonstrating how health information technology meets such certification criteria or other requirements publicly available. Such information may in-

clude summaries, screenshots, video demonstrations, or any other information the National Coordinator determines appropriate.

"(II) PROTECTION OF PROPRIETARY INFORMATION.—The National Coordinator shall take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section.";

(2) in subparagraph (B), by adding at the end the following: "Beginning 18 months after reporting criteria are finalized under section 3009A, certification criteria shall include, in addition to criteria to establish that the technology meets such standards and implementation specifications, criteria consistent with section 3009A(b) to establish that technology meets applicable security requirements, incorporates user-centered design, and achieves interoperability."; and

(3) by adding at the end the following:

"(D) CONDITIONS OF CERTIFICATION.—Beginning 1 year after the date of enactment of the _____ Act of _____, the Secretary shall require that each developer of health information technology and entity seeking certification of health information technology, as a condition of certification and maintenance of certification of such technology, provide to the Secretary periodically, as necessary, an attestation that—

"(i) the health information technology developer or entity, unless for a legitimate purpose specified by the Secretary, does not take any action that constitutes information blocking with respect to health information technology;

"(ii) the health information technology developer or entity permits unimpeded communication among and between health information technology users and an authorized certification body, the Office of the National Coordinator, and the Office of the Inspector General regarding the usability, interoperability, security, business practices, or other relevant infor-

mation about the health information technology or users' experience with the health information technology; and

''(iii) health information from such technology may be exchanged, accessed, and used through the use of application programming interfaces or successor [technology/standard] as provided for under applicable law.''.

(b) HEALTH INFORMATION TECHNOLOGY RATING PROGRAM.—Subtitle A of title XXX of the Public Health Service Act (42 U.S.C. 300jj–11 et seq.) is amended by adding at the end the following:

''SEC. 3009A. HEALTH INFORMATION TECHNOLOGY RATING PROGRAM.

''(a) ESTABLISHMENT.—Not later than 180 days after the date of enactment of the _____ Act of _____, the Secretary shall recognize a development council made up of one representative from each of the authorized certifying bodies accredited by the Office of the National Coordinator and the testing laboratories accredited under section 13201(b) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17911(b)), one representative from the National Institute of Standards and Technology, and one represent-

ative from the Office of the National Coordinator. The development council shall meet as needed for the purposes of carrying out its activities in accordance with this section.

"(b) REPORTING CRITERIA.—

"(1) IN GENERAL.—Not later than 1 year after the date of enactment of the _____ Act of _____, the Secretary, in consultation with the development council described in subsection (a), shall convene stakeholders as described in paragraph (2) for the purpose of developing the reporting criteria in accordance with paragraph (3).

"(2) DEVELOPMENT OF REPORTING CRITERIA.—The reporting criteria under this subsection shall be developed through a public, transparent process that reflects input from relevant stakeholders, including—

"(A) health care providers, including primary care and specialty care health care professionals;

"(B) hospitals and hospital systems;

"(C) health information technology developers;

"(D) advocates for patients or consumers;

"(E) data sharing networks, such as health information exchanges;

"(F) authorized certification bodies and testing laboratories;

"(G) security experts;

"(H) relevant manufacturers of medical devices;

"(I) experts in health information technology market economics; and

"(J) other entities or persons, as the Secretary, in consultation with the development council, determines appropriate.

"(3) CONSIDERATIONS FOR REPORTING CRITERIA.—The reporting criteria developed under this subsection—

"(A) shall include measures that reflect categories including, with respect to the technology—

"(i) security;

"(ii) usability and user-centered design;

"(iii) interoperability;

"(iv) conformance to certification testing; and

"(v) other categories as appropriate to measure the performance of health information technology;

"(B) may include measures such as—

"(i) enabling the user to order and view the results of laboratory tests, imaging tests, and other diagnostic tests;

"(ii) submitting, editing, and retrieving data from registries such as clinician-led clinical data registries;

"(iii) accessing and exchanging information and data from medical devices;

"(iv) accessing and exchanging information and data held by Federal, State, and local agencies and other applicable entities useful to a health care provider or other applicable user in the furtherance of patient care;

"(v) accessing and exchanging information from other health care providers or applicable users;

"(vi) accessing and exchanging patient generated information;

"(vii) providing the patient or an authorized designee with a complete copy of

their health information from an electronic record in a computable format;

"(viii) providing accurate patient information for the correct patient, including exchanging such information, and avoiding the duplication of patients records; and

"(ix) other appropriate functionalities; and

"(C) shall be designed to ensure that small and start-up health information technology developers are not unduly disadvantaged by the reporting criteria or rating scale methodology.

"(4) CONSIDERATION OF DEVELOPMENT COUNCIL RECOMMENDATIONS.—In promulgating proposed rules under this subsection, including modifications to such rules under subsection (c), the Secretary may accept, reject, or [modify] the recommendations of the development council, but may not promulgate a proposed rule that does not represent a complete recommendation of such council.

"(5) PUBLIC COMMENT.—In promulgating proposed rules under this subsection, the Secretary shall conduct a public comment period of not less than 60 days during which any member of the public may provide comments on the proposed reporting

criteria and the methodology for the rating body (defined in subsection (g)) to use in determining the star ratings.

''(6) FINAL RULES.—The final rule promulgated under this subsection shall be accompanied by timely responses to the public comments described in paragraph (5).

''(7) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development council described in this section.

''(c) FEEDBACK.—The Secretary, in consultation with the development council, shall establish a process for the rating body (described in subsection (g)) to collect and verify confidential feedback from—

''(1) health care providers, patients, and other users of certified health information technology on the usability, security, and interoperability of health information technology products; and

''(2) developers of certified health information technology on practices of health information technology users that may inhibit interoperability.

''(d) METHODOLOGY.—The Secretary, in consultation with the development council, shall develop a methodology to be used by the rating body described in subsection (g) to calculate the star ratings for certified health infor-

mation technology described in subsection (a). The methodology shall use the reporting criteria developed in subsection (b), and the confidential feedback collected under subsection (c).

''(e) MODIFICATIONS.—

''(1) TO THE NUMBER OF STARS IN THE RATING PROGRAM.—The development council may modify the number of star ratings employed by the system, but not more frequently than every 4 years. In no case shall the rating system employ fewer than 3 stars.

''(2) TO THE REPORTING CRITERIA.—After the final reporting criteria have been established under this section, the Secretary, in consultation with the development council, may convene stakeholders and conduct a public reporting period for the purpose of modifying the reporting criteria developed under subsection (b) and methodology for determining the star ratings proposed under subsection (e).

''(3) TO THE METHODOLOGY.—After the final methodology to be used by the rating body is established under subsection (e), the Secretary, in consultation with the development council, may modify the methodology used to calculate the star ratings for certified health information technology using the

reporting criteria developed under subsection (b) and the confidential feedback collected under subsection (c).

''(4) CONSIDERATION OF GAO REPORT.—The Secretary and the development council shall take into account the recommendations from the Comptroller General under subsection (k), where available, for the purposes of this paragraph.

''(f) PARTICIPATION.—As a condition of maintaining their certification, developers of certified health information technology shall report on the criteria developed under subsection (b) for all such certified technology beginning at least 2 years after such certification and at least every 2 years thereafter to the rating body described in subsection (g).

''(g) RATING BODY.—The National Coordinator shall recognize an independent entity with appropriate expertise in certifying information technology to carry out the rating program established by the development council under subsection (a) and shall re-determine such recognition at least every 4 years.

''(h) ONE STAR RATING.—Each health information technology developer, or entity offering health information technology for certification, that receives a 1 star rating shall take action, through a corrective action plan devel-

oped with the rating body and approved by the Secretary, to improve the health information technology rating within a timeframe that the Secretary determines appropriate.

"(i) ENFORCEMENT AUTHORITIES.—

"(1) FINES.—

"(A) IN GENERAL.—The Secretary may assess fines against such a developer or entity if the developer or entity—

"(i) does not meet the requirements of the corrective action plan described in subsection (h);

"(ii) does not improve from a one star rating in accordance with subsection (h); or

"(iii) does not report on criteria in accordance with subsection (f).

"(B) FINE AMOUNTS.—Not later than 1 year after the date of enactment of the _____ Act of _____, the Secretary shall establish fine amounts for violations of clauses (i), (ii), and (iii) of subparagraph (A). In setting such amounts, the Secretary shall consider the amounts necessary to reimburse, in part or in full, the users of decertified health information technology for the amounts in-

vested in purchasing new certified health information technology, as applicable.

''(2) DECERTIFICATION.—The Secretary may decertify health information technology if—

''(A) the health information technology does not improve from a one star rating within the timeframe established under subsection (h);

''(B) the developer or entity offering health information technology does not report on criteria in accordance with subsection (f); or

''(C) in other circumstances, as the Secretary determines appropriate.

''(j) GAO REPORTS.—During the 12-year period beginning on the date of enactment of the _____ Act of _____, the Comptroller General of the United States shall submit to Congress a report every 4 years on the rating scale methodology developed pursuant to subsection (b), providing observations on the appropriateness of the current methodology and recommendations for changes to the methodology. The Development Council shall recommend to Congress and the Secretary if additional reports are needed after the expiration of such 12-year period.

''(k) INTERNET WEBSITE.—On the Internet website of the Office of the National Coordinator, the Secretary

shall publish the criteria and methodology used to determine the star ratings, and, for each certified health information technology, the star rating, and a report outlining such technology's performance with regard to the reporting criteria developed under subsection (b), and if a corrective action plan has been administered. Following the biennial reporting described in subsection (f), the rating body shall have 30 days to calculate and submit updated ratings to the Secretary and each developer of health information technology, and updated ratings shall be published on such Internet website not later than 30 days following such submission, notwithstanding an appeal of a rating by a developer or entity through the process developed under subsection (n).

''(l) USER COMPENSATION FUND.—The Secretary shall establish a revolving user compensation fund in which amounts collected under subsection (i)(1) shall be directed and used to assist users of health information technology that are decertified under subsection (i)(2) to reimburse users for the costs of purchasing new certified health information technology products and to administer the fund.

''(m) HARDSHIP EXEMPTION.—The Secretary shall, on a case-by-case basis, exempt an eligible professional, eligible hospital, or critical access hospital from the appli-

cation of the payment adjustment under the Meaningful Use of Certified EHR Technology program under sections 1848(a)(7)(A), 1886(b)(3)(B)(ix)(I), and 1814(l)(4), respectively, of the Social Security Act for 1 year if the eligible professional, eligible hospital, or critical access hospital uses health information technology that becomes decertified under subsection (i)(2), to help such eligible professional, eligible hospital, or critical access hospital transition to a new certified electronic health record technology.

''(n) NOTIFICATION AND APPEALS.—The Secretary shall establish a process whereby any health information technology developer, or entity offering health information technology, is notified not less than 30 days before being made public and can appeal—

''(1) the health information technology product's star rating; or

''(2) the Secretary's decision to decertify a product, as applicable.''.

SEC. 4. INFORMATION BLOCKING.

Subtitle C of title XXX of the Public Health Service Act (42 U.S.C. 300jj-51 et seq.) is amended by adding at the end the following:

''SEC. 3022. INFORMATION BLOCKING.

''(a) DEFINITION.—

"(1) IN GENERAL.—The term 'information blocking' means—

"(A) with respect to a health information technology developer, exchange, or network, business, technical, or organizational practices that—

"(i) except as required by law or specified by the Secretary, interferes with, prevents, or materially discourages access, exchange, or use of electronic health information; and

"(ii) the developer, exchange, or network knows, or should know, are likely to interfere with or prevent or materially discourage the access, exchange, or use of electronic health information; and

"(B) with respect to a health care provider, the person or entity knowingly and unreasonably restricts electronic health information exchange for patient care or other priorities as determined appropriate by the Secretary.

"(2) RULEMAKING.—The Secretary shall, through rulemaking—

"(A) identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1)(A); and

"(B) identify actions that meet the definition of information blocking with respect to health care providers for purposes of paragraph (1)(B).

"(b) INSPECTOR GENERAL AUTHORITY.—

"(1) IN GENERAL.—The Inspector General of the Department of Health and Human Services may investigate any claim that—

"(A) a health information technology developer of, or other entity offering [for sale], certified health information technology—

"(i) submits a false attestation made under subparagraph (C); or

"(ii) engaged in information blocking with respect to the use of such health information technology by a health care provider, unless for a legitimate purpose specified by the Secretary;

"(B) a health care provider engaged in information blocking with respect to access or exchange of certified health information tech-

nology, unless for a legitimate purpose specified by the Secretary; and

"(C) a health information network or exchange provider engaged in information blocking with respect to the access, exchange, or use of such certified health information technology, unless for a legitimate purpose specified by the Secretary.

"(2) JURISDICTION OF THE INSPECTOR GENERAL.—For purposes of this section, the Office of the Inspector General shall have jurisdiction with respect to any developer or entity offering health information technology for certification under a program or programs kept or recognized by the National Coordinator under section 3001(c)(5). The National Coordinator shall notify developers of health information technology as appropriate regarding the jurisdiction of the Inspector General under this paragraph.

"(3) PENALTY.—

"(A) DEVELOPERS, NETWORKS, AND EXCHANGES.—With respect to a health information technology developer, exchange, or network, a person or entity determined by the Inspector General to have committed information blocking

as described in subparagraph (A) or (C) of paragraph (1) shall be subject to a civil monetary penalty in an amount determined to be sufficient as a deterrent by the Secretary.

''(B) PROVIDERS.—With respect to health care providers, any person or entity determined by the Inspector General to have committed information blocking as described in subparagraph (B) of paragraph (1) shall be subject to a sufficient deterrent using authorities under applicable Federal law, as determined appropriate by the Secretary.

''(C) PROCEDURE.—The provisions of section 1128A of the Social Security Act (other than subsections (a) and (b)) shall apply to a civil money penalty applied under this subsection in the same manner as such provisions apply to a civil money penalty or proceeding under section 1128A(a).

''(D) RECOVERY OF FUNDS.—Notwithstanding section 3302 of title 31, United States Code, or any other provision of law affecting the crediting of collections, the Inspector General of the Department of Health and Human Services may receive and retain for current use

any amounts recovered under subparagraphs (A) and (C). In addition to amounts otherwise available to the Inspector General, funds received by the Inspector General under this paragraph shall be deposited, as an offsetting collection, to the credit of any appropriation available for purposes of carrying out this subsection and shall be available without fiscal year limitation and without further appropriation.

''(4) RESOLUTION OF CLAIMS.—

''(A) IN GENERAL.—The Office of the Inspector General, if such Office determines that a simple consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note) will resolve the claim at issue, may report instances of information blocking to the Office for Civil Rights of the Department of Health and Human Services for resolution.

''(B) LIMITATION ON LIABILITY.—If a health information technology developer makes information available based on a good faith reliance on consultations with the Office for Civil Rights of the Department of Health and

Human Services with respect to such information, the developer shall not be liable for such disclosure.''.

SEC. 5. INTEROPERABILITY.

(a) DEFINITION.—Section 3000 of the Public Health Service Act (42 U.S.C. 300jj) is amended—

(1) by redesignating paragraphs (10) through (14), as paragraphs (11) through (15), respectively; and

(2) by inserting after paragraph (9) the following:

''(10) INTEROPERABILITY.—The term 'interoperability' with respect to health information technology means such health information technology that has the ability to securely exchange electronic health information with and use electronic health information from other health information technology without special effort on the part of the user.''.

(b) SUPPORT FOR INTEROPERABLE NETWORK EXCHANGE.—Section 3001 of the Public Health Service Act (42 U.S.C. 300jj-11(c)) is amended by adding at the end the following:

''(9) SUPPORT FOR INTEROPERABLE NETWORKS EXCHANGE.—

"(A) IN GENERAL.—The National Coordinator shall, in collaboration with the National Institute of Standards and Technology and other relevant agencies within the Department of Health and Human Services, for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop a trusted exchange framework, including a common agreement among health information networks nationally. Such convention may occur at a frequency determined appropriate by the Secretary.

"(B) ESTABLISHING A TRUSTED EXCHANGE FRAMEWORK.—

"(i) IN GENERAL.—Not later than six months after the date of enactment of this paragraph, the National Coordinator shall convene appropriate public and private stakeholders to develop a trusted exchange framework for trust policies and practices and for a common agreement for exchange between health information networks. The common agreement may include—

"(I) a common method for authenticating trusted health information network participants;

"(II) a common set of rules for trusted exchange;

"(III) organizational and operational policies to enable the exchange of health information among networks, including minimum conditions for such exchange to occur; and

"(IV) a process for filing and adjudicating non-compliance with the terms of the common agreement.

"(ii) TECHNICAL ASSISTANCE.—The National Coordinator, in conjunction with National Institute of Standards and Technology, shall provide technical assistance on how to implement the trusted exchange framework and common agreement under this paragraph.

"(iii) PILOT TESTING.—The National Institute of Standards and Technology shall provide for the pilot testing of the trusted exchange framework and common agreement established under this sub-

section (as authorized under section 13201 of the Health Information Technology for Economic and Clinical Health Act).

"(C) PUBLICATION OF A TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—Not later than one year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register, the trusted exchange framework and common agreement developed under subparagraph (B). Such trusted exchange framework and common agreement shall be published in a manner that protects proprietary and security information, including trade secrets and any other protected intellectual property.

"(D) DIRECTORY OF PARTICIPATING HEALTH INFORMATION NETWORKS.—Not later than two years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of those health information networks that have adopted the common agreement and are capable of trusted

exchange pursuant to the common agreement developed under paragraph (B).

"(E) APPLICATION OF THE TRUSTED EXCHANGE FRAMEWORK AND COMMON AGREEMENT.—As appropriate, Federal agencies contracting or entering into agreements with health information exchange networks may require that as each such network upgrades health information technology or trust and operational practices, it may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).".

(c) PROVIDER DIGITAL CONTACT INFORMATION INDEX.—

(1) IN GENERAL.—Not later than _____ after the date of enactment of this Act, the Secretary of Health and Human Services shall either directly, or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals, health facilities, and other individuals or organizations.

(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary of Health and Human Services may utilize an exist-

ing provider directory to make such digital contact information available.

(3) CONTACT INFORMATION.—An index established under this subsection shall ensure that contact information is available at the individual health care provider level and at the health facility or practice level.

(d) STANDARDS DEVELOPMENT ORGANIZATIONS.—Section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14) is amended by adding at the end the following:

''(c) DEFERENCE TO STANDARDS DEVELOPMENT ORGANIZATIONS.—In adopting and implementing standards under this section, the Secretary shall give deference to standards published by Standards Development Organizations.''.

[(e) HIT ADVISORY COMMITTEE.—]

[(1) IN GENERAL.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by striking sections 3002 and 3003 and inserting the following:]

[''SEC. 3002. HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE.

[''(a) ESTABLISHMENT.—There is established a Health Information Technology Advisory Committee (referred to in this section as the 'HIT Advisory Committee')

to recommend to the National Coordinator policies, standards, implementation specifications, and certification criteria—]

[“(1) to advance the electronic exchange and use of health information across the care continuum for purposes of adoption under section 3004, consistent with the implementation of the strategic plan described in section 3001(c)(3) and beginning with the areas listed in subsection (b)(2)(B); and]

[“(2) relating to the implementation of a health information technology infrastructure nationally and locally.]

[“(b) DUTIES.—]

[“(1) HEALTH INFORMATION TECHNOLOGY POLICY DUTIES.—]

[“(A) RECOMMENDATIONS ON HEALTH INFORMATION TECHNOLOGY INFRASTRUCTURE.—The HIT Advisory Committee shall recommend a policy framework for the development and adoption of health information technology infrastructure nationally and locally that permits the electronic exchange and use of health information consistent with the strategic plan under section 3001(c)(3) and that includes the recommendations under subparagraph (B). The

HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate.]

[''(B) SPECIFIC AREAS OF STANDARD DEVELOPMENT.—]

[''(i) IN GENERAL.—The HIT Advisory Committee shall recommend the areas in which standards, implementation specifications, and certification criteria are needed for the electronic exchange and use of health information for purposes of adoption under section 3004 and shall recommend an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria among the areas so recommended. Such recommendations shall include recommended standards, architectures, and software schemes for access to electronic individually identifiable health information across disparate systems including user vetting, authentication, privilege management and access control.]

[''(ii) AREAS REQUIRED FOR CONSIDERATION.—For purposes of clause (i), the

HIT Advisory Committee shall make recommendations for at least the following areas:]

[“(I) The promotion and protection of privacy and security of health information in health information technology, including technologies that allow for an accounting of disclosures and protections against disclosures of individually identifiable health information made by a covered entity for purposes of treatment, payment, and health care operations (as such terms are defined for purposes of the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996), including for the segmentation and protection from disclosure of specific and sensitive individually identifiable health information with the goal of minimizing the reluctance of patients to seek care.]

[“(II) Technology that provides accurate patient information for the

correct patient, including exchanging such information, and avoids the duplication of patient records.]

[“(III) The use of health information technology to improve the quality of health care, such as by promoting the coordination of health care and improving continuity of health care among health care providers, by reducing medical errors, by improving population health, by reducing health disparities, by reducing chronic disease, and by advancing research and education.]

[“(IV) Technologies that allow individually identifiable health information to be rendered unusable, unreadable, or indecipherable to unauthorized individuals when such information is transmitted in a health information network or transported outside of the secure facilities or systems where the disclosing covered entity is responsible for security conditions.]

[“(V) Technologies that address the needs of children and other vulnerable populations.]

[“(VI) Health information technology infrastructure, nationally and locally, that allows for the electronic use and accurate exchange of health information.]

[“(VII) The utilization of a certified electronic health record for each individual in the United States.]

[“(VIII) The use of electronic systems to ensure the comprehensive collection of patient demographic data, including, at a minimum race, ethnicity, primary language, and gender information.]

[“(iii) OTHER AREAS FOR CONSIDERATION.—In making recommendations under clause (i), the HIT Advisory Committee may consider additional areas determined appropriate, such as:]

[“(I) Self-service, telemedicine, home health care, and remote monitoring technologies.]

[“(II) Technologies that meet the needs of diverse populations.]

[“(III) The facilitation of secure access by an individual to such individual’s protected health information and access to such information by a family member, caregiver, or guardian acting on behalf of a patient, including due to age related and other disability, cognitive impairment, or dementia.]

[“(IV) technologies that support—]

[“(aa) data for use in quality and public reporting programs;]

[“(bb) public health ; and]

[“(cc) drug safety.]

[“(C) CONSISTENCY WITH EVALUATION CONDUCTED UNDER MIPPA AND MACRA.—]

[“(i) REQUIREMENT FOR CONSISTENCY.—The HIT Advisory Committee shall ensure that recommendations made under subparagraph (B)(ii)(V) are consistent with the evaluation and report con-

ducted under section 1809 of the Social Security Act, and consider the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary.]

[''(ii) RULE OF CONSTRUCTION.—Nothing in clause (i) shall be construed to limit the recommendations under subparagraph (B)(ii)(V) to the elements described in section 1809(a)(3) of the Social Security Act or the report or programs referred to in clause (i).]

[''(iii) TIMING.—The requirement under clause (i) shall be applicable to the extent that evaluations have been conducted under section 1809(a) of the Social Security Act, regardless of whether the report described in subsection (b) of such section has been submitted.]

[''(2) STANDARDS, IMPLEMENTATION, AND CERTIFICATION CRITERIA.—]

["(A) IN GENERAL.—The HIT Advisory Committee shall recommend to the National Coordinator standards, implementation specifications, and certification criteria described in subsection (a) that have been developed, harmonized, or recognized by the HIT Advisory Committee. The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 3004(a)(2)(B). Such recommendations shall be consistent with the latest recommendations made by the Committee.**]**

["(B) HARMONIZATION.—The HIT Advisory Committee may recognize harmonized or updated standards from an entity or entities for the purpose of harmonizing or updating standards and implementation specifications in order to achieve uniform and consistent implementation of the standards and implementation specifications.**]**

["(C) PILOT TESTING OF STANDARDS AND IMPLEMENTATION SPECIFICATIONS.—In the development, harmonization, or recognition of standards and implementation specifications,

the HIT Advisory Committee shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 13201(a) of the Health Information Technology for Economic and Clinical Health Act.]

[''(D) CONSISTENCY.—The standards, implementation specifications, and certification criteria recommended under this paragraph shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1173 of the Social Security Act.]

[''(3) FORUM.—The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies relating to the matters described in paragraphs (1) and (2) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certification criteria necessary for the development and adoption of a health information technology infrastructure nationally and locally that allows for the electronic use and exchange of health information.]

[“(4) SCHEDULE.—Not later than 30 days after the date on which the HIT Advisory Committee first meets, such HIT Advisory Committee shall develop a schedule for the assessment of policy recommendations developed under paragraph (1). The HIT Advisory Committee shall update such schedule annually. The Secretary shall publish such schedule in the Federal Register.]

[“(5) PUBLIC INPUT.—The HIT Advisory Committee shall conduct open public meetings and develop a process to allow for public comment on the schedule described in paragraph (4) and recommendations described in this subsection. Under such process comments shall be submitted in a timely manner after the date of publication of a recommendation under this subsection.]

[“(c) MEMBERSHIP AND OPERATIONS.—]

[“(1) IN GENERAL.—The National Coordinator shall take a leading position in the establishment and operations of the HIT Advisory Committee.]

[“(2) MEMBERSHIP.—The membership of the HIT Advisory Committee shall—]

[“(A) include at least 25 members;]

[“(B) at least reflect providers, ancillary healthcare workers, consumers, purchasers,

health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, privacy, security, and on the electronic exchange and use of health information; and]

[“(C) Include no fewer than two members who are advocates for patients or consumers of health information technology.]

[“(3) PARTICIPATION.—The members of the HIT Advisory Committee shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of the Committee.]

[“(4) TERMS.—]

[“(A) IN GENERAL.—The terms of the members of the HIT Advisory Committee shall be for 3 years, except that the Secretary shall designate staggered terms for the members first appointed.]

[“(B) VACANCIES.—Any member appointed to fill a vacancy in the membership of the HIT Advisory Committee that occurs prior to the expiration of the term for which the member’s predecessor was appointed shall be

appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has been appointed. A vacancy in the HIT Advisory Committee shall be filled in the manner in which the original appointment was made.]

[''(C) LIMITS.—Members of the HIT Advisory Committee shall be limited to two 3-year terms, for a total of not to exceed 6 years of service on the Committee.]

[''(5) OUTSIDE INVOLVEMENT.—The HIT Advisory Committee shall ensure an opportunity for the participation in activities of the Committee of outside advisors, including individuals with expertise in the development of policies and standards for the electronic exchange and use of health information, including in the areas of health information privacy and security.]

[''(6) QUORUM.—A majority of the member of the HIT Advisory Committee shall constitute a quorum for purposes of voting, but a lesser number of members may meet and hold hearings.]

[''(7) CONSIDERATION.—The National Coordinator shall ensure that the relevant and available recommendations and comments from the National

Committee on Vital and Health Statistics are considered in the development of policies.]

[''(8) ASSISTANCE.—For the purposes of carrying out this section, the Secretary may provide or ensure that financial assistance is provided by the HIT Advisory Committee to defray in whole or in part any membership fees or dues charged by such Committee to those consumer advocacy groups and not for profit entities that work in the public interest as a part of their mission.]

[''(d) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of such Act, shall apply to the HIT Advisory Committee.]

[''(e) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Office of the National Coordinator for Health Information Technology of all policy recommendations made by the HIT Advisory Committee under this section.''.]

[(2) TECHNICAL AND CONFORMING AMENDMENTS.—Title XXX of the Public Health Service Act is amended—]

[(A) by striking—]

[(i) ''HIT Policy Committee'' and ''HIT Standards Committee'' each place that such terms appear and inserting '' HIT Advisory Committee'';]

[(ii) ''HIT Policy Committee and the HIT Standards Committee'' each place that such term appears and inserting '' HIT Advisory Committee''; and]

[(iii) ''HIT Policy Committee or the HIT Standards Committee'' each place that such term appears and inserting '' HIT Advisory Committee'';]

[(B) in section 3000 (42 U.S.C. 300jj), by striking paragraphs (7) and (8) and insert the following:]

[''(7) HIT ADVISORY COMMITTEE.—The term ' HIT Advisory Committee' means such Committee established under section 3002(a).'';]

[(C) in section 3001(c) (42 U.S.C. 300jj-11(c))—]

[(i) in paragraph (1)(A), by striking ''HIT Standards Committee under section 3003'' and inserting ''HIT Advisory Committee under section 3002'';]

[(ii) in paragraph (2), by striking subparagraph (B) and inserting the following:]

["(B) HIT ADVISORY COMMITTEE.—The National Coordinator shall be a leading member in the establishment and operations of the HIT Advisory Committee and shall serve as a liaison between that Committee and the Federal Government.";]

[(D) in section 3004(b)(3) (42 U.S.C. 300jj-14(b)(3)), by striking "3003(b)(2)" and inserting "3002(b)(4)";]

[(E) in section 3007(b) (42 U.S.C. 300jj-17(b)), by striking "3003(a)" and inserting "3002(a)(2)"; and]

[(F) in section 3008 (42 U.S.C. 300jj-18)—]

[(i) in subsection (b), by striking "or 3003"; and]

[(ii) in subsection (c), by striking "3003(b)(1)(A)" and inserting "3002(b)(2)".]

[(3) TRANSITION TO HIT ADVISORY COMMITTEE.—The Secretary of Health and Human Services shall provide for an orderly and timely tran-

sition to the HIT Advisory Committee established under the amendments made by this section.]

[(f) PRIORITIES FOR ADOPTION OF STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA.—Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), as amended by subsection (e)(1), is further amended by inserting after section 3002 the following:]

["SEC. 3003. SETTING PRIORITIES FOR STANDARDS ADOPTION.

["(a) IDENTIFYING PRIORITIES.—Not later than 6 months after the date on which the HIT Advisory Committee first meets, the National Coordinator shall periodically convene the HIT Advisory Committee to—]

["(1) identify priority uses of health information technology, focusing on priorities—]

["(A) arising from the implementation of the incentive programs for the meaningful use of certified EHR technology, the Merit-based Incentive Payment System, the Alternative Payment Models, the Hospital Value-Based Purchasing Program, and any other value-based payment program determined appropriate by the Secretary;]

[“(B) related to the quality of patient care;]

[“(C) related to public health;]

[“(D) related to clinical research;]

[“(E) related to the privacy and security of electronic health information;]

[“(F) related to innovation in the field of health information technology;]

[“(G) related to patient safety;]

[“(H) related to the usability of health information technology;]

[“(I) related to individuals’ access to electronic health information; and]

[“(J) other priorities determined appropriate by the Secretary;]

[“(2) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in paragraph (1); and]

[“(3) publish a report summarizing the findings of the analysis conducted under paragraphs (1) and (2) and make appropriate recommendations.]

[In identifying such standards and implementation specifications under paragraph (2), the HIT Advisory Committee shall prioritize standards and implementation spec-

ifications developed by consensus-based standards development organizations.]

[“(b) ENSURING STAKEHOLDER INPUT FOR STANDARDS ADOPTION.—]

[“(1) IN GENERAL.—The National Coordinator shall establish a process in accordance with this paragraph, that shall be carried out with respect to recommendations that are made by the HIT Advisory Committee for purposes of adopting standards, implementation specifications, and certification criteria. Under such process—]

[“(A) the National Coordinator shall convene stakeholders to provide input to the HIT Advisory Committee on standards, implementation specifications, and certification criteria for adoption under section 3004;]

[“(B) such stakeholders shall be selected through a process that allows for public nominations for, and the opportunity for public comment on, the selection of such stakeholders;]

[“(C) the National Coordinator shall provide for an open and transparent process for the activities conducted pursuant to such convening;]

["(D) the stakeholders shall transmit their recommendations to the HIT Advisory Committee and the National Coordinator;**]**

["(E) the National Coordinator shall take into consideration the input from stakeholders in selecting standards, implementation specifications, and certification criteria for endorsement; and**]**

["(F) the Federal Advisory Committee Act shall not apply to such stakeholder organization.**]**

["(2) REVIEW OF ADOPTED STANDARDS.—Beginning 5 years after the date of enactment of this section, and every 3 years thereafter, the National Coordinator shall convene stakeholders to review the existing set of adopted standards and implementation specifications and make recommendations with respect to whether to—**]**

["(A) maintain the use of such standards and implementation specifications; or**]**

["(B) phase out such standards and implementation specifications.**]**

["(3) PRIORITIES.—The HIT Advisory Committee, in collaboration with the National Institute for Standards and Technology, shall annually and

through the use of public input, review and publish priorities for the use of health information technology, standards, and implementation specifications to support those priorities.]

[''(c) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent the use or adoption of novel standards that improve upon the existing health information technology infrastructure and facilitate the secure exchange of health information.''.]

[(g) COMMON DATA ELEMENTS.—]

[(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall adopt standards, implementation specifications, and certification criteria under section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14) for a core set of common data elements and associated value sets to enhance the ability of certified health information technology to capture, use, and exchange structured electronic health information.]

[(2) CONSULTATION.—In adopting such standards the Secretary shall require that the HIT Advisory Committee and the National Coordinator consult with stakeholders, including health care providers, hospitals, health plans, developers of health

information technology, representatives of patients, the National Committee on Vital and Health Statistics, and the consensus-based entity described in section 1890 of the Social Security Act (42 U.S.C. 1395aaa).]

[(3) PRIORITIES.—The Secretary shall prioritize standards, implementation specifications, and certification criteria for a core set of common data elements based on priorities that include—]

[(A) the facilitation of the development of electronically-specified clinical quality measures, including measures for specialist physicians;]

[(B) the exchange of electronic health information, and integration of such information from other sources;]

[(C) access to standardized clinical data related to health and clinical research;]

[(D) access to standardized clinical data related to public health activities;]

[(E) the facilitation of individuals' access to electronic health information; and]

[(F) the capture of clinical information that supports the treatment of populations with unique needs, such as children.]

[(4) ADOPTION.—The Secretary shall adopt standards, implementation specifications, and certification criteria under section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14), not later than 2 years after the date of enactment of this section.]

[(5) ADDITIONAL STANDARDS.—The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary to establish a core set of common data elements to enhance the ability of certified health information technology to capture, use, and exchange electronic health information, and other standards as appropriate to support meaningful use and value based payment programs.]

[(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated $_____ to carry out this section.]

SEC. 6. LEVERAGING HEALTH INFORMATION TECHNOLOGY TO IMPROVE PATIENT CARE.

(a) REQUIREMENT RELATING TO REGISTRIES.—To be certified in accordance with title XXX of the Public Health Service Act, health information technology (as defined by section 3000(5) of the Public Health Service Act (42 U.S.C. 300jj(5))) shall be capable of transmitting, re-

ceiving, and accepting data from registries, including clinician-led clinical registries, that are also certified under section 3001(c)(5) of such Act (42 U.S.C. 300jj-11(c)(5)) and such registries shall be capable of transmitting, receiving, and accepting data from other certified health information technology.

(b) DEFINITION.—For purposes of this Act (including amendments made to title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), the term ''clinician-led clinical data registry'' means a clinical data repository—

(1) that is established and operated by a clinician-led or controlled, tax-exempt (pursuant to section 501(c) of the Internal Revenue Code of 1986), professional society or other similar clinician-led or -controlled organization, or such organization's controlled affiliate, devoted to the care of a population defined by a particular disease, condition, exposure or therapy;

(2) that is designed to collect detailed, standardized data on an ongoing basis for medical procedures, services, or therapies for particular diseases, conditions, or exposures;

(3) that provides feedback to participants who submit reports to the repository;

(4) that meets standards for data quality including—

(A) systematically collecting clinical and other health care data, using standardized data elements and has procedures in place to verify the completeness and validity of those data; and

(B) being subject to regular data checks or audits to verify completeness and validity; and

(5) that provides ongoing participant training and support.

(c) TREATMENT OF HEALTH INFORMATION TECHNOLOGY DEVELOPERS WITH RESPECT TO PATIENT SAFETY ORGANIZATIONS.—

(1) IN GENERAL.—In applying part C of title IX of the Public Health Service Act (42 U.S.C. 299b-21 et seq.), a health information technology developer shall be treated as a provider (as defined in section 921 of such Act) for purposes of reporting and conducting patient safety activities concerning improving clinical care through the use of health information technology that could result in improved patient safety, health care quality, or health care outcomes.

(2) REPORT.—Not later than 48 months after the date of enactment of this Act, the Secretary of

Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pension of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning best practices and current trends voluntarily provided, and without identifying individual providers, by Patient Safety Organizations to improve the integration of health information technology into clinical practice.

SEC. 7. EMPOWERING PATIENTS AND IMPROVING PATIENT ACCESS TO THEIR ELECTRONIC HEALTH INFORMATION.

(a) USE OF HEALTH INFORMATION EXCHANGED FOR PATIENT ACCESS.—Section 3009 of the Public Health Service Act (42 U.S.C. 300jj-19) is amended by adding at the end the following:

''(c) PROMOTING PATIENT ACCESS TO ELECTRONIC HEALTH INFORMATION THROUGH HEALTH INFORMATION EXCHANGES.—

''(1) IN GENERAL.—The Office of the National Coordinator, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall use existing authorities to encourage health information exchange organizations and networks to partner with health care providers, health

plans, and other appropriate entities to offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may update such information automatically.

''(2) EDUCATION OF PROVIDERS.—The Office of the National Coordinator, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

''(A) educate health care providers on ways in which to leverage the capabilities of Health Information Exchanges (or other relevant platforms) to provide patients with access to their electronic health information;

''(B) clarify misunderstandings by health care providers about using Health Information Exchanges (or other relevant platforms) for patient access to electronic health information; and

''(C) to the extent practicable, educate providers about health information exchanges (or other relevant platforms) that employ some or all of the capabilities described in paragraph (1).

"(3) REQUIREMENTS.—In carrying out paragraph (1), the Office of the National Coordinator, in coordination with the Office for Civil Rights, shall issue guidance to health information exchanges related to best practices to ensure that the electronic health information provided to patients is—

"(A) secure;

"(B) accurate;,

"(C) verifiable; and

"(D) easily exchanged, under correct authorizations.

"(4) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to preempt State laws applicable to patient consent for the access of information through a Health Information Exchange (or other relevant platforms) that provide protections to patients that are greater than the protections otherwise provided for under applicable Federal law.

"(d) EFFORTS TO PROMOTE ACCESS TO HEALTH INFORMATION.—The Office of the National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly, through the development of policies that support dynamic technology solutions, promote patient access to health information in a

manner that would ensure that such information is available in a form convenient for the patient, in a reasonable manner, and without burdening the health care provider involved.

"(e) ACCESSIBILITY OF PATIENT RECORDS.—

"(1) ACCESSIBILITY AND UPDATING OF INFORMATION.—

"(A) IN GENERAL.—The Secretary, in consultation with the Office of the National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient, and their designees, in a manner that facilitates communication with the patient's health care providers and such patient's choices, including with respect to research.

"(B) UPDATING EDUCATION ON ACCESSING AND EXCHANGING PERSONAL HEALTH INFORMATION.—The Director of the Office for Civil Rights, in consultation with the National Coordinator, shall, as appropriate, update the Internet website of the Office and any other education initiatives with information to assist individuals and health care providers in understanding a patient's rights to access and protect

their personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including best practices for requesting personal health information in a computable format, including using patient portals or third-party applications and common cases when a provider is permitted to exchange and provide access to health information.

''(2) CERTIFYING USABILITY FOR PATIENTS.—In carrying out certification programs under section 3001(c)(5), the National Coordinator shall require that such program or programs require the following:

''(A) That certification criteria support patient access to their electronic health information, including in a single longitudinal format that is easy to understand, secure, and may be updated automatically.

''(B) That developers of health information technology support patient access to an electronic health record in a longitudinal format that is easy to understand, secure, and may be updated automatically.

"(C) That certification criteria support patient access to their personal electronic health information for research at the option of the patient.

"(D) That certification criteria support patient and health care provider communication, including—

"(i) the ability for the patient to electronically communicate patient reported information (such as family history and medical history); and

"(ii) the ability for the patient to electronically share patient health information, at the option of the patient.

"(E) That certified health information technology used for health programs where certified health information technology is required, include the function for patient access to their own health information, including—

"(i) ensuring that, as a condition of certification, health care providers have options for making such information accessible for patients;

"(ii) ensuring that patients have options for accessing such information; and

"(iii) ensuring that patients have access to information regarding their legal rights and responsibilities, as well the options available to them for accessing their electronic health information.

"(F) That the HIT Advisory Committee develop and prioritize standards, implementation specifications, and certification criteria required to help support patient access to electronic health information, patient usability, and support for technologies that offer patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.".

(b) ACCESS TO INFORMATION IN AN ELECTRONIC FORMAT.—Section 13405(e) of the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. 17935) is amended—

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

(2) by redesignating paragraph (2) as paragraph (3); and

(3) by inserting after paragraph (1), the following:

''(2) if the individual makes a request to a business associate for access to, or a copy of, protected health information about the individual, or if an individual makes a request to a business associate to grant such access to, or transmit such copy directly to, a person or entity designated by the individual, a business associate may provide the individual with such access or copy, which may be in an electronic form, or grant or transmit such access or copy to such person or entity designated by the individual; and''.

SEC. 8. ENCOURAGING TRUST RELATIONSHIPS FOR CERTIFIED ELECTRONIC HEALTH RECORDS.

(a) TECHNICAL CAPABILITIES FOR TRUSTED EXCHANGE.—

(1) CERTIFICATION.—

(A) IN GENERAL.—To be certified under the program or programs provided for under section 3001(c)(5), certified electronic health records shall be determined by an authorized certification body to be capable of trusted exchange with multiple other certified electronic health records.

(B) MULTIPLE EXCHANGE RELATIONSHIPS.—Certified electronic health records shall

demonstrate design elements that technically allow for the trusted exchange with multiple other certified electronic health records for participation in multiple trusted exchange relationships.

(C) TRUSTED EXCHANGE DEFINED.—In this section, the term ''trusted exchange'' with respect to certified electronic health records means that the certified electronic health record has the technical capability to enable semantic health information exchange between users and multiple certified electronic health record systems.

(2) GUIDANCE.—The Office of the National Coordinator, in consultation with the Office for Civil Rights of the Department of Health and Human Services, shall issue guidance on common legal and governance barriers that prevent trusted exchange as certified in accordance with the requirements established in paragraph (1).

(3) CONFIRMATION OF TRUSTED EXCHANGE AND SECURITY FUNCTIONALITIES.—

(A) SECURITY FUNCTIONALITIES.—To be certified under the program provided for under section 3001(c)(5), certified electronic health

records shall be determined by an authorized certification body to be in compliance with applicable security functionalities that meet the requirements established by Office of the National Coordinator for Health Information Technology and the National Institute of Standards and Technology.

(B) CONFIRMING TRUSTED EXCHANGE.—A refusal to exchange health information with an individual or entity using a certified electronic health record that meets the minimum requirements to be technically capable of trusted exchange as certified in accordance with the requirements established in paragraph (1) or the security functionalities established in subparagraph (A), or a pattern of interfering with trusted exchange based on the common legal and governance barriers published in the guidance described in paragraph (2), may be subject to consideration of the Inspector General under section 3022(b) of the Public Health Service Act (as added by section 4).

(b) MEANINGFUL USE STATISTICS.—Not later than **[**_____**]** after the date of enactment of this Act, the Secretary of Health and Human Services shall submit

to the Office of the National Coordinator for Health Information Technology's HIT Advisory Committee a report concerning health information technology meaningful use attestation statistics and information to provide information on standards development and related practices. Such statistics shall include attestation information delineated by State, and shall be made publicly available on the Internet website of the Secretary on at least a quarterly basis.

SEC. 9. GAO STUDY ON PATIENT MATCHING.

(a) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study to review the policies and activities of the Office of the National Coordinator for Health Information Technology and other relevant stakeholders to ensure appropriate patient matching to protect patient privacy and security with respect to electronic health records and the exchange of electronic health information.

(b) AREAS OF CONCENTRATION.—In conducting the study under subsection (a), the Comptroller General shall—

(1) evaluate current methods used in certified electronic health records for patient matching based on performance related to factors such as—

(A) the privacy of patient information;

(B) the security of patient information;

(C) improving matching rates;

(D) reducing matching errors; and

(E) reducing duplicate records; and

(2) determine whether the Office of the National Coordinator for Health Information Technology could improve patient matching by taking steps including—

(A) defining additional data elements to assist in patient data matching;

(B) agreeing on a required minimum set of elements that need to be collected and exchanged;

(C) requiring electronic health records to have the ability to make certain fields required and use specific standards; or

(D) other options recommended by the relevant stakeholders consulted pursuant to subsection (a).

(c) REPORT.—Not later than 3 years after the date of enactment of this Act, the Comptroller General shall submit to the appropriate committees of Congress a report concerning the findings of the study conducted under subsection (a).