(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 subparagraphs (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.)

Editorial Notes

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

[1] See References in Text note below.

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).

(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.)

Editorial Notes

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).

Statutory Notes and Related Subsidiaries

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.