Stat. 4451, effective as if included in the enactment of Pub. L. 101--508.

Another prior section 1395zz, act Aug. 14, 1935, ch. 531, title XVIII, §1889, formerly §1833(f), as added Jan. 2, 1968, Pub. L. 90-248, title I, §132(b), 81 Stat. 850, and amended Oct. 30, 1972, Pub. L. 92-603, title II, §245(d), 86 Stat. 1424; Oct. 25, 1977, Pub. L. 95-142, §16(a), 91 Stat. 1200; renumbered §1889 and amended July 18, 1984, Pub. L. 98-369, div. B, title III, §2321(d), 98 Stat. 1084, provided for purchase of durable medical equipment, covering (a) lease-purchase basis or rental and determination by Secretary, (b) waiver of coinsurance amount in purchase of used equipment, (c) reimbursement procedures, and (d) encouragement of lease-purchase basis, prior to repeal by Pub. L. 100-203, title IV, §4062(d)(5), (e), Dec. 22, 1987, 101 Stat. 1330-109, applicable to cov-ered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989.

AMENDMENTS

2003—Subsecs. (b), (c). Pub. L. 108–173, 921(d)(1), added subsecs. (b) and (c).

Subsec. (d). Pub. L. 108-173, §921(e)(1), added subsec. (d).

Subsecs. (e) to (g). Pub. L. 108-173, §921(f)(1), added subsecs. (e) to (g).

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108-173, title IX, §921(d)(2), Dec. 8, 2003, 117 Stat. 2391, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on October 1, 2004."

Pub. L. 108-173, title IX, §921(e)(2), Dec. 8, 2003, 117 Stat. 2391, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on October 1, 2004."

Pub. L. 108-173, title IX, §921(f)(2), Dec. 8, 2003, 117 Stat. 2392, provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003]."

EFFECTIVE DATE

Pub. L. 108-173, title IX, §921(a)(2), Dec. 8, 2003, 117 Stat. 2388, provided that: "The amendment made by paragraph (1) [enacting this section] shall take effect on the date of the enactment of this Act [Dec. 8, 2003]."

SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM

Pub. L. 108-173, title IX, §922, Dec. 8, 2003, 117 Stat. 2392, provided that:

"(a) ESTABLISHMENT.-

"(1) IN GENERAL.—The Secretary [of Health and Human Services] shall establish a demonstration program (in this section referred to as the 'demonstration program') under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act [this subchapter] (including provisions of title XI of such Act [subchapter XI of this chapter] insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human Services).

"(2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is—

"(A) evaluation and recommendations regarding billing and related systems; and

"(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

"(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.— In this section, the term 'small providers of services or suppliers' means—

"(A) a provider of services with fewer than 25 fulltime-equivalent employees; or "(B) a supplier with fewer than 10 full-time-equivalent employees.

"(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review [now "quality improvement"] organizations or entities described in section 1889(g)(2) of the Social Security Act [subsec. (g)(2) of this section], as inserted by section 921(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

"(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means of achieving such compliance.

"(d) GAO EVALUATION.—Not later than 2 years after the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

"(e) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program) to be equal to 25 percent of the cost of the technical assistance.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated, from amounts not otherwise appropriated in the Treasury, such sums as may be necessary to carry out this section."

§1395aaa. Contract with a consensus-based entity regarding performance measurement

(a) Contract

(1) In general

For purposes of activities conducted under this chapter, the Secretary shall identify and have in effect a contract with a consensusbased entity, such as the National Quality Forum, that meets the requirements described in subsection (c). Such contract shall provide that the entity will perform the duties described in subsection (b).

(2) Timing for first contract

As soon as practicable after July 15, 2008, the Secretary shall enter into the first contract under paragraph (1).

(3) Period of contract

A contract under paragraph (1) shall be for a period of 4 years (except as may be renewed after a subsequent bidding process).

(4) Competitive procedures

Competitive procedures (as defined in section 132 of title 41) shall be used to enter into a contract under paragraph (1).

(b) Duties

The duties described in this subsection are the following:

(1) Priority setting process

The entity shall synthesize evidence and convene key stakeholders to make recommendations, with respect to activities conducted under this chapter, on an integrated national strategy and priorities for health care performance measurement in all applicable settings. In making such recommendations, the entity shall—

(A) ensure that priority is given to measures—

(i) that address the health care provided to patients with prevalent, high-cost chronic diseases;

(ii) with the greatest potential for improving the quality, efficiency, and patient-centeredness of health care; and

(iii) that may be implemented rapidly due to existing evidence, standards of care, or other reasons; and

(B) take into account measures that-

(i) may assist consumers and patients in making informed health care decisions;

(ii) address health disparities across groups and areas; and

(iii) address the continuum of care a patient receives, including services furnished by multiple health care providers or practitioners and across multiple settings.

(2) Endorsement of measures

The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—

(A) is evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level; and

(B) is consistent across types of health care providers, including hospitals and physicians.

(3) Maintenance of measures

The entity shall establish and implement a process to ensure that measures endorsed under paragraph (2) are updated (or retired if obsolete) as new evidence is developed.

(4) Repealed. Pub. L. 112-240, title VI, § 609(a)(2), Jan. 2, 2013, 126 Stat. 2349

(5) Annual report to Congress and the Secretary; secretarial publication and comment

(A) Annual report

By not later than March 1 of each year (beginning with 2009), the entity shall submit to Congress and the Secretary a report containing a description of—

(i) the implementation of quality measurement initiatives under this chapter and the coordination of such initiatives with quality initiatives implemented by other payers;

(ii) the recommendations made under paragraph (1);

(iii) the performance by the entity of the duties required under the contract entered into with the Secretary under subsection (a):

(iv) gaps in endorsed quality measures, which shall include measures that are within priority areas identified by the Secretary under the national strategy established under section 280j of this title, and where quality measures are unavailable or inadequate to identify or address such gaps;

(v) areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy established under section 280j of this title and where targeted research may address such gaps; and

(vi) the matters described in clauses (i) and (ii) of paragraph (7)(A).

(B) Secretarial review and publication of annual report

Not later than 6 months after receiving a report under subparagraph (A) for a year, the Secretary shall—

(i) review such report; and

(ii) publish such report in the Federal Register, together with any comments of the Secretary on such report.

(6) Review and endorsement of episode grouper under the physician feedback program

The entity shall provide for the review and, as appropriate, the endorsement of the episode grouper developed by the Secretary under section 1395w-4(n)(9)(A) of this title. Such review shall be conducted on an expedited basis.

(7) Convening multi-stakeholder groups

(A) In general

The entity shall convene multi-stakeholder groups to provide input on—

(i) the selection of quality and efficiency measures described in subparagraph (B), from among—

(I) such measures that have been endorsed by the entity; and

(II) such measures that have not been considered for endorsement by such entity but are used or proposed to be used by the Secretary for the collection or reporting of quality and efficiency measures; and

(ii) national priorities (as identified under section 280j of this title) for improvement in population health and in the delivery of health care services for consideration under the national strategy established under section 280j of this title.

(B) Quality and efficiency measures

(i) In general

Subject to clause (ii), the quality and efficiency measures described in this subparagraph are quality and efficiency measures(I) for use pursuant to sections 1395f(i)(5)(D), 1395l(i)(7), 1395l(t)(17), 1395l(t)(17), 1395w-4(k)(2)(C), 1395cc(k)(3), 1395rr(h)(2)(A)(iii), 1395ww(b)(3)(B)(viii), 1395ww(j)(7)(D), 1395ww(m)(5)(D), 1395ww(s)(2), 1395ww(s)(4)(D), and 1395ff(b)(3)(B)(v) of this title;

(II) for use in reporting performance information to the public; and

(III) for use in health care programs other than for use under this chapter.

(ii) Exclusion

Data sets (such as the outcome and assessment information set for home health services and the minimum data set for skilled nursing facility services) that are used for purposes of classification systems used in establishing payment rates under this subchapter shall not be quality and efficiency measures described in this subparagraph.

(C) Requirement for transparency in process (i) In general

In convening multi-stakeholder groups under subparagraph (A) with respect to the selection of quality and efficiency measures, the entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.

(ii) Selection of organizations participating in multi-stakeholder groups

The process described in clause (i) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

(D) Multi-stakeholder group defined

In this paragraph, the term "multi-stakeholder group" means, with respect to a quality and efficiency measure, a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the use of such quality and efficiency measure.

(8) Transmission of multi-stakeholder input

Not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stakeholder groups provided under paragraph (7).

(c) Requirements described

The requirements described in this subsection are the following:

(1) Private nonprofit

The entity is a private nonprofit entity governed by a board.

(2) Board membership

The members of the board of the entity include—

(A) representatives of health plans and health care providers and practitioners or representatives of groups representing such health plans and health care providers and practitioners;

(B) health care consumers or representatives of groups representing health care consumers; and (C) representatives of purchasers and employers or representatives of groups representing purchasers or employers.

(3) Entity membership

The membership of the entity includes persons who have experience with—

(A) urban health care issues;

(B) safety net health care issues;

(C) rural and frontier health care issues; and

(D) health care quality and safety issues.

(4) Open and transparent

With respect to matters related to the contract with the Secretary under subsection (a), the entity conducts its business in an open and transparent manner and provides the opportunity for public comment on its activities.

(5) Voluntary consensus standards setting organization

The entity operates as a voluntary consensus standards setting organization as defined for purposes of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (Public Law 104–113) and Office of Management and Budget Revised Circular A–119 (published in the Federal Register on February 10, 1998).

(6) Experience

The entity has at least 4 years of experience in establishing national consensus standards.

(7) Membership fees

If the entity requires a membership fee for participation in the functions of the entity, such fees shall be reasonable and adjusted based on the capacity of the potential member to pay the fee. In no case shall membership fees pose a barrier to the participation of individuals or groups with low or nominal resources to participate in the functions of the entity.

(d) Funding

For purposes of carrying out this section, the Secretary shall provide for the transfer, from 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), of \$10,000,000 to the Centers for Medicare & Medicaid Services Program Management Account for each of fiscal years 2009 through 2013.

(Aug. 14, 1935, ch. 531, title XVIII, §1890, as added Pub. L. 110-275, title I, §183(a)(1), July 15, 2008, 122 Stat. 2583; amended Pub. L. 111-148, title III, §§ 3003(b), 3014(a), title X, §§ 10304, 10322(b), Mar. 23, 2010, 124 Stat. 367, 384, 938, 954; Pub. L. 112-240, title VI, §609(a), Jan. 2, 2013, 126 Stat. 2349.)

References in Text

Section 12(d) of the National Technology Transfer and Advancement Act of 1995, referred to in subsec. (c)(5), is section 12(d) of Pub. L. 104–113, which is set out as a note under section 272 of Title 15, Commerce and Trade.

CODIFICATION

In subsec. (a)(4), "section 132 of title 41" substituted for "section 4(5) of the Office of Federal Procurement

Policy Act (41 U.S.C. 403(5))" on authority of Pub. L. 111-350, (c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

PRIOR PROVISIONS

A prior section 1395aaa, act Aug. 14, 1935, ch. 531, title XVIII, §1890, as added Aug. 18, 1987, Pub. L. 100–93, §10, 101 Stat. 696, which related to limitation of liability of beneficiaries with respect to services furnished by excluded individuals and entities, was amended and transferred to section 1862(e)(2) of act Aug. 14, 1935, by Pub. L. 100–360, title IV, §411(i)(4)(D)(ii), July 1, 1988, 102 Stat. 790, as amended by Pub. L. 100–485, title VI, §608(d)(24)(C)(ii), Oct. 13, 1988, 102 Stat. 2421, and is classified to section 1395y(e)(2) of this title.

Amendments

2013—Subsec. (b)(4). Pub. L. 112–240, 609(a)(2), struck out par. (4). Text read as follows: "The entity shall promote the development and use of electronic health records that contain the functionality for automated collection, aggregation, and transmission of performance measurement information."

Subsec. (d). Pub. L. 112-240, §609(a)(1), substituted "fiscal years 2009 through 2013" for "fiscal years 2009 through 2012".

2010—Subsec. (b)(5)(A)(iv) to (vi). Pub. L. 111–148, 3014(a)(2), added cls. (iv) to (vi).

Subsec. (b)(6). Pub. L. 111-148, §3003(b), added par. (6). Subsec. (b)(7). Pub. L. 111-148, §10304, substituted "quality and efficiency" for "quality" wherever appearing in text.

Pub. L. 111-148, §3014(a)(1), added par. (7).

Subsec. (b)(7)(B). Pub. L. 111–148, 10304, which directed substitution of "quality and efficiency" for "quality" wherever appearing, was executed by substituting "Quality and efficiency" for "Quality" in subpar. heading to reflect the probable intent of Congress. Subsec. (b)(7)(B)(i)(D, Pub. L. 111–148, 10322(b), in-

Subsec. (b)(7)(B)(i)(I). Pub. L. 111-148, §10322(b), inserted "1395ww(s)(4)(D)," after "1395ww(o)(2),". Subsec. (b)(8). Pub. L. 111-148, §3014(a)(1), added par.

Subsec. (b)(8). Pub. L. 111–148, $\S3014(a)(1)$, added par. (8).

§1395aaa-1. Quality and efficiency measurement

(a) Multi-stakeholder group input into selection of quality and efficiency measures

The Secretary shall establish a pre-rulemaking process under which the following steps occur with respect to the selection of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title:

(1) Input

Pursuant to section 1395aaa(b)(7) of this title, the entity with a contract under section 1395aaa of this title shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B) of such paragraph.

(2) Public availability of measures considered for selection

Not later than December 1 of each year (beginning with 2011), the Secretary shall make available to the public a list of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that the Secretary is considering under this subchapter.

(3) Transmission of multi-stakeholder input

Pursuant to section 1395aaa(b)(8) of this title, not later than February 1 of each year (beginning with 2012), the entity shall transmit to the Secretary the input of multi-stake-holder groups described in paragraph (1).

(4) Consideration of multi-stakeholder input

The Secretary shall take into consideration the input from multi-stakeholder groups described in paragraph (1) in selecting quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that have been endorsed by the entity with a contract under section 1395aaa of this title and measures that have not been endorsed by such entity.

(5) Rationale for use of quality and efficiency measures

The Secretary shall publish in the Federal Register the rationale for the use of any quality and efficiency measure described in section 1395aaa(b)(7)(B) of this title that has not been endorsed by the entity with a contract under section 1395aaa of this title.

(6) Assessment of impact

Not later than March 1, 2012, and at least once every three years thereafter, the Secretary shall—

(A) conduct an assessment of the quality and efficiency impact of the use of endorsed measures described in section 1395aaa(b)(7)(B) of this title: and

(B) make such assessment available to the public.

(b) Process for dissemination of measures used by the Secretary

(1) In general

The Secretary shall establish a process for disseminating quality and efficiency measures used by the Secretary. Such process shall include the following:

(A) The incorporation of such measures, where applicable, in workforce programs, training curricula, and any other means of dissemination determined appropriate by the Secretary.

(B) The dissemination of such quality and efficiency measures through the national strategy developed under section 280j of this title.

(2) Existing methods

To the extent practicable, the Secretary shall utilize and expand existing dissemination methods in disseminating quality and efficiency measures under the process established under paragraph (1).

(c) Review of quality and efficiency measures used by the Secretary

(1) In general

The Secretary shall—

(A) periodically (but in no case less often than once every 3 years) review quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title; and

(B) with respect to each such measure, determine whether to—

(i) maintain the use of such measure; or (ii) phase out such measure.

(2) Considerations

In conducting the review under paragraph (1), the Secretary shall take steps to—

(A) seek to avoid duplication of measures used; and