fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(g) Term of grants or cooperative agreements

(1) In general

The Secretary shall award grants or cooperative agreements under this section for terms that do not exceed 5 years.

(2) Renewal

The Secretary may renew a grant or cooperative agreement under this section at the end of the term of the grant or cooperative agreement determined under paragraph (1).

(h) Maintenance of effort

Funds made available under this section shall be used to supplement and not supplant other Federal, State, and local funds available for respite care services.

(July 1, 1944, ch. 373, title XXIX, § 2902, as added Pub. L. 109–442, § 2, Dec. 21, 2006, 120 Stat. 3292.)

§ 300ii–2. National lifespan respite resource center

(a) Establishment

The Secretary may award a grant or cooperative agreement to a public or private nonprofit entity to establish a National Resource Center on Lifespan Respite Care (referred to in this section as the ''center'').

(b) Purposes of the center

The center shall—

(1) maintain a national database on lifespan respite care;

(2) provide training and technical assistance to State, community, and nonprofit respite care programs; and

(3) provide information, referral, and educational programs to the public on lifespan respite care.

(July 1, 1944, ch. 373, title XXIX, § 2903, as added Pub. L. 109–442, § 2, Dec. 21, 2006, 120 Stat. 3295.)

§ 300ii–3. Report

Not later than January 1, 2009, the Secretary shall report to the Congress on the activities undertaken under this subchapter. Such report shall evaluate—

(1) the number of States that have lifespan respite care programs;

(2) the demographics of the caregivers receiving respite care services through grants or cooperative agreements under this subchapter; and

(3) the effectiveness of entities receiving grants or cooperative agreements under this subchapter.

(July 1, 1944, ch. 373, title XXIX, § 2904, as added Pub. L. 109–442, § 2, Dec. 21, 2006, 120 Stat. 3295.)

§ 300ii–4. Authorization of appropriations

There are authorized to be appropriated to carry out this subchapter—

(1) $30,000,000 for fiscal year 2007;
(2) $40,000,000 for fiscal year 2008;
(3) $53,330,000 for fiscal year 2009;
(4) $71,110,000 for fiscal year 2010; and
(5) $94,810,000 for fiscal year 2011.

(July 1, 1944, ch. 373, title XXIX, § 2905, as added Pub. L. 109–442, § 2, Dec. 21, 2006, 120 Stat. 3296.)

SUBCHAPTER XXVIII—HEALTH INFORMATION TECHNOLOGY AND QUALITY

§ 300jj. Definitions

In this subchapter:

(1) Certified EHR technology

The term ''certified EHR technology'' means a qualified electronic health record that is certified pursuant to section 300jj–11(c)(5) of this title as meeting standards adopted under section 300jj–14 of this title that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(2) Enterprise integration

The term ''enterprise integration'' means the electronic linkage of health care providers, health plans, the government, and other interested parties, to enable the electronic exchange and use of health information among all the components in the health care infrastructure in accordance with applicable law, and such term includes related application protocols and other related standards.

(3) Health care provider

The term ''health care provider'' includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care clinic, community mental health center (as defined in section 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395*l*(i) of this title,[1] emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395*l*(i) of this title,[1] a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

(4) Health information

The term ''health information'' has the meaning given such term in section 1320d(4) of this title.

[1] So in original. The words ''ambulatory surgical center described in section 1395*l*(i) of this title'' appear in two places.

(5) Health information technology

The term ''health information technology'' means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information[2]

(6) Health plan

The term ''health plan'' has the meaning given such term in section 1320d(5) of this title.

(7) HIT Advisory Committee

The term ''HIT Advisory Committee'' means such Committee established under section 300jj–12(a) of this title.

(8) Individually identifiable health information

The term ''individually identifiable health information'' has the meaning given such term in section 1320d(6) of this title.

(9) Interoperability

The term ''interoperability'', with respect to health information technology, means such health information technology that—

(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

(C) does not constitute information blocking as defined in section 300jj–52(a) of this title.

(10) Laboratory

The term ''laboratory'' has the meaning given such term in section 263a(a) of this title.

(11) National Coordinator

The term ''National Coordinator'' means the head of the Office of the National Coordinator for Health Information Technology established under section 300jj–11(a) of this title.

(12) Pharmacist

The term ''pharmacist'' has the meaning given such term in section 384(2) of title 21.

(13) Qualified electronic health record

The term ''qualified electronic health record'' means an electronic record of health-related information on an individual that—

(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

(B) has the capacity—

(i) to provide clinical decision support;

(ii) to support physician order entry;

(iii) to capture and query information relevant to health care quality; and

(iv) to exchange electronic health information with, and integrate such information from other sources.

(15)[3] State

The term ''State'' means each of the several States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

(July 1, 1944, ch. 373, title XXX, § 3000, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 228; amended Pub. L. 114–255, div. A, title IV, § 4003(a), (e)(2)(B), Dec. 13, 2016, 130 Stat. 1165, 1174.)

REFERENCES IN TEXT

The Indian Self-Determination and Education Assistance Act, referred to in par. (3), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§ 5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

AMENDMENTS

2016—Par. (7). Pub. L. 114–255, § 4003(e)(2)(B), added par. (7) and struck out former par. (7). Prior to amendment, text read as follows: ''The term 'HIT Policy Committee' means such Committee established under section 300jj–12(a) of this title.''

Par. (8). Pub. L. 114–255, § 4003(e)(2)(B)(i), redesignated par. (9) as (8) and struck out former par. (8). Prior to amendment, text of par. (8) read as follows: ''The term 'HIT Standards Committee' means such Committee established under section 300jj–13(a) of this title.''

Par. (9). Pub. L. 114–255, § 4003(e)(2)(B)(i), redesignated par. (10) as (9). Former par. (9) redesignated (8).

Par. (10). Pub. L. 114–255, § 4003(e)(2)(B)(i), redesignated par. (11) as (10). Former par. (10) redesignated (9).

Pub. L. 114–255, § 4003(a)(2), added par. (10). Former par. (10) redesignated (11).

Pars. (11) to (14). Pub. L. 114–255, § 4003(e)(2)(B)(i), redesignated pars. (12) to (14) as (11) to (13), respectively. Former par. (11) redesignated (10).

Pub. L. 114–255, § 4003(a)(1), redesignated pars. (10) to (13) as (11) to (14), respectively. Former par. (14) redesignated (15).

Par. (15). Pub. L. 114–255, § 4003(a)(1), redesignated par. (14) as (15).

ASSISTING DOCTORS AND HOSPITALS IN IMPROVING QUALITY OF CARE FOR PATIENTS

Pub. L. 111–5, div. A, title XIII, § 13103, as added by Pub. L. 114–255, div. A, title IV, § 4001(a)(1), Dec. 13, 2016, 130 Stat. 1157, provided that:

''(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 goal established under subsection (a)(1), the Secretary, in consultation with the entities described in such subsection, shall, not later than 1 year after the date of enactment of the 21st Century Cures Act [Dec. 13, 2016], develop a strategy and recommendations to meet the goal in accordance with this subsection.

[2] So in original. Probably should be followed by a period.

[3] So in original. There is no par. (14).

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

''(A)(i) incentives for meaningful use of certified EHR technology for eligible professionals and hospitals under sections 1848(a)(7) and 1886(b)(3)(B)(ix), respectively, of the Social Security Act (42 U.S.C. 1395w–4(a)(7), 1395ww(b)(3)(B)(ix));

''(ii) the program for making payments under section 1903(a)(3)(F) of the Social Security Act (42 U.S.C. 1396b(a)(3)(F)) to encourage the adoption and use of certified EHR technology by Medicaid providers;

''(iii) the Merit-based Incentive Payment System under section 1848(q) of the Social Security Act (42 U.S.C. 1395w–4(q));

''(iv) alternative payment models (as defined in section 1833(z)(3)(C) of the Social Security Act (42 U.S.C. 1395*l*(z)(3)(C));

''(v) the Hospital Value-Based Purchasing Program under section 1886(*o*) of the Social Security Act (42 U.S.C. 1395ww(*o*)); and

''(vi) other value-based payment programs, as the Secretary determines appropriate;

''(B) health information technology certification;

''(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, as the Secretary determines appropriate.

''(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, as the Secretary determines appropriate, to reduce the reporting burden required of health care providers.

''(4) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the development of the goal, strategies, or recommendations described in this section.

''(c) APPLICATION OF CERTAIN REGULATORY REQUIREMENTS.—A physician (as defined in section 1861(r)(1) of the Social Security Act [42 U.S.C. 1395x(r)(1)]), to the extent consistent with applicable State law, may delegate electronic medical record documentation requirements specified in regulations promulgated by the Centers for Medicare & Medicaid Services to a person performing a scribe function who is not such physician if such physician has signed and verified the documentation.''

PART A—PROMOTION OF HEALTH INFORMATION TECHNOLOGY

§ 300jj–11. 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 (referred to in this section as the ''Office''). The Office shall be headed by a National Coordinator who shall be appointed by the Secretary and shall report directly to the Secretary.

(b) Purpose

The National Coordinator shall perform the duties under subsection (c) in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information and that—

(1) ensures that each patient's health information is secure and protected, in accordance with applicable law;

(2) improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;

(3) reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;

(4) provides appropriate information to help guide medical decisions at the time and place of care;

(5) ensures the inclusion of meaningful public input in such development of such infrastructure;

(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

(7) improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;

(8) facilitates health and clinical research and health care quality;

(9) promotes early detection, prevention, and management of chronic diseases;

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

(11) improves efforts to reduce health disparities.

(c) Duties of the National Coordinator

(1) Standards

The National Coordinator shall—

(A) review and determine whether to endorse each standard, implementation specification, and certification criterion for the electronic exchange and use of health information that is recommended by the HIT Advisory Committee under section 300jj–12 of this title for purposes of adoption under section 300jj–14 of this title;

(B) make such determinations under subparagraph (A), and report to the Secretary such determinations, not later than 45 days after the date the recommendation is received by the Coordinator; and

(C) review Federal health information technology investments to ensure that Federal health information technology pro-

grams are meeting the objectives of the strategic plan published under paragraph (3).

(2) HIT policy coordination

(A) In general

The National Coordinator shall coordinate health information technology policy and programs of the Department with those of other relevant executive branch agencies with a goal of avoiding duplication of efforts and of helping to ensure that each agency undertakes health information technology activities primarily within the areas of its greatest expertise and technical capability and in a manner towards a coordinated national goal.

(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.

(3) Strategic plan

(A) In general

The National Coordinator shall, in consultation with other appropriate Federal agencies (including the National Institute of Standards and Technology), update the Federal Health IT Strategic Plan (developed as of June 3, 2008) to include specific objectives, milestones, and metrics with respect to the following:

(i) The electronic exchange and use of health information and the enterprise integration of such information.

(ii) The utilization of an electronic health record for each person in the United States by 2014.

(iii) The incorporation of privacy and security protections for the electronic exchange of an individual's individually identifiable health information.

(iv) Ensuring security methods to ensure appropriate authorization and electronic authentication of health information and specifying technologies or methodologies for rendering health information unusable, unreadable, or indecipherable.

(v) Specifying a framework for coordination and flow of recommendations and policies under this part among the Secretary, the National Coordinator, the HIT Advisory Committee, and other health information exchanges and other relevant entities.

(vi) Methods to foster the public understanding of health information technology.

(vii) Strategies to enhance the use of health information technology in improving the quality of health care, reducing medical errors, reducing health disparities, improving public health, increasing prevention and coordination with community resources, and improving the continuity of care among health care settings.

(viii) Specific plans for ensuring that populations with unique needs, such as children, are appropriately addressed in the technology design, as appropriate, which may include technology that automates enrollment and retention for eligible individuals.

(B) Collaboration

The strategic plan shall be updated through collaboration of public and private entities.

(C) Measurable outcome goals

The strategic plan update shall include measurable outcome goals.

(D) Publication

The National Coordinator shall republish the strategic plan, including all updates.

(4) Website

The National Coordinator shall maintain and frequently update an Internet website on which there is posted information on the work, schedules, reports, recommendations, and other information to ensure transparency in promotion of a nationwide health information technology infrastructure.

(5) Certification

(A) In general

The National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this part. Such program shall include, as appropriate, testing of the technology in accordance with section 17911(b) of this title.

(B) Certification criteria described

In this subchapter, the term ''certification criteria'' means, with respect to standards and implementation specifications for health information technology, criteria to establish that the technology meets such standards and implementation specifications.

(C) Health information technology for medical specialties and sites of service

(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 and sites of service for which no such technology is available or where more technological advancement or integration is needed.

(ii) Specific medical specialties

The Secretary shall accept public comment on specific medical specialties and sites of service, in addition to those described in clause (i), for the purpose of selecting additional specialties and sites of service as necessary.

(iii) Health information technology for pediatrics

Not later than 18 months after December 13, 2016, the Secretary, 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 2 years after December 13, 2016, the Secretary shall adopt certification criteria under section 300jj–14 of this title to support the voluntary certification of health information technology for use by pediatric health providers to support the health care of children.

(D) Conditions of certification

Not later than 1 year after December 13, 2016, the Secretary, through notice and comment rulemaking, shall require, as a condition of certification and maintenance of certification for programs maintained or recognized under this paragraph, consistent with other conditions and requirements under this subchapter, that the health information technology developer or entity—

(i) does not take any action that constitutes information blocking as defined in section 300jj–52(a) of this title;

(ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

(iii) does not prohibit or restrict communication regarding—

(I) the usability of the health information technology;

(II) the interoperability of the health information technology;

(III) the security of the health information technology;

(IV) relevant information regarding users' experiences when using the health information technology;

(V) the business practices of developers of health information technology related to exchanging electronic health information; and

(VI) the manner in which a user of the health information technology has used such technology;

(iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws;

(v) has successfully tested the real world use of the technology for interoperability (as defined in section 300jj of this title) in the type of setting in which such technology would be marketed;

(vi) provides to the Secretary an attestation that the developer or entity—

(I) has not engaged in any of the conduct described in clause (i);

(II) has provided assurances satisfactory to the Secretary in accordance with clause (ii);

(III) does not prohibit or restrict communication as described in clause (iii);

(IV) has published information in accordance with clause (iv);

(V) ensures that its technology allows for health information to be exchanged, accessed, and used, in the manner described in clause (iv); and

(VI) has undertaken real world testing as described in clause (v); and

(vii) submits reporting criteria in accordance with section 300jj–19a(b) of this title.

(E) Compliance with conditions of certification

The Secretary may encourage compliance with the conditions of certification described in subparagraph (D) and take action to discourage noncompliance, as appropriate.

(6) Reports and publications

(A) Report on additional funding or authority needed

Not later than 12 months after February 17, 2009, the National Coordinator shall submit to the appropriate committees of jurisdiction of the House of Representatives and the Senate a report on any additional funding or authority the Coordinator or the HIT Policy Committee or HIT Standards Committee requires to evaluate and develop standards, implementation specifications, and certification criteria, or to achieve full participation of stakeholders in the adoption of a nationwide health information technology infrastructure that allows for the electronic use and exchange of health information.

(B) Implementation report

The National Coordinator shall prepare a report that identifies lessons learned from major public and private health care systems in their implementation of health information technology, including information on whether the technologies and practices developed by such systems may be applicable to and usable in whole or in part by other health care providers.

(C) Assessment of impact of HIT on communities with health disparities and uninsured, underinsured, and medically underserved areas

The National Coordinator shall assess and publish the impact of health information technology in communities with health disparities and in areas with a high proportion of individuals who are uninsured, underinsured, and medically underserved individuals (including urban and rural areas) and identify practices to increase the adoption of such technology by health care providers in such communities, and the use of health information technology to reduce and better manage chronic diseases.

(D) Evaluation of benefits and costs of the electronic use and exchange of health information

The National Coordinator shall evaluate and publish evidence on the benefits and costs of the electronic use and exchange of health information and assess to whom these benefits and costs accrue.

(E) Resource requirements

The National Coordinator shall estimate and publish resources required annually to reach the goal of utilization of an electronic health record for each person in the United States by 2014, including—

(i) the required level of Federal funding;

(ii) expectations for regional, State, and private investment;

(iii) the expected contributions by volunteers to activities for the utilization of such records; and

(iv) the resources needed to establish a health information technology workforce sufficient to support this effort (including education programs in medical informatics and health information management).

(7) Assistance

The National Coordinator may provide financial assistance to consumer advocacy groups and not-for-profit entities that work in the public interest for purposes of defraying the cost to such groups and entities to participate under, whether in whole or in part, the National Technology Transfer Act of 1995 (15 U.S.C. 272 note).[1]

(8) Governance for nationwide health information network

The National Coordinator shall establish a governance mechanism for the nationwide health information network.

(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 or support 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 6 months after December 13, 2016, the National Coordinator shall convene appropriate public and private stakeholders to develop or support 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 noncompliance with the terms of the common agreement.

(ii) Technical assistance

The National Coordinator, in collaboration with the 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 Coordinator, in consultation with the National Institute of Standards and Technology, shall provide for the pilot testing of the trusted exchange framework and common agreement established or supported under this subsection (as authorized under section 17911 of this title). The National Coordinator, in consultation with the National Institute of Standards and Technology, may delegate pilot testing activities under this clause to independent entities with appropriate expertise.

(C) Publication of a trusted exchange framework and common agreement

Not later than 1 year after convening stakeholders under subparagraph (A), the National Coordinator shall publish on its public Internet website, and in the Federal register,[2] the trusted exchange framework and common agreement developed or supported 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

(i) In general

Not later than 2 years after convening stakeholders under subparagraph (A), and annually thereafter, the National Coordinator shall publish on its public Internet website a list of the health information networks that have adopted the common agreement and are capable of trusted exchange pursuant to the common agreement developed or supported under paragraph[3] (B).

(ii) Process

The Secretary shall, through notice and comment rulemaking, establish a process

[1] See References in Text note below.

[2] So in original. Probably should be ''Register,''.

[3] So in original. Probably should be ''subparagraph''.

for health information networks that voluntarily elect to adopt the trusted exchange framework and common agreement to attest to such adoption of the framework and agreement.

(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, such network may adopt, where available, the trusted exchange framework and common agreement published under subparagraph (C).

(F) Rule of construction

(i) General adoption

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement.

(ii) Adoption when exchange of information is within network

Nothing in this paragraph shall be construed to require a health information network to adopt the trusted exchange framework or common agreement for the exchange of electronic health information between participants of the same network.

(iii) Existing frameworks and agreements

The trusted exchange framework and common agreement published under subparagraph (C) shall take into account existing trusted exchange frameworks and agreements used by health information networks to avoid the disruption of existing exchanges between participants of health information networks.

(iv) Application by Federal agencies

Notwithstanding clauses (i), (ii), and (iii), Federal agencies may require the adoption of the trusted exchange framework and common agreement published under subparagraph (C) for health information exchanges contracting with or entering into agreements pursuant to subparagraph (E).

(v) Consideration of ongoing work

In carrying out this paragraph, the Secretary shall ensure the consideration of activities carried out by public and private organizations related to exchange between health information exchanges to avoid duplication of efforts.

(d) Detail of Federal employees

(1) In general

Upon the request of the National Coordinator, the head of any Federal agency is authorized to detail, with or without reimbursement from the Office, any of the personnel of such agency to the Office to assist it in carrying out its duties under this section.

(2) Effect of detail

Any detail of personnel under paragraph (1) shall—

(A) not interrupt or otherwise affect the civil service status or privileges of the Federal employee; and

(B) be in addition to any other staff of the Department employed by the National Coordinator.

(3) Acceptance of detailees

Notwithstanding any other provision of law, the Office may accept detailed personnel from other Federal agencies without regard to whether the agency described under paragraph (1) is reimbursed.

(e) Chief Privacy Officer of the Office of the National Coordinator

Not later than 12 months after February 17, 2009, the Secretary shall appoint a Chief Privacy Officer of the Office of the National Coordinator, whose duty it shall be to advise the National Coordinator on privacy, security, and data stewardship of electronic health information and to coordinate with other Federal agencies (and similar privacy officers in such agencies), with State and regional efforts, and with foreign countries with regard to the privacy, security, and data stewardship of electronic individually identifiable health information.

(July 1, 1944, ch. 373, title XXX, § 3001, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 230; amended Pub. L. 114–255, div. A, title IV, §§ 4001(b), 4002(a), 4003(b), (e)(2)(A)(i), (ii), (C), Dec. 13, 2016, 130 Stat. 1158, 1159, 1165, 1174.)

REFERENCES IN TEXT

The National Technology Transfer Act of 1995 (15 U.S.C. 272 note), referred to in subsec. (c)(7), probably means section 12(d) of Pub. L. 104–113, known as the National Technology Transfer and Advancement Act of 1995, which is set out as a note under section 272 of Title 15, Commerce and Trade.

AMENDMENTS

2016—Subsec. (c)(1)(A). Pub. L. 114–255, § 4003(e)(2)(C)(i), substituted ''under section 300jj–12 of this title'' for ''under section 300jj–13 of this title''.

Pub. L. 114–255, § 4003(e)(2)(A)(i), substituted ''HIT Advisory Committee'' for ''HIT Standards Committee''.

Subsec. (c)(2)(B). Pub. L. 114–255, § 4003(e)(2)(C)(ii), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: ''The National Coordinator shall be a leading member in the establishment and operations of the HIT Policy Committee and the HIT Standards Committee and shall serve as a liaison among those two Committees and the Federal Government.''

Subsec. (c)(3)(A)(v). Pub. L. 114–255, § 4003(e)(2)(A)(ii), which directed amendment of this section by substituting ''HIT Advisory Committee'' for ''HIT Policy Committee and the HIT Standards Committee'' wherever appearing, was executed to cl. (v) by making the substitution for ''HIT Policy Committee, the HIT Standards Committee'', to reflect the probable intent of Congress.

Subsec. (c)(5)(C). Pub. L. 114–255, § 4001(b), added subpar. (C).

Subsec. (c)(5)(D), (E). Pub. L. 114–255, § 4002(a), added subpars. (D) and (E).

Subsec. (c)(6)(A). Pub. L. 114–255, § 4003(e)(2)(A)(i), which directed amendment of this section by substituting ''HIT Advisory Committee'' for both ''HIT Policy Committee'' and ''HIT Standards Committee'' wherever appearing, but not within the term ''HIT Policy Committee or the HIT Standards Committee'', was not executed to subpar. (A) as provided in the exception, not-

withstanding text that reads ''HIT Policy Committee or HIT Standards Committee'', to reflect the probable intent of Congress.

Subsec. (c)(9). Pub. L. 114–255, § 4003(b), added par. (9).

PROVIDER DIGITAL CONTACT INFORMATION INDEX

Pub. L. 114–255, div. A, title IV, § 4003(c), Dec. 13, 2016, 130 Stat. 1167, provided that:

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall, directly or through a partnership with a private entity, establish a provider digital contact information index to provide digital contact information for health professionals and health facilities.

''(2) USE OF EXISTING INDEX.—In establishing the initial index under paragraph (1), the Secretary may utilize an existing 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.

''(4) RULE OF CONSTRUCTION.—

''(A) IN GENERAL.—The purpose of this subsection is to encourage the exchange of electronic health information by providing the most useful, reliable, and comprehensive index of providers possible. In furthering such purpose, the Secretary shall include all health professionals and health facilities applicable to provide a useful, reliable, and comprehensive index for use in the exchange of health information.

''(B) LIMITATION.—In no case shall exclusion from the index of providers be used as a measure to achieve objectives other [than] the objectives described in subparagraph (A).''

§ 300jj–12. 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, consistent with the implementation of the strategic plan described in section 300jj–11(c)(3) of this title, policies, and, for purposes of adoption under section 300jj–14 of this title, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Such Committee shall serve to unify the roles of, and replace, the HIT Policy Committee and the HIT Standards Committee, as in existence before December 13, 2016.

(b) Duties

(1) Recommendations on policy framework to advance an interoperable health information technology infrastructure

(A) In general

The HIT Advisory Committee shall recommend to the National Coordinator a policy framework for adoption by the Secretary consistent with the strategic plan under section 300jj–11(c)(3) of this title for advancing the target areas described in this subsection. Such policy framework shall seek to prioritize achieving advancements in the target areas specified in subparagraph (B) of paragraph (2) and may, to the extent consistent with this section, incorporate policy recommendations made by the HIT Policy Committee, as in existence before December 13, 2016.

(B) Updates

The HIT Advisory Committee shall propose updates to such recommendations to the policy framework and make new recommendations, as appropriate.

(2) General duties and target areas

(A) In general

The HIT Advisory Committee shall recommend to the National Coordinator for purposes of adoption under section 300jj–14 of this title, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. 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.

(B) Priority target areas

For purposes of this section, the HIT Advisory Committee shall make recommendations under subparagraph (A) with respect to at least each of the following target areas:

(i) Achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information, including through technology that provides accurate patient information for the correct patient, including exchanging such information, and avoids the duplication of patient records.

(ii) 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 regulation 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.

(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) Subject to subparagraph (D), any other target area that the HIT Advisory Committee identifies as an appropriate

target area to be considered under this subparagraph.

(C) Additional target areas

For purposes of this section, the HIT Advisory Committee may make recommendations under subparagraph (A), in addition to areas described in subparagraph (B), with respect to any of the following areas:

(i) 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, reducing medical errors, improving population health, reducing chronic disease, and advancing research and education.

(ii) The use of technologies that address the needs of children and other vulnerable populations.

(iii) 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.

(iv) The use of self-service, telemedicine, home health care, and remote monitoring technologies.

(v) The use of technologies that meet the needs of diverse populations.

(vi) The use of technologies that support—

(I) data for use in quality and public reporting programs;

(II) public health; or

(III) drug safety.

(vii) The use of 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.

(viii) The use of a certified health information technology for each individual in the United States.

(D) Authority for temporary additional priority target areas

For purposes of subparagraph (B)(iv), the HIT Advisory Committee may identify an area to be considered for purposes of recommendations under this subsection as a target area described in subparagraph (B) if—

(i) the area is so identified for purposes of responding to new circumstances that have arisen in the health information technology community that affect the interoperability, privacy, or security of health information, or affect patient safety; and

(ii) at least 30 days prior to treating such area as if it were a target area described in subparagraph (B), the National Coordinator provides adequate notice to Congress of the intent to treat such area as so described.

(E) Focus of committee work

It is the sense of Congress that the HIT Advisory Committee shall focus its work on the priority areas described in subparagraph (B) before proceeding to other work under subparagraph (C).

(3) Rules relating to recommendations for standards, implementation specifications, 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), which may include standards, implementation specifications, and certification criteria that have been developed, harmonized, or recognized by the HIT Advisory Committee or predecessor committee. The HIT Advisory Committee shall update such recommendations and make new recommendations as appropriate, including in response to a notification sent under section 300jj–14(a)(2)(B) of this title. 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 specification.

(C) Pilot testing of standards and implementation specifications

In the development, harmonization, or recognition of standards and implementation specifications, the HIT Advisory Committee for purposes of recommendations under paragraph (2)(B), shall, as appropriate, provide for the testing of such standards and specifications by the National Institute for Standards and Technology under section 17911(a) of this title.

(D) Consistency

The standards, implementation specifications, and certification criteria recommended under paragraph (2)(B) shall be consistent with the standards for information transactions and data elements adopted pursuant to section 1320d–2 of this title.

(E) Special rule related to interoperability

Any recommendation made by the HIT Advisory Committee after December 13, 2016, with respect to interoperability of health information technology shall be consistent with interoperability as described in section 300jj of this title.

(4) Forum

The HIT Advisory Committee shall serve as a forum for the participation of a broad range of stakeholders with specific expertise in policies, including technical expertise, relating to the matters described in paragraphs (1), (2), and (3) to provide input on the development, harmonization, and recognition of standards, implementation specifications, and certifi-

cation criteria necessary for the development and adoption of health information technology infrastructure nationally and locally that allows for the electronic access, exchange, and use of health information.

(5) 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.

(6) 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 (5) 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) Measured progress in advancing priority areas

(1) In general

For purposes of this section, the National Coordinator, in collaboration with the Secretary, shall establish, and update as appropriate, objectives and benchmarks for advancing and measuring the advancement of the priority target areas described in subsection (b)(2)(B).

(2) Annual progress reports on advancing interoperability

(A) In general

The HIT Advisory Committee, in consultation with the National Coordinator, shall annually submit to the Secretary and Congress a report on the progress made during the preceding fiscal year in—

(i) achieving a health information technology infrastructure, nationally and locally, that allows for the electronic access, exchange, and use of health information; and

(ii) meeting the objectives and benchmarks described in paragraph (1).

(B) Content

Each such report shall include, for a fiscal year—

(i) a description of the work conducted by the HIT Advisory Committee during the preceding fiscal year with respect to the areas described in subsection (b)(2)(B);

(ii) an assessment of the status of the infrastructure described in subparagraph (A), including the extent to which electronic health information is appropriately and readily available to enhance the access, exchange, and the use of electronic health information between users and across technology offered by different developers;

(iii) the extent to which advancements have been achieved with respect to areas described in subsection (b)(2)(B);

(iv) an analysis identifying existing gaps in policies and resources for—

(I) achieving the objectives and benchmarks established under paragraph (1); and

(II) furthering interoperability throughout the health information technology infrastructure;

(v) recommendations for addressing the gaps identified in clause (iii); and

(vi) a description of additional initiatives as the HIT Advisory Committee and National Coordinator determine appropriate.

(3) Significant advancement determination

The Secretary shall periodically, based on the reports submitted under this subsection, review the target areas described in subsection (b)(2)(B), and, based on the objectives and benchmarks established under paragraph (1), the Secretary shall determine if significant advancement has been achieved with respect to such an area. Such determination shall be taken into consideration by the HIT Advisory Committee when determining to what extent the Committee makes recommendations for an area other than an area described in subsection (b)(2)(B).

(d) 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, of which—

(i) no fewer than 2 members are advocates for patients or consumers of health information technology;

(ii) 3 members are appointed by the Secretary, 1 of whom shall be appointed to represent the Department of Health and Human Services and 1 of whom shall be a public health official;

(iii) 2 members are appointed by the majority leader of the Senate;

(iv) 2 members are appointed by the minority leader of the Senate;

(v) 2 members are appointed by the Speaker of the House of Representatives;

(vi) 2 members are appointed by the minority leader of the House of Representatives; and

(vii) such other members are appointed by the Comptroller General of the United States; and

(B) at least reflect providers, ancillary health care workers, consumers, purchasers, health plans, health information technology developers, researchers, patients, relevant Federal agencies, and individuals with technical expertise on health care quality, system functions, privacy, security, and on the electronic exchange and use of health information, including the use standards for such activity.

(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 of 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 members 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 party of their mission.

(e) 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.

(f) 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.

(July 1, 1944, ch. 373, title XXX, §3002, as added Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(2)(B)(ii), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

The Federal Advisory Committee Act, referred to in subsec. (e), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 300jj–12, act July 1, 1944, ch. 373, title XXX, §3002, as added Pub. L. 111–5, div. A, title XIII, §13101, Feb. 17, 2009, 123 Stat. 234, related to the establishment, duties, and membership of the HIT Policy Committee, prior to repeal by Pub. L. 114–255, div. A, title IV, §4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

TRANSITION TO THE HIT ADVISORY COMMITTEE

Pub. L. 114–255, div. A, title IV, §4003(e)(3), Dec. 13, 2016, 130 Stat. 1175, provided that: ''The Secretary of Health and Human Services shall provide for an orderly and timely transition to the HIT Advisory Committee established under amendments made by this section [enacting this section and section 300jj–13 of this title, amending sections 300jj, 300jj–11, 300jj–14, 300jj–17, 300jj–18, and 300jj–51 of this title, and repealing former sections 300jj–12 and 300jj–13 of this title].''

§ 300jj–13. Setting priorities for standards adoption

(a) Identifying priorities

(1) In general

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—

(A) identify priority uses of health information technology, focusing on priorities—

(i) arising from the implementation of 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) related to the quality of patient care;

(iii) related to public health;

(iv) related to clinical research;

(v) related to the privacy and security of electronic health information;

(vi) related to innovation in the field of health information technology;

(vii) related to patient safety;

(viii) related to the usability of health information technology;

(ix) related to individuals' access to electronic health information; and

(x) other priorities determined appropriate by the Secretary;

(B) identify existing standards and implementation specifications that support the use and exchange of electronic health information needed to meet the priorities identified in subparagraph (A); and

(C) publish a report summarizing the findings of the analysis conducted under sub-

paragraphs (A) and (B) and make appropriate recommendations.

(2) Prioritization

In identifying such standards and implementation specifications under paragraph (1)(B), the HIT Advisory Committee shall prioritize standards and implementation specifications developed by consensus-based standards development organizations.

(3) Guidelines for review of existing standards and specifications

In consultation with the consensus-based entity described in section 1395aaa of this title and other appropriate Federal agencies, the analysis of existing standards under paragraph (1)(B) shall include an evaluation of the need 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.

(b) Review of adopted standards

(1) In general

Beginning 5 years after December 13, 2016, 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.

(2) 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.

(July 1, 1944, ch. 373, title XXX, § 3003, as added Pub. L. 114–255, div. A, title IV, § 4003(f), Dec. 13, 2016, 130 Stat. 1175.)

PRIOR PROVISIONS

A prior section 300jj–13, act July 1, 1944, ch. 373, title XXX, § 3003, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 238, related to the establishment, duties, and membership of the HIT Standards Committee, prior to repeal by Pub. L. 114–255, div. A, title IV, § 4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

§ 300jj–14. Process for adoption of endorsed recommendations; adoption of initial set of standards, implementation specifications, and certification criteria

(a) Process for adoption of endorsed recommendations

(1) Review of endorsed standards, implementation specifications, and certification criteria

Not later than 90 days after the date of receipt of standards, implementation specifications, or certification criteria endorsed under section 300jj–11(c) of this title, the Secretary, in consultation with representatives of other relevant Federal agencies, shall jointly review such standards, implementation specifications, or certification criteria and shall determine whether or not to propose adoption of such standards, implementation specifications, or certification criteria.

(2) Determination to adopt standards, implementation specifications, and certification criteria

If the Secretary determines—

(A) to propose adoption of any grouping of such standards, implementation specifications, or certification criteria, the Secretary shall, by regulation under section 553 of title 5, determine whether or not to adopt such grouping of standards, implementation specifications, or certification criteria; or

(B) not to propose adoption of any grouping of standards, implementation specifications, or certification criteria, the Secretary shall notify the National Coordinator and the HIT Advisory Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation.

(3) Publication

The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under paragraph (1).

(b) Adoption of standards, implementation specifications, and certification criteria

(1) In general

Not later than December 31, 2009, the Secretary shall, through the rulemaking process consistent with subsection (a)(2)(A), adopt an initial set of standards, implementation specifications, and certification criteria for the areas required for consideration under section 300jj–12(b)(2)(B)[1] of this title. The rulemaking for the initial set of standards, implementation specifications, and certification criteria may be issued on an interim, final basis.

(2) Application of current standards, implementation specifications, and certification criteria

The standards, implementation specifications, and certification criteria adopted before February 17, 2009, through the process existing through the Office of the National Coordinator for Health Information Technology may be applied towards meeting the requirement of paragraph (1).

[1] See References in Text note below.

(3) Subsequent standards activity

The Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published under section 300jj–12(b)(4) of this title.

(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 and voluntary consensus-based standards bodies.

(July 1, 1944, ch. 373, title XXX, § 3004, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 240; amended Pub. L. 114–255, div. A, title IV, § 4003(d), (e)(2)(A)(i), (D), Dec. 13, 2016, 130 Stat. 1168, 1174, 1175.)

REFERENCES IN TEXT

Section 300jj–12(b)(2)(B) of this title, referred to in subsec. (b)(1), related to areas of health information technology required to be considered by the HIT Policy Committee and was repealed by Pub. L. 114–255, div. A, title IV, § 4003(e)(1), Dec. 13, 2016, 130 Stat. 1168.

AMENDMENTS

2016—Subsec. (a)(2)(B). Pub. L. 114–255, § 4003(e)(2)(A)(i), substituted ''HIT Advisory Committee'' for ''HIT Standards Committee''.

Subsec. (b)(3). Pub. L. 114–255, § 4003(e)(2)(D), substituted ''300jj–12(b)(4)'' for ''300jj–13(b)(2)''.

Subsec. (c). Pub. L. 114–255, § 4003(d), added subsec. (c).

LEVERAGING ELECTRONIC HEALTH RECORDS TO IMPROVE PATIENT CARE

Pub. L. 114–255, div. A, title IV, § 4005, Dec. 13, 2016, 130 Stat. 1180, provided that:

''(a) REQUIREMENT RELATING TO REGISTRIES.—

''(1) IN GENERAL.—To be certified in accordance with title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.), electronic health records shall be capable of transmitting to, and where applicable, receiving and accepting data from, registries in accordance with standards recognized by the Office of the National Coordinator for Health Information Technology, including clinician-led clinical data registries, that are also certified to be technically capable of receiving and accepting from, and where applicable, transmitting data to certified electronic health record technology in accordance with such standards.

''(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require the certification of registries beyond the technical capability to exchange data in accordance with applicable recognized standards.

''(b) DEFINITION.—For purposes of this Act [see Tables for classification], 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 [26 U.S.C. 501(c)]), 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 having 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 [42 U.S.C. 299b–21]) 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 4 years after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions 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, without identifying individual providers or disclosing or using protected health information or individually identifiable information, by patient safety organizations to improve the integration of health information technology into clinical practice.''

§ 300jj–15. Application and use of adopted standards and implementation specifications by Federal agencies

For requirements relating to the application and use by Federal agencies of the standards and implementation specifications adopted under section 300jj–14 of this title, see section 17901 of this title.

(July 1, 1944, ch. 373, title XXX, § 3005, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 241.)

§ 300jj–16. Voluntary application and use of adopted standards and implementation specifications by private entities

(a) In general

Except as provided under section 13112 of the HITECH Act [42 U.S.C. 17902], nothing in such Act or in the amendments made by such Act shall be construed—

(1) to require a private entity to adopt or comply with a standard or implementation specification adopted under section 300jj–14 of this title; or

(2) to provide a Federal agency authority, other than the authority such agency may have under other provisions of law, to require a private entity to comply with such a standard or implementation specification.

(b) Rule of construction

Nothing in this part shall be construed to require that a private entity that enters into a contract with the Federal Government apply or use the standards and implementation specifications adopted under section 300jj–14 of this title with respect to activities not related to the contract.

(July 1, 1944, ch. 373, title XXX, § 3006, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 241.)

REFERENCES IN TEXT

The HITECH Act, referred to in subsec. (a), is title XIII of div. A and title IV of div. B of Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 226, 467, also known as the Health Information Technology for Economic and Clinical Health Act. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 201 of this title and Tables.

§ 300jj–17. Federal health information technology

(a) In general

The National Coordinator shall support the development and routine updating of qualified electronic health record technology (as defined in section 300jj of this title) consistent with subsections (b) and (c) and make available such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace.

(b) Certification

In making such electronic health record technology publicly available, the National Coordinator shall ensure that the qualified electronic health record technology described in subsection (a) is certified under the program developed under section 300jj–11(c)(3) of this title to be in compliance with applicable standards adopted under section 300jj–12(a)(2)[1] of this title.

(c) Authorization to charge a nominal fee

The National Coordinator may impose a nominal fee for the adoption by a health care provider of the health information technology system developed or approved under subsection[2] (a) and (b). Such fee shall take into account the financial circumstances of smaller providers, low income providers, and providers located in rural or other medically underserved areas.

(d) Rule of construction

Nothing in this section shall be construed to require that a private or government entity adopt or use the technology provided under this section.

(July 1, 1944, ch. 373, title XXX, § 3007, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 241; amended Pub. L. 114–255, div. A, title IV, § 4003(e)(2)(E), Dec. 13, 2016, 130 Stat. 1175.)

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255 substituted ''300jj–12(a)(2)'' for ''300jj–13(a)''.

§ 300jj–18. Transitions

(a) ONCHIT

To the extent consistent with section 300jj–11 of this title, all functions, personnel, assets, liabilities, and administrative actions applicable to the National Coordinator for Health Information Technology appointed under Executive Order No. 13335 or the Office of such National Coordinator on the date before February 17, 2009, shall be transferred to the National Coordinator appointed under section 300jj–11(a) of this title and the Office of such National Coordinator as of February 17, 2009.

(b) National eHealth Collaborative

Nothing in sections[1] 300jj–12 of this title or this subsection shall be construed as prohibiting the AHIC Successor, Inc. doing business as the National eHealth Collaborative from modifying its charter, duties, membership, and any other structure or function required to be consistent with section[2] 300jj–12 and 300jj–13[3] of this title so as to allow the Secretary to recognize such AHIC Successor, Inc. as the HIT Advisory Committee.

(c) Consistency of recommendations

In carrying out section 300jj–12(b)(2) of this title, until recommendations are made by the HIT Advisory Committee,[4] recommendations of the HIT Advisory Committee[4] shall be consistent with the most recent recommendations made by such AHIC Successor, Inc.

(July 1, 1944, ch. 373, title XXX, § 3008, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 241; amended Pub. L. 114–255, div. A, title IV, § 4003(e)(2)(A)(i), (iii), (F), Dec. 13, 2016, 130 Stat. 1174, 1175.)

REFERENCES IN TEXT

Executive Order No. 13335, referred to in subsec. (a), is set out as a note under section 300u of this title.

Section 300jj–13 of this title, referred to in subsec. (b), was repealed, and a new section 300jj–13 was enacted by Pub. L. 114–255, div. A, title IV, § 4003(e)(1), (f), Dec. 13, 2016, 130 Stat. 1168, 1175.

AMENDMENTS

2016—Subsec. (b). Pub. L. 114–255, § 4003(e)(2)(F)(i), struck out ''or 300jj–13'' after ''Nothing in sections 300jj–12''.

Pub. L. 114–255, § 4003(e)(2)(A)(iii), substituted ''HIT Advisory Committee'' for ''HIT Policy Committee or the HIT Standards Committee''.

Subsec. (c). Pub. L. 114–255, § 4003(e)(2)(F)(ii), substituted ''300jj–12(b)(2)'' for ''300jj–13(b)(1)(A)''.

Pub. L. 114–255, § 4003(e)(2)(A)(i), substituted ''HIT Advisory Committee'' for ''HIT Policy Committee'' after ''recommendations are made by the'' and ''HIT Advisory Committee'' for ''HIT Standards Committee'' after ''recommendations of the''. See section 300jj–12(a) of this title.

§ 300jj–19. Miscellaneous provisions

(a) Relation to HIPAA privacy and security law

(1) In general

With respect to the relation of this subchapter to HIPAA privacy and security law:

(A) This subchapter may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.

(B) The purposes of this subchapter include ensuring that the health information

[1] So in original. No par. (2) of section 300jj–12(a) has been enacted.

[2] So in original. Probably should be ''subsections''.

[1] So in original. Probably should be ''section''.

[2] So in original. Probably should be ''sections''.

[3] See References in Text note below.

[4] So in original. See 2016 Amendment note below.

technology standards and implementation specifications adopted under section 300jj–14 of this title take into account the requirements of HIPAA privacy and security law.

(2) Definition

For purposes of this section, the term ''HIPAA privacy and security law'' means—

(A) the provisions of part C of title XI of the Social Security Act [42 U.S.C. 1320d et seq.], section 264 of the Health Insurance Portability and Accountability Act of 1996, and subtitle D of title IV[1] of the Health Information Technology for Economic and Clinical Health Act; and

(B) regulations under such provisions.

(b) Flexibility

In administering the provisions of this subchapter, the Secretary shall have flexibility in applying the definition of health care provider under section 300jj(3) of this title, including the authority to omit certain entities listed in such definition when applying such definition under this subchapter, where appropriate.

(c) Promoting patient access to electronic health information through health information exchanges

(1) In general

The Secretary shall use existing authorities to encourage partnerships between health information exchange organizations and networks and health care providers, health plans, and other appropriate entities with the goal of offering patients access to their electronic health information in a single, longitudinal format that is easy to understand, secure, and may be updated automatically.

(2) Education of providers

The Secretary, in coordination with the Office for Civil Rights of the Department of Health and Human Services, shall—

(A) educate health care providers on ways of leveraging 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 Secretary, 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) private and secure;

(B) accurate;

(C) verifiable; and

(D) where a patient's authorization to exchange information is required by law, easily exchanged pursuant to such authorization.

(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 platform) 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 National Coordinator and the Office for Civil Rights of the Department of Health and Human Services shall jointly 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, 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 National Coordinator, shall promote policies that ensure that a patient's electronic health information is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent.

(B) Updating education on accessing and exchanging personal health information

To promote awareness that an individual has a right of access to inspect, obtain a copy of, and transmit to a third party a copy of such individual's protected health information pursuant to the Health Information Portability and Accountability Act, Privacy Rule (subpart E of part 164 of title 45, Code of Federal Regulations), the Director of the Office for Civil Rights, in consultation with the National Coordinator, shall assist individuals and health care providers in understanding a patient's rights to access and protect personal health information under the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191), including providing 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]

(2) Certifying usability for patients

In carrying out certification programs under section 300jj–11(c)(5) of this title, the National Coordinator may require that—

(A) the certification criteria support—

(i) patient access to their electronic health information, including in a single

[1] See References in Text note below.

[2] So in original.

longitudinal format that is easy to understand, secure, and may be updated automatically;

(ii) the patient's ability to electronically communicate patient-reported information (such as family history and medical history); and

(iii) patient access to their personal electronic health information for research at the option of the patient; and

(B) 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.

(July 1, 1944, ch. 373, title XXX, § 3009, as added Pub. L. 111–5, div. A, title XIII, § 13101, Feb. 17, 2009, 123 Stat. 242; amended Pub. L. 114–255, div. A, title IV, § 4006(a), Dec. 13, 2016, 130 Stat. 1181.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Part C of title XI of the Act is classified generally to part C (§ 1320d et seq.) of subchapter XI of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

The Health Insurance Portability and Accountability Act of 1996, referred to in subsecs. (a)(2)(A) and (e)(1)(B), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. Section 264 of the Act is set out as a note under section 1320d–2 of this title. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

The Health Information Technology for Economic and Clinical Health Act, referred to in subsec. (a)(2)(A), is title XIII of div. A and title IV of div. B of Pub. L. 111–5, Feb. 17, 2009, 123 Stat. 226, 467, also known as the HITECH Act. Subtitle D of title IV of the Act probably means subtitle D of title XIII of div. A of the Act, which is classified generally to subchapter III (§ 17921 et seq.) of chapter 156 of this title. Title IV of div. B of the Act does not contain a subtitle D. For complete classification of this Act to the Code, see Short Title of 2009 Amendment note set out under section 201 of this title and Tables.

AMENDMENTS

2016—Subsecs. (c) to (e). Pub. L. 114–255 added subsecs. (c) to (e).

§ 300jj–19a. Electronic health record reporting program

(a) Reporting criteria

(1) Convening of stakeholders

Not later than 1 year after December 13, 2016, the Secretary 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) patients, consumers, and their advocates;

(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;

(J) public and private entities engaged in the evaluation of health information technology performance;

(K) quality organizations, including the consensus based entity described in section 1395aaa of this title;

(L) experts in human factors engineering and the measurement of user-centered design; and

(M) other entities or individuals, as the Secretary determines appropriate.

(3) Considerations for reporting criteria

The reporting criteria developed under this subsection—

(A) shall include measures that reflect categories including—

(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 electronic health record technology;

(B) may include categories 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 and through health information exchanges;

(iv) accessing and exchanging information and data from medical devices;

(v) 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;

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

(vii) accessing and exchanging patient generated information;

(viii) providing the patient or an authorized designee with a complete copy of their health information from an electronic record in a computable format;

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

(x) other categories regarding performance, accessibility,[1] as the Secretary determines appropriate; and

(C) shall be designed to ensure that small and startup health information technology developers are not unduly disadvantaged by the reporting criteria.

(4) Modifications

After the reporting criteria have been developed under paragraph (3), the Secretary may convene stakeholders and conduct a public comment period for the purpose of modifying the reporting criteria developed under such paragraph.

(b) Participation

As a condition of maintaining certification under section 300jj–11(c)(5)(D) of this title, a developer of certified electronic health records shall submit to an appropriate recipient of a grant, contract, or agreement under subsection (c)(1) responses to the criteria developed under subsection (a), with respect to all certified technology offered by such developer.

(c) Reporting program

(1) In general

Not later than 1 year after December 13, 2016, the Secretary shall award grants, contracts, or agreements to independent entities on a competitive basis to support the convening of stakeholders as described in subsection (a)(2), collect the information required to be reported in accordance with the criteria established as described subsection (a)(3), and develop and implement a process in accordance with paragraph (5) and report such information to the Secretary.

(2) Applications

An independent entity that seeks a grant, contract, or agreement under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require, including a description of—

(A) the proposed method for reviewing and summarizing information gathered based on reporting criteria established under subsection (a);

(B) if applicable, the intended focus on a specific subset of certified electronic health record technology users, such as health care providers, including primary care, specialty care, and care provided in rural settings; hospitals and hospital systems; and patients, consumers, and patients and consumer advocates;

(C) the plan for widely distributing reports described in paragraph (6);

(D) the period for which the grant, contract, or agreement is requested, which may be up to 2 years; and

(E) the budget for reporting program participation, and whether the eligible independent entity intends to continue participation after the period of the grant, contract, or agreement.

(3) Considerations for independent entities

In awarding grants, contracts, and agreements under paragraph (1), the Secretary shall give priority to independent entities with appropriate expertise in health information technology usability, interoperability, and security (especially entities with such expertise in electronic health records) with respect to—

(A) health care providers, including primary care, specialty care, and care provided in rural settings;

(B) hospitals and hospital systems; and

(C) patients, consumers, and patient and consumer advocates.

(4) Limitations

(A) Assessment and redetermination

Not later than 4 years after December 13, 2016, and every 2 years thereafter, the Secretary, in consultation with stakeholders, shall—

(i) assess performance of the recipients of the grants, contracts, and agreements under paragraph (1) based on quality and usability of reports described in paragraph (6); and

(ii) re-determine grants, contracts, and agreements as necessary.

(B) Prohibitions on participation

The Secretary may not award a grant, contract, or cooperative agreement under paragraph (1) to—

(i) a proprietor of certified health information technology or a business affiliate of such a proprietor;

(ii) a developer of certified health information technology; or

(iii) a State or local government agency.

(5) Feedback

Based on reporting criteria established under subsection (a), the recipients of grants, contracts, and agreements under paragraph (1) shall develop and implement a process to collect and verify confidential feedback on such criteria from—

(A) health care providers, patients, and other users of certified electronic health record technology; and

(B) developers of certified electronic health record technology.

(6) Reports

(A) Development of reports

Each recipient of a grant, contract, or agreement under paragraph (1) shall report on the information reported to such recipient pursuant to subsection (a) and the user feedback collected under paragraph (5) by preparing summary reports and detailed reports of such information.

(B) Distribution of reports

Each recipient of a grant, contract, or agreement under paragraph (1) shall submit the reports prepared under subparagraph (A) to the Secretary for public distribution in accordance with subsection (d).

(d) Publication

The Secretary shall distribute widely, as appropriate, and publish, on the Internet website of the Office of the National Coordinator—

[1] So in original. Probably should be ''performance or accessibility,''.

(1) the reporting criteria developed under subsection (a); and

(2) the summary and detailed reports under subsection (c)(6).

(e) Review

Each recipient of a grant, contract, or agreement under paragraph (1) shall develop and implement a process through which participating electronic health record technology developers may review and recommend changes to the reports created under subsection (c)(6) for products developed by such developer prior to the publication of such report under subsection (d).

(f) Additional resources

The Secretary may provide additional resources on the Internet website of the Office of the National Coordinator to better inform consumers of health information technology. Such reports may be carried out through partnerships with private organizations with appropriate expertise.

(July 1, 1944, ch. 373, title XXX, § 3009A, as added Pub. L. 114–255, div. A, title IV, § 4002(c), Dec. 13, 2016, 130 Stat. 1161.)

PART B—INCENTIVES FOR THE USE OF HEALTH INFORMATION TECHNOLOGY

§ 300jj–31. Immediate funding to strengthen the health information technology infrastructure

(a) In general

The Secretary shall, using amounts appropriated under section 300jj–38 of this title, invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States consistent with the goals outlined in the strategic plan developed by the National Coordinator (and as available) under section 300jj–11 of this title. The Secretary shall invest funds through the different agencies with expertise in such goals, such as the Office of the National Coordinator for Health Information Technology, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers of Medicare & Medicaid Services, the Centers for Disease Control and Prevention, and the Indian Health Service to support the following:

(1) Health information technology architecture that will support the nationwide electronic exchange and use of health information in a secure, private, and accurate manner, including connecting health information exchanges, and which may include updating and implementing the infrastructure necessary within different agencies of the Department of Health and Human Services to support the electronic use and exchange of health information.

(2) Development and adoption of appropriate certified electronic health records for categories of health care providers not eligible for support under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.] for the adoption of such records.

(3) Training on and dissemination of information on best practices to integrate health information technology, including electronic health records, into a provider's delivery of care, consistent with best practices learned from the Health Information Technology Research Center developed under section 300jj–32(b) of this title, including community health centers receiving assistance under section 254b of this title, covered entities under section 256b of this title, and providers participating in one or more of the programs under titles XVIII, XIX, and XXI of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq., 1397aa et seq.] (relating to Medicare, Medicaid, and the State Children's Health Insurance Program).

(4) Infrastructure and tools for the promotion of telemedicine, including coordination among Federal agencies in the promotion of telemedicine.

(5) Promotion of the interoperability of clinical data repositories or registries.

(6) Promotion of technologies and best practices that enhance the protection of health information by all holders of individually identifiable health information.

(7) Improvement and expansion of the use of health information technology by public health departments.

(b) Coordination

The Secretary shall ensure funds under this section are used in a coordinated manner with other health information promotion activities.

(c) Additional use of funds

In addition to using funds as provided in subsection (a), the Secretary may use amounts appropriated under section 300jj–38 of this title to carry out health information technology activities that are provided for under laws in effect on February 17, 2009.

(d) Standards for acquisition of health information technology

To the greatest extent practicable, the Secretary shall ensure that where funds are expended under this section for the acquisition of health information technology, such funds shall be used to acquire health information technology that meets applicable standards adopted under section 300jj–14 of this title. Where it is not practicable to expend funds on health information technology that meets such applicable standards, the Secretary shall ensure that such health information technology meets applicable standards otherwise adopted by the Secretary.

(July 1, 1944, ch. 373, title XXX, § 3011, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 246.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(2), (3), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII, XIX, and XXI of the Act are classified generally to subchapters XVIII (§ 1395 et seq.), XIX (§ 1396 et seq.), and XXI (§ 1397aa et seq.) of chapter 7 of this title, respectively. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§ 300jj–32. Health information technology implementation assistance

(a) Health information technology extension program

To assist health care providers to adopt, implement, and effectively use certified EHR tech-

nology that allows for the electronic exchange and use of health information, the Secretary, acting through the Office of the National Coordinator, shall establish a health information technology extension program to provide health information technology assistance services to be carried out through the Department of Health and Human Services. The National Coordinator shall consult with other Federal agencies with demonstrated experience and expertise in information technology services, such as the National Institute of Standards and Technology, in developing and implementing this program.

(b) Health Information Technology Research Center

(1) In general

The Secretary shall create a Health Information Technology Research Center (in this section referred to as the ''Center'') to provide technical assistance and develop or recognize best practices to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 300jj–14 of this title.

(2) Input

The Center shall incorporate input from—

(A) other Federal agencies with demonstrated experience and expertise in information technology services such as the National Institute of Standards and Technology;

(B) users of health information technology, such as providers and their support and clerical staff and others involved in the care and care coordination of patients, from the health care and health information technology industry; and

(C) others as appropriate.

(3) Purposes

The purposes of the Center are to—

(A) provide a forum for the exchange of knowledge and experience;

(B) accelerate the transfer of lessons learned from existing public and private sector initiatives, including those currently receiving Federal financial support;

(C) assemble, analyze, and widely disseminate evidence and experience related to the adoption, implementation, and effective use of health information technology that allows for the electronic exchange and use of information including through the regional centers described in subsection (c);

(D) provide technical assistance for the establishment and evaluation of regional and local health information networks to facilitate the electronic exchange of information across health care settings and improve the quality of health care;

(E) provide technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information; and

(F) learn about effective strategies to adopt and utilize health information technology in medically underserved communities.

(c) Health information technology regional extension centers

(1) In general

The Secretary shall provide assistance for the creation and support of regional centers (in this subsection referred to as ''regional centers'') to provide technical assistance and disseminate best practices and other information learned from the Center to support and accelerate efforts to adopt, implement, and effectively utilize health information technology that allows for the electronic exchange and use of information in compliance with standards, implementation specifications, and certification criteria adopted under section 300jj–14 of this title. Activities conducted under this subsection shall be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 300jj–11 of this title.

(2) Affiliation

Regional centers shall be affiliated with any United States-based nonprofit institution or organization, or group thereof, that applies and is awarded financial assistance under this section. Individual awards shall be decided on the basis of merit.

(3) Objective

The objective of the regional centers is to enhance and promote the adoption of health information technology through—

(A) assistance with the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to healthcare providers nationwide;

(B) broad participation of individuals from industry, universities, and State governments;

(C) active dissemination of best practices and research on the implementation, effective use, upgrading, and ongoing maintenance of health information technology, including electronic health records, to health care providers in order to improve the quality of healthcare and protect the privacy and security of health information;

(D) participation, to the extent practicable, in health information exchanges;

(E) utilization, when appropriate, of the expertise and capability that exists in Federal agencies other than the Department; and

(F) integration of health information technology, including electronic health records, into the initial and ongoing training of health professionals and others in the healthcare industry that would be instrumental to improving the quality of healthcare through the smooth and accurate electronic use and exchange of health information.

(4) Regional assistance

Each regional center shall aim to provide assistance and education to all providers in a region, but shall prioritize any direct assistance first to the following:

(A) Public or not-for-profit hospitals or critical access hospitals.

(B) Federally qualified health centers (as defined in section 1395x(aa)(4) of this title).

(C) Entities that are located in rural and other areas that serve uninsured, underinsured, and medically underserved individuals (regardless of whether such area is urban or rural).

(D) Individual or small group practices (or a consortium thereof) that are primarily focused on primary care.

(5) Financial support

The Secretary may provide financial support to any regional center created under this subsection for a period not to exceed four years. The Secretary may not provide more than 50 percent of the capital and annual operating and maintenance funds required to create and maintain such a center, except in an instance of national economic conditions which would render this cost-share requirement detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(6) Notice of program description and availability of funds

The Secretary shall publish in the Federal Register, not later than 90 days after February 17, 2009, a draft description of the program for establishing regional centers under this subsection. Such description shall include the following:

(A) A detailed explanation of the program and the programs [1] goals.

(B) Procedures to be followed by the applicants.

(C) Criteria for determining qualified applicants.

(D) Maximum support levels expected to be available to centers under the program.

(7) Application review

The Secretary shall subject each application under this subsection to merit review. In making a decision whether to approve such application and provide financial support, the Secretary shall consider at a minimum the merits of the application, including those portions of the application regarding—

(A) the ability of the applicant to provide assistance under this subsection and utilization of health information technology appropriate to the needs of particular categories of health care providers;

(B) the types of service to be provided to health care providers;

(C) geographical diversity and extent of service area; and

(D) the percentage of funding and amount of in-kind commitment from other sources.

(8) Biennial evaluation

Each regional center which receives financial assistance under this subsection shall be evaluated biennially by an evaluation panel appointed by the Secretary. Each evaluation panel shall be composed of private experts, none of whom shall be connected with the center involved, and of Federal officials. Each evaluation panel shall measure the involved center's performance against the objective specified in paragraph (3). The Secretary shall not continue to provide funding to a regional center unless its evaluation is overall positive.

(9) Continuing support

After the second year of assistance under this subsection, a regional center may receive additional support under this subsection if it has received positive evaluations and a finding by the Secretary that continuation of Federal funding to the center was in the best interest of provision of health information technology extension services.

(July 1, 1944, ch. 373, title XXX, § 3012, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 247.)

§ 300jj–33. State grants to promote health information technology

(a) In general

The Secretary, acting through the National Coordinator, shall establish a program in accordance with this section to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards.

(b) Planning grants

The Secretary may award a grant to a State or qualified State-designated entity (as described in subsection (f)) that submits an application to the Secretary at such time, in such manner, and containing such information as the Secretary may specify, for the purpose of planning activities described in subsection (d).

(c) Implementation grants

The Secretary may award a grant to a State or qualified State designated [1] entity that—

(1) has submitted, and the Secretary has approved, a plan described in subsection (e) (regardless of whether such plan was prepared using amounts awarded under subsection (b); [2] and

(2) submits an application at such time, in such manner, and containing such information as the Secretary may specify.

(d) Use of funds

Amounts received under a grant under subsection (c) shall be used to conduct activities to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards through activities that include—

(1) enhancing broad and varied participation in the authorized and secure nationwide electronic use and exchange of health information;

(2) identifying State or local resources available towards a nationwide effort to promote health information technology;

(3) complementing other Federal grants, programs, and efforts towards the promotion of health information technology;

[1] So in original.

[1] So in original. Probably should be ''State-designated''.

[2] So in original. Another closing parenthesis probably should precede the semicolon.

(4) providing technical assistance for the development and dissemination of solutions to barriers to the exchange of electronic health information;

(5) promoting effective strategies to adopt and utilize health information technology in medically underserved communities;

(6) assisting patients in utilizing health information technology;

(7) encouraging clinicians to work with Health Information Technology Regional Extension Centers as described in section 300jj–32 of this title, to the extent they are available and valuable;

(8) supporting public health agencies' authorized use of and access to electronic health information;

(9) promoting the use of electronic health records for quality improvement including through quality measures reporting; and

(10) such other activities as the Secretary may specify.

(e) Plan

(1) In general

A plan described in this subsection is a plan that describes the activities to be carried out by a State or by the qualified State-designated entity within such State to facilitate and expand the electronic movement and use of health information among organizations according to nationally recognized standards and implementation specifications.

(2) Required elements

A plan described in paragraph (1) shall—

(A) be pursued in the public interest;

(B) be consistent with the strategic plan developed by the National Coordinator, (and, as available) under section 300jj–11 of this title;

(C) include a description of the ways the State or qualified State-designated entity will carry out the activities described in subsection (b); and

(D) contain such elements as the Secretary may require.

(f) Qualified State-designated entity

For purposes of this section, to be a qualified State-designated entity, with respect to a State, an entity shall—

(1) be designated by the State as eligible to receive awards under this section;

(2) be a not-for-profit entity with broad stakeholder representation on its governing board;

(3) demonstrate that one of its principal goals is to use information technology to improve health care quality and efficiency through the authorized and secure electronic exchange and use of health information;

(4) adopt nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory participation by stakeholders; and

(5) conform to such other requirements as the Secretary may establish.

(g) Required consultation

In carrying out activities described in subsections (b) and (c), a State or qualified State-designated entity shall consult with and consider the recommendations of—

(1) health care providers (including providers that provide services to low income and underserved populations);

(2) health plans;

(3) patient or consumer organizations that represent the population to be served;

(4) health information technology vendors;

(5) health care purchasers and employers;

(6) public health agencies;

(7) health professions schools, universities and colleges;

(8) clinical researchers;

(9) other users of health information technology such as the support and clerical staff of providers and others involved in the care and care coordination of patients; and

(10) such other entities, as may be determined appropriate by the Secretary.

(h) Continuous improvement

The Secretary shall annually evaluate the activities conducted under this section and shall, in awarding grants under this section, implement the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the Secretary, will lead towards the greatest improvement in quality of care, decrease in costs, and the most effective authorized and secure electronic exchange of health information.

(i) Required match

(1) In general

For a fiscal year (beginning with fiscal year 2011), the Secretary may not make a grant under this section to a State unless the State agrees to make available non-Federal contributions (which may include in-kind contributions) toward the costs of a grant awarded under subsection (c) in an amount equal to—

(A) for fiscal year 2011, not less than $1 for each $10 of Federal funds provided under the grant;

(B) for fiscal year 2012, not less than $1 for each $7 of Federal funds provided under the grant; and

(C) for fiscal year 2013 and each subsequent fiscal year, not less than $1 for each $3 of Federal funds provided under the grant.

(2) Authority to require State match for fiscal years before fiscal year 2011

For any fiscal year during the grant program under this section before fiscal year 2011, the Secretary may determine the extent to which there shall be required a non-Federal contribution from a State receiving a grant under this section.

(July 1, 1944, ch. 373, title XXX, § 3013, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 250.)

§ 300jj–34. Competitive grants to States and Indian tribes for the development of loan programs to facilitate the widespread adoption of certified EHR technology

(a) In general

The National Coordinator may award competitive grants to eligible entities for the establish-

ment of programs for loans to health care providers to conduct the activities described in subsection (e).

(b) Eligible entity defined

For purposes of this subsection, the term ''eligible entity'' means a State or Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]) that—

(1) submits to the National Coordinator an application at such time, in such manner, and containing such information as the National Coordinator may require;

(2) submits to the National Coordinator a strategic plan in accordance with subsection (d) and provides to the National Coordinator assurances that the entity will update such plan annually in accordance with such subsection;

(3) provides assurances to the National Coordinator that the entity will establish a Loan Fund in accordance with subsection (c);

(4) provides assurances to the National Coordinator that the entity will not provide a loan from the Loan Fund to a health care provider unless the provider agrees to—

(A) submit reports on quality measures adopted by the Federal Government (by not later than 90 days after the date on which such measures are adopted), to—

(i) the Administrator of the Centers for Medicare & Medicaid Services (or his or her designee), in the case of an entity participating in the Medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or the Medicaid program under title XIX of such Act [42 U.S.C. 1396 et seq.]; or

(ii) the Secretary in the case of other entities;

(B) demonstrate to the satisfaction of the Secretary (through criteria established by the Secretary) that any certified EHR technology purchased, improved, or otherwise financially supported under a loan under this section is used to exchange health information in a manner that, in accordance with law and standards (as adopted under section 300jj–14 of this title) applicable to the exchange of information, improves the quality of health care, such as promoting care coordination; and[1]

(C) comply with such other requirements as the entity or the Secretary may require;

(D) include a plan on how health care providers involved intend to maintain and support the certified EHR technology over time;

(E) include a plan on how the health care providers involved intend to maintain and support the certified EHR technology that would be purchased with such loan, including the type of resources expected to be involved and any such other information as the State or Indian Tribe, respectively, may require; and

(5) agrees to provide matching funds in accordance with subsection (h).

[1] So in original. The word ''and'' probably should appear at end of subpar. (D).

(c) Establishment of fund

For purposes of subsection (b)(3), an eligible entity shall establish a certified EHR technology loan fund (referred to in this subsection as a ''Loan Fund'') and comply with the other requirements contained in this section. A grant to an eligible entity under this section shall be deposited in the Loan Fund established by the eligible entity. No funds authorized by other provisions of this subchapter to be used for other purposes specified in this subchapter shall be deposited in any Loan Fund.

(d) Strategic plan

(1) In general

For purposes of subsection (b)(2), a strategic plan of an eligible entity under this subsection shall identify the intended uses of amounts available to the Loan Fund of such entity.

(2) Contents

A strategic plan under paragraph (1), with respect to a Loan Fund of an eligible entity, shall include for a year the following:

(A) A list of the projects to be assisted through the Loan Fund during such year.

(B) A description of the criteria and methods established for the distribution of funds from the Loan Fund during the year.

(C) A description of the financial status of the Loan Fund as of the date of submission of the plan.

(D) The short-term and long-term goals of the Loan Fund.

(e) Use of funds

Amounts deposited in a Loan Fund, including loan repayments and interest earned on such amounts, shall be used only for awarding loans or loan guarantees, making reimbursements described in subsection (g)(4)(A), or as a source of reserve and security for leveraged loans, the proceeds of which are deposited in the Loan Fund established under subsection (c). Loans under this section may be used by a health care provider to—

(1) facilitate the purchase of certified EHR technology;

(2) enhance the utilization of certified EHR technology (which may include costs associated with upgrading health information technology so that it meets criteria necessary to be a certified EHR technology);

(3) train personnel in the use of such technology; or

(4) improve the secure electronic exchange of health information.

(f) Types of assistance

Except as otherwise limited by applicable State law, amounts deposited into a Loan Fund under this section may only be used for the following:

(1) To award loans that comply with the following:

(A) The interest rate for each loan shall not exceed the market interest rate.

(B) The principal and interest payments on each loan shall commence not later than 1 year after the date the loan was awarded, and each loan shall be fully amortized not later than 10 years after the date of the loan.

(C) The Loan Fund shall be credited with all payments of principal and interest on each loan awarded from the Loan Fund.

(2) To guarantee, or purchase insurance for, a local obligation (all of the proceeds of which finance a project eligible for assistance under this subsection) if the guarantee or purchase would improve credit market access or reduce the interest rate applicable to the obligation involved.

(3) As a source of revenue or security for the payment of principal and interest on revenue or general obligation bonds issued by the eligible entity if the proceeds of the sale of the bonds will be deposited into the Loan Fund.

(4) To earn interest on the amounts deposited into the Loan Fund.

(5) To make reimbursements described in subsection (g)(4)(A).

(g) Administration of loan funds

(1) Combined financial administration

An eligible entity may (as a convenience and to avoid unnecessary administrative costs) combine, in accordance with applicable State law, the financial administration of a Loan Fund established under this subsection with the financial administration of any other revolving fund established by the entity if otherwise not prohibited by the law under which the Loan Fund was established.

(2) Cost of administering fund

Each eligible entity may annually use not to exceed 4 percent of the funds provided to the entity under a grant under this section to pay the reasonable costs of the administration of the programs under this section, including the recovery of reasonable costs expended to establish a Loan Fund which are incurred after February 17, 2009.

(3) Guidance and regulations

The National Coordinator shall publish guidance and promulgate regulations as may be necessary to carry out the provisions of this section, including—

(A) provisions to ensure that each eligible entity commits and expends funds allotted to the entity under this section as efficiently as possible in accordance with this subchapter and applicable State laws; and

(B) guidance to prevent waste, fraud, and abuse.

(4) Private sector contributions

(A) In general

A Loan Fund established under this section may accept contributions from private sector entities, except that such entities may not specify the recipient or recipients of any loan issued under this subsection. An eligible entity may agree to reimburse a private sector entity for any contribution made under this subparagraph, except that the amount of such reimbursement may not be greater than the principal amount of the contribution made.

(B) Availability of information

An eligible entity shall make publicly available the identity of, and amount contributed by, any private sector entity under subparagraph (A) and may issue letters of commendation or make other awards (that have no financial value) to any such entity.

(h) Matching requirements

(1) In general

The National Coordinator may not make a grant under subsection (a) to an eligible entity unless the entity agrees to make available (directly or through donations from public or private entities) non-Federal contributions in cash to the costs of carrying out the activities for which the grant is awarded in an amount equal to not less than $1 for each $5 of Federal funds provided under the grant.

(2) Determination of amount of non-Federal contribution

In determining the amount of non-Federal contributions that an eligible entity has provided pursuant to subparagraph (A),[2] the National Coordinator may not include any amounts provided to the entity by the Federal Government.

(i) Effective date

The Secretary may not make an award under this section prior to January 1, 2010.

(July 1, 1944, ch. 373, title XXX, § 3014, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 253.)

REFERENCES IN TEXT

The Indian Self-Determination and Education Assistance Act, referred to in subsec. (b), is Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2203, which is classified principally to chapter 46 (§ 5301 et seq.) of Title 25, Indians. For complete classification of this Act to the Code, see Short Title note set out under section 5301 of Title 25 and Tables.

The Social Security Act, referred to in subsec. (b)(4)(A)(i), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§ 300jj–35. Demonstration program to integrate information technology into clinical education

(a) In general

The Secretary may award grants under this section to carry out demonstration projects to develop academic curricula integrating certified EHR technology in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

(b) Eligibility

To be eligible to receive a grant under subsection (a), an entity shall—

(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

(2) submit to the Secretary a strategic plan for integrating certified EHR technology in

[2] So in original. Probably means ''paragraph (1),''.

the clinical education of health professionals to reduce medical errors, increase access to prevention, reduce chronic diseases, and enhance health care quality;

(3) be—

(A) a school of medicine, osteopathic medicine, dentistry, or pharmacy, a graduate program in behavioral or mental health, or any other graduate health professions school;

(B) a graduate school of nursing or physician assistant studies;

(C) a consortium of two or more schools described in subparagraph (A) or (B); or

(D) an institution with a graduate medical education program in medicine, osteopathic medicine, dentistry, pharmacy, nursing, or physician assistance studies;

(4) provide for the collection of data regarding the effectiveness of the demonstration project to be funded under the grant in improving the safety of patients, the efficiency of health care delivery, and in increasing the likelihood that graduates of the grantee will adopt and incorporate certified EHR technology, in the delivery of health care services; and

(5) provide matching funds in accordance with subsection (d).

(c) Use of funds

(1) In general

With respect to a grant under subsection (a), an eligible entity shall—

(A) use grant funds in collaboration with 2 or more disciplines; and

(B) use grant funds to integrate certified EHR technology into community-based clinical education.

(2) Limitation

An eligible entity shall not use amounts received under a grant under subsection (a) to purchase hardware, software, or services.

(d) Financial support

The Secretary may not provide more than 50 percent of the costs of any activity for which assistance is provided under subsection (a), except in an instance of national economic conditions which would render the cost-share requirement under this subsection detrimental to the program and upon notification to Congress as to the justification to waive the cost-share requirement.

(e) Evaluation

The Secretary shall take such action as may be necessary to evaluate the projects funded under this section and publish, make available, and disseminate the results of such evaluations on as wide a basis as is practicable.

(f) Reports

Not later than 1 year after February 17, 2009, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate, and the Committee on Energy and Commerce of the House of Representatives a report that—

(1) describes the specific projects established under this section; and

(2) contains recommendations for Congress based on the evaluation conducted under subsection (e).

(July 1, 1944, ch. 373, title XXX, § 3015, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 256.)

§ 300jj–36. Information technology professionals in health care

(a) In general

The Secretary, in consultation with the Director of the National Science Foundation, shall provide assistance to institutions of higher education (or consortia thereof) to establish or expand medical health informatics education programs, including certification, undergraduate, and masters degree programs, for both health care and information technology students to ensure the rapid and effective utilization and development of health information technologies (in the United States health care infrastructure).

(b) Activities

Activities for which assistance may be provided under subsection (a) may include the following:

(1) Developing and revising curricula in medical health informatics and related disciplines.

(2) Recruiting and retaining students to the program involved.

(3) Acquiring equipment necessary for student instruction in these programs, including the installation of testbed networks for student use.

(4) Establishing or enhancing bridge programs in the health informatics fields between community colleges and universities.

(c) Priority

In providing assistance under subsection (a), the Secretary shall give preference to the following:

(1) Existing education and training programs.

(2) Programs designed to be completed in less than six months.

(July 1, 1944, ch. 373, title XXX, § 3016, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 257.)

§ 300jj–37. General grant and loan provisions

(a) Reports

The Secretary may require that an entity receiving assistance under this part shall submit to the Secretary, not later than the date that is 1 year after the date of receipt of such assistance, a report that includes—

(1) an analysis of the effectiveness of the activities for which the entity receives such assistance, as compared to the goals for such activities; and

(2) an analysis of the impact of the project on health care quality and safety.

(b) Requirement to improve quality of care and decrease in costs

The National Coordinator shall annually evaluate the activities conducted under this part and shall, in awarding grants, implement

the lessons learned from such evaluation in a manner so that awards made subsequent to each such evaluation are made in a manner that, in the determination of the National Coordinator, will result in the greatest improvement in the quality and efficiency of health care.

(July 1, 1944, ch. 373, title XXX, § 3017, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 257.)

§ 300jj–38. Authorization for appropriations

For the purposes of carrying out this part, there is authorized to be appropriated such sums as may be necessary for each of the fiscal years 2009 through 2013.

(July 1, 1944, ch. 373, title XXX, § 3018, as added Pub. L. 111–5, div. A, title XIII, § 13301, Feb. 17, 2009, 123 Stat. 258.)

PART C—OTHER PROVISIONS

§ 300jj–51. Health information technology enrollment standards and protocols

(a) In general

(1) Standards and protocols

Not later than 180 days after March 23, 2010,[1] the Secretary, in consultation with the HIT Advisory Committee, shall develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs, as determined by the Secretary.

(2) Methods

The Secretary shall facilitate enrollment in such programs through methods determined appropriate by the Secretary, which shall include providing individuals and third parties authorized by such individuals and their designees notification of eligibility and verification of eligibility required under such programs.

(b) Content

The standards and protocols for electronic enrollment in the Federal and State programs described in subsection (a) shall allow for the following:

(1) Electronic matching against existing Federal and State data, including vital records, employment history, enrollment systems, tax records, and other data determined appropriate by the Secretary to serve as evidence of eligibility and in lieu of paper-based documentation.

(2) Simplification and submission of electronic documentation, digitization of documents, and systems verification of eligibility.

(3) Reuse of stored eligibility information (including documentation) to assist with retention of eligible individuals.

(4) Capability for individuals to apply, recertify and manage their eligibility information online, including at home, at points of service, and other community-based locations.

(5) Ability to expand the enrollment system to integrate new programs, rules, and functionalities, to operate at increased volume, and to apply streamlined verification and eligibility processes to other Federal and State programs, as appropriate.

(6) Notification of eligibility, recertification, and other needed communication regarding eligibility, which may include communication via email and cellular phones.

(7) Other functionalities necessary to provide eligibles with streamlined enrollment process.

(c) Approval and notification

With respect to any standard or protocol developed under subsection (a) that has been approved by the HIT Advisory Committee, the Secretary—

(1) shall notify States of such standards or protocols; and

(2) may require, as a condition of receiving Federal funds for the health information technology investments, that States or other entities incorporate such standards and protocols into such investments.

(d) Grants for implementation of appropriate enrollment HIT

(1) In general

The Secretary shall award grant[2] to eligible entities to develop new, and adapt existing, technology systems to implement the HIT enrollment standards and protocols developed under subsection (a) (referred to in this subsection as ''appropriate HIT technology'').

(2) Eligible entities

To be eligible for a grant under this subsection, an entity shall—

(A) be a State, political subdivision of a State, or a local governmental entity; and

(B) submit to the Secretary an application at such time, in such manner, and containing—

(i) a plan to adopt and implement appropriate enrollment technology that includes—

(I) proposed reduction in maintenance costs of technology systems;

(II) elimination or updating of legacy systems; and

(III) demonstrated collaboration with other entities that may receive a grant under this section that are located in the same State, political subdivision, or locality;

(ii) an assurance that the entity will share such appropriate enrollment technology in accordance with paragraph (4); and

(iii) such other information as the Secretary may require.

(3) Sharing

(A) In general

The Secretary shall ensure that appropriate enrollment HIT adopted under grants under this subsection is made available to other qualified State, qualified political subdivisions of a State, or other appropriate qualified entities (as described in subparagraph (B)) at no cost.

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[1] See References in Text note below.

[2] So in original. Probably should be ''grants''.

(B) Qualified entities

The Secretary shall determine what entities are qualified to receive enrollment HIT under subparagraph (A), taking into consideration the recommendations of the HIT Advisory Committee.

(July 1, 1944, ch. 373, title XXX, § 3021, as added Pub. L. 111–148, title I, § 1561, Mar. 23, 2010, 124 Stat. 262; amended Pub. L. 114–255, div. A, title IV, § 4003(e)(2)(A)(ii), Dec. 13, 2016, 130 Stat. 1174.)

REFERENCES IN TEXT

March 23, 2010, referred to in subsec. (a)(1), was in the original ''the date of enactment of this title'', which was translated as meaning the date of enactment of Pub. L. 111–148, which enacted this part, to reflect the probable intent of Congress.

AMENDMENTS

2016—Subsecs. (a)(1), (c), (d)(3)(B). Pub. L. 114–255 substituted ''HIT Advisory Committee'' for ''HIT Policy Committee and the HIT Standards Committee''.

§ 300jj–52. Information blocking

(a) Definition

(1) In general

In this section, the term ''information blocking'' means a practice that—

(A) except as required by law or specified by the Secretary pursuant to rulemaking under paragraph (3), is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; and

(B)(i) if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; or

(ii) if conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(2) Practices described

The information blocking practices described in paragraph (1) may include—

(A) practices that restrict authorized access, exchange, or use under applicable State or Federal law of such information for treatment and other permitted purposes under such applicable law, including transitions between certified health information technologies;

(B) implementing health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using electronic health information; and

(C) implementing health information technology in ways that are likely to—

(i) restrict the access, exchange, or use of electronic health information with respect to exporting complete information sets or in transitioning between health information technology systems; or

(ii) lead to fraud, waste, or abuse, or impede innovations and advancements in health information access, exchange, and use, including care delivery enabled by health information technology.

(3) Rulemaking

The Secretary, through rulemaking, shall identify reasonable and necessary activities that do not constitute information blocking for purposes of paragraph (1).

(4) No enforcement before exception identified

The term ''information blocking'' does not include any practice or conduct occurring prior to the date that is 30 days after December 13, 2016.

(5) Consultation

The Secretary may consult with the Federal Trade Commission in promulgating regulations under this subsection, to the extent that such regulations define practices that are necessary to promote competition and consumer welfare.

(6) Application

The term ''information blocking'', with respect to an individual or entity, shall not include an act or practice other than an act or practice committed by such individual or entity.

(7) Clarification

In carrying out this section, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under this subchapter.

(b) Inspector General authority

(1) In general

The inspector general of the Department of Health and Human Services (referred to in this section as the ''Inspector General'') may investigate any claim that—

(A) a health information technology developer of certified health information technology or other entity offering certified health information technology—

(i) submitted a false attestation under section 300jj–11(c)(5)(D)(vii) of this title; or

(ii) engaged in information blocking;

(B) a health care provider engaged in information blocking; or

(C) a health information exchange or network engaged in information blocking.

(2) Penalties

(A) Developers, networks, and exchanges

Any individual or entity described in subparagraph (A) or (C) of paragraph (1) that the Inspector General, following an investigation conducted under this subsection, determines to have committed information blocking shall be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which may not exceed $1,000,000

per violation. Such determination shall take into account factors such as the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted.

(B) Providers

Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking.

(C) Procedure

The provisions of section 1320a–7a of this title (other than subsections (a) and (b) of such section) shall apply to a civil money penalty applied under this paragraph in the same manner as such provisions apply to a civil money penalty or proceeding under such section 1320a–7a(a) of this title.

(D) Recovered penalty funds

The amounts recovered under this paragraph shall be allocated as follows:

(i) Annual operating expenses

Each year following the establishment of the authority under this subsection, the Office of the Inspector General shall provide to the Secretary an estimate of the costs to carry out investigations under this section. Such estimate may include reasonable reserves to account for variance in annual amounts recovered under this paragraph. There is authorized to be appropriated for purposes of carrying out this section an amount equal to the amount specified in such estimate for the fiscal year.

(ii) Application to other programs

The amounts recovered under this paragraph and remaining after amounts are made available under clause (i) shall be transferred to the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, in such proportion as the Secretary determines appropriate.

(E) Authorization of appropriations

There is authorized to be appropriated to the Office of the Inspector General to carry out this section $10,000,000, to remain available until expended.

(3) Resolution of claims

(A) In general

The Office of the Inspector General, if such Office determines that a 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 an information blocking claim, may refer such 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 care provider or 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 pursuant to a referral under subparagraph (A), with respect to such information, the health care provider or developer shall not be liable for such disclosure or disclosures made pursuant to subparagraph (A).

(c) Identifying barriers to exchange of certified health information technology

(1) Trusted exchange defined

In this section, the term ''trusted exchange'' with respect to certified electronic health records means that the certified electronic health record technology has the technical capability to enable secure health information exchange between users and multiple certified electronic health record technology systems.

(2) Guidance

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, governance, and security barriers that prevent the trusted exchange of electronic health information.

(3) Referral

The National Coordinator and the Office for Civil Rights of the Department of Health and Human Services may refer to the Inspector General instances or patterns of refusal to exchange health information with an individual or entity using certified electronic health record technology that is technically capable of trusted exchange and under conditions when exchange is legally permissible.

(d) Additional provisions

(1) Information sharing provisions

The National Coordinator may serve as a technical consultant to the Inspector General and the Federal Trade Commission for purposes of carrying out this section. The National Coordinator may, notwithstanding any other provision of law, share information related to claims or investigations under subsection (b) with the Federal Trade Commission for purposes of such investigations and shall share information with the Inspector General, as required by law.

(2) Protection from disclosure of information

Any information that is received by the National Coordinator in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information—

(A) shall not be disclosed by the National Coordinator except as may be necessary to carry out the purpose of this section;

(B) shall be exempt from mandatory disclosure under section 552 of title 5, as provided by subsection (b)(3) of such section; and

(C) may be used by the Inspector General or Federal Trade Commission for reporting purposes to the extent that such information could not reasonably be expected to facilitate identification of the source of such information.

(3) Standardized process

(A) In general

The National Coordinator shall implement a standardized process for the public to submit reports on claims of—

(i) health information technology products or developers of such products (or other entities offering such products to health care providers) not being interoperable or resulting in information blocking;

(ii) actions described in subsection (b)(1) that result in information blocking as described in subsection (a); and

(iii) any other act described in subsection (a).

(B) Collection of information

The standardized process implemented under subparagraph (A) shall provide for the collection of such information as the originating institution, location, type of transaction, system and version, timestamp, terminating institution, locations, system and version, failure notice, and other related information.

(4) Nonduplication of penalty structures

In carrying out this subsection, the Secretary shall, to the extent possible, ensure that penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before December 13, 2016.

(July 1, 1944, ch. 373, title XXX, § 3022, as added Pub. L. 114–255, div. A, title IV, § 4004, Dec. 13, 2016, 130 Stat. 1176.)

REFERENCES IN TEXT

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(3)(A), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

SUBCHAPTER XXIX—DATA COLLECTION, ANALYSIS, AND QUALITY

§ 300kk. Data collection, analysis, and quality

(a) Data collection

(1) In general

The Secretary shall ensure that, by not later than 2 years after March 23, 2010, any federally conducted or supported health care or public health program, activity or survey (including Current Population Surveys and American Community Surveys conducted by the Bureau of Labor Statistics and the Bureau of the Census) collects and reports, to the extent practicable—

(A) data on race, ethnicity, sex, primary language, and disability status for applicants, recipients, or participants;

(B) data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;

(C) sufficient data to generate statistically reliable estimates by racial, ethnic, sex, primary language, and disability status subgroups for applicants, recipients or participants using, if needed, statistical oversamples of these subpopulations; and

(D) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

(2) Collection standards

In collecting data described in paragraph (1), the Secretary or designee shall—

(A) use Office of Management and Budget standards, at a minimum, for race and ethnicity measures;

(B) develop standards for the measurement of sex, primary language, and disability status;

(C) develop standards for the collection of data described in paragraph (1) that, at a minimum—

(i) collects self-reported data by the applicant, recipient, or participant; and

(ii) collects data from a parent or legal guardian if the applicant, recipient, or participant is a minor or legally incapacitated;

(D) survey health care providers and establish other procedures in order to assess access to care and treatment for individuals with disabilities and to identify—

(i) locations where individuals with disabilities access primary, acute (including intensive), and long-term care;

(ii) the number of providers with accessible facilities and equipment to meet the needs of the individuals with disabilities, including medical diagnostic equipment that meets the minimum technical criteria set forth in section 794f of title 29; and

(iii) the number of employees of health care providers trained in disability awareness and patient care of individuals with disabilities; and

(E) require that any reporting requirement imposed for purposes of measuring quality under any ongoing or federally conducted or supported health care or public health program, activity, or survey includes requirements for the collection of data on individuals receiving health care items or services under such programs activities[1] by race, ethnicity, sex, primary language, and disability status.

(3) Data management

In collecting data described in paragraph (1), the Secretary, acting through the National Coordinator for Health Information Technology shall—

(A) develop national standards for the management of data collected; and

(B) develop interoperability and security systems for data management.

[1] So in original.