amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment notes below.

1988—Pub. L. 100–360, §203(e)(4)(A), inserted ''and for qualified home intravenous drug therapy providers'' at end of section catchline.

Subsec. (a). Pub. L. 100–360, §411(g)(3)(G)(i)(I), as amended by Pub. L. 100–485, substituted ''approved'' for ''certified''.

Pub. L. 100–360, §411(g)(3)(G)(i)(II), inserted ''or for coverage'' after ''conditions of participation''.

Pub. L. 100–360, §411(g)(3)(G)(i)(III), which directed amendment of subsec. (a) by substituting ''terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory'' for ''cancelling immediately the certification of the provider or clinical laboratory'', was executed by making the substitution for ''canceling immediately the certification of the provider or clinical laboratory'' to reflect the probable intent of Congress.

Pub. L. 100–360, §203(e)(4)(B), inserted ''or that a qualified home intravenous drug therapy provider that is certified for participation under this subchapter no longer substantially meets the requirements of section 1395x(jj)(3) of this title'' after ''under this part''.

Subsec. (b)(1)(A). Pub. L. 100–360, §411(g)(3)(G)(ii), struck out ''certified'' before ''clinical laboratories''.

Subsec. (b)(2)(A). Pub. L. 100–360, §411(g)(3)(G)(iv), inserted at end ''The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.''

Subsec. (b)(2)(A)(ii). Pub. L. 100–360, §411(g)(3)(G)(iii), substituted ''civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance'' for ''civil fines and penalties''.

Subsec. (b)(2)(A)(iii). Pub. L. 100–360, §411(g)(3)(G)(v), struck out ''certification'' before ''surveys''.

Subsec. (b)(2)(A)(iv). Pub. L. 100–360, §411(g)(3)(G)(ii), (vi), struck out ''certified'' before ''clinical laboratory'' and substituted ''furnished on or after the date on'' for ''provided on or after the date in''.

Pub. L. 100–360, §203(e)(4)(C), inserted ''or home intravenous drug therapy services'' after ''clinical diagnostic laboratory tests''.

Subsec. (b)(3). Pub. L. 100–360, §411(g)(3)(G)(vii), substituted ''any penalties'' for ''any fines'' and ''severe penalties'' for ''severe fines''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101–508 effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239, see section 4154(e)(5) of Pub. L. 101–508, set out as a note under section 1395*l* of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

Amendment by Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1320a–7a of this title.

EFFECTIVE DATE OF 1988 AMENDMENTS

Amendment by Pub. L. 100–485 effective as if included in the enactment of the Medicare Catastrophic Coverage Act of 1988, Pub. L. 100–360, see section 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 203(e)(4) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(g)(3)(G) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE

Pub. L. 100–203, title IV, §4064(d)(2), Dec. 22, 1987, 101 Stat. 1330–111, provided that: ''The amendment made by paragraph (1) [enacting this section] shall become effective on January 1, 1990.''

§ 1395w–3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs

(i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable

from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008;

(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation

(i) In general

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or

(II) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term ''covered document'' means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition

program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(G) Requiring bid bonds for bidding entities

With respect to rounds of competitions beginning under this subsection for contracts beginning not earlier than January 1, 2017, and not later than January 1, 2019, an entity may not submit a bid for a competitive acquisition area unless, as of the deadline for bid submission, the entity has obtained (and provided the Secretary with proof of having obtained) a bid surety bond (in this paragraph referred to as a ''bid bond'') in a form specified by the Secretary consistent with subparagraph (H) and in an amount that is not less than $50,000 and not more than $100,000 for each competitive acquisition area in which the entity submits the bid.

(H) Treatment of bid bonds submitted

(i) For bidders that submit bids at or below the median and are offered but do not accept the contract

In the case of a bidding entity that is offered a contract for any product category for a competitive acquisition area, if—

(I) the entity's composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts for such product category and area; and

(II) the entity does not accept the contract offered for such product category and area,

the bid bond submitted by such entity for such area shall be forfeited by the entity and the Secretary shall collect on it.

(ii) Treatment of other bidders

In the case of a bidding entity for any product category for a competitive acquisition area, if the entity does not meet the bid forfeiture conditions in subclauses (I) and (II) of clause (i) for any product category for such area, the bid bond submitted by such entity for such area shall be returned within 90 days of the public announcement of the contract suppliers for such area.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher, complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes) (and related accessories when furnished in connection with such complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, and certain manual wheelchairs), and excluding drugs and biologicals described in section 1395u(*o*)(1)(D) of this title.

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment oth-

erwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician's or practitioner's own patients as part of the physician's or practitioner's professional service; or

(ii) by a hospital to the hospital's own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)—

(i) that are furnished by a hospital to the hospital's own patients during an admission or on the date of discharge; and

(ii) to which such programs would not apply, as specified by the Secretary, if furnished by a physician to the physician's own patients as part of the physician's professional service.

(b) Program requirements

(1) In general

The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in an[1] competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(v) The entity meets applicable State licensure requirements.

(B) Timely implementation of program

Any delay in the implementation of quality standards under section 1395m(a)(20) of this title or delay in the receipt of advice from the program oversight committee established under subsection (c) shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts

The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on—

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.

(ii) Subsequent disclosure

Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors

(A) In general

The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners

The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

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

(5) Payment

(A) In general

Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing

(i) Application of coinsurance

Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible

Before applying clause (i), the individual shall be required to meet the deductible described in section 1395*l*(b) of this title.

(C) Payment on assignment-related basis

Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction

Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

(6) Participating contractors

(A) In general

Except as provided in subsection (a)(4), payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which competition is conducted under this section unless—

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined

In this section, the term ''bid'' means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions

In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids

The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services

The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring quality of services with respect to the program.

(9) Authority to contract for implementation

The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips

(A) In general

With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. With respect to bids to furnish such types of products on or after January 1, 2019, the volume for such types of products shall be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.

(B) Study of types of testing strip products

Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquistion[2] program described in subparagraph (A).

(C) Demonstration of ability to furnish types of diabetic testing strip products

With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, an entity shall attest to the Secretary that the entity has the ability to obtain an

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

inventory of the types and quantities of diabetic testing strip products that will allow the entity to furnish such products in a manner consistent with its bid and—

(i) demonstrate to the Secretary, through letters of intent with manufacturers, wholesalers, or other suppliers, or other evidence as the Secretary may specify, such ability; or

(ii) demonstrate to the Secretary that it made a good faith attempt to obtain such a letter of intent or such other evidence.

(D) Use of unlisted types in calculation of percentage

With respect to bids to furnish diabetic testing strip products on or after January 1, 2019, in determining under subparagraph (A) whether a bid submitted by an entity under such subparagraph covers 50 percent (or such higher percentage as the Secretary may specify) of all types of diabetic testing strip products, the Secretary may not attribute a percentage to types of diabetic testing strip products that the Secretary does not identify by brand, model, and market share volume.

(E) Adherence to demonstration

(i) In general

In the case of an entity that is furnishing diabetic testing strip products on or after January 1, 2019, under a contract entered into under the competition conducted pursuant to paragraph (1), the Secretary shall establish a process to monitor, on an ongoing basis, the extent to which such entity continues to cover the product types included in the entity's bid.

(ii) Termination

If the Secretary determines that an entity described in clause (i) fails to maintain in inventory, or otherwise maintain ready access to (through requirements, contracts, or otherwise) a type of product included in the entity's bid, the Secretary may terminate such contract unless the Secretary finds that the failure of the entity to maintain inventory of, or ready access to, the product is the result of the discontinuation of the product by the product manufacturer, a market-wide shortage of the product, or the introduction of a newer model or version of the product in the market involved.

(11) Additional special rules in case of competition for diabetic testing strips

(A) In general

With respect to an entity that is furnishing diabetic testing strip products to individuals under a contract entered into under the competitive acquisition program established under this section, the entity shall furnish to each individual a brand of such products that is compatible with the home blood glucose monitor selected by the individual.

(B) Prohibition on influencing and incentivizing

An entity described in subparagraph (A) may not attempt to influence or incentivize an individual to switch the brand of glucose monitor or diabetic testing strip product selected by the individual, including by—

(i) persuading, pressuring, or advising the individual to switch; or

(ii) furnishing information about alternative brands to the individual where the individual has not requested such information.

(C) Provision of information

(i) Standardized information

Not later than January 1, 2019, the Secretary shall develop and make available to entities described in subparagraph (A) standardized information that describes the rights of an individual with respect to such an entity. The information described in the preceding sentence shall include information regarding—

(I) the requirements established under subparagraphs (A) and (B);

(II) the right of the individual to purchase diabetic testing strip products from another mail order supplier of such products or a retail pharmacy if the entity is not able to furnish the brand of such product that is compatible with the home blood glucose monitor selected by the individual; and

(III) the right of the individual to return diabetic testing strip products furnished to the individual by the entity.

(ii) Requirement

With respect to diabetic testing strip products furnished on or after the date on which the Secretary develops the standardized information under clause (i), an entity described in subparagraph (A) may not communicate directly to an individual until the entity has verbally provided the individual with such standardized information.

(D) Order refills

With respect to diabetic testing strip products furnished on or after January 1, 2019, the Secretary shall require an entity furnishing diabetic testing strip products to an individual to contact and receive a request from the individual for such products not more than 14 days prior to dispensing a refill of such products to the individual.

(12) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of—

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

(D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);

(E) the selection of items and services for competitive acquisition under subsection (a)(2);

(F) the bidding structure and number of contractors selected under this section; or

(G) the implementation of the special rule described in paragraph (10).

(c) Program Advisory and Oversight Committee

(1) Establishment

The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the ''Committee'').

(2) Membership; terms

The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties

(A) Advice

The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii).

(iii) The establishment of requirements for collection of data for the efficient management of the program.

(iv) The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1395x(d) of this title), and individuals.

(v) The establishment of quality standards under section 1395m(a)(20) of this title.

(B) Additional duties

The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

(4) Inapplicability of FACA

The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply.

(5) Termination

The Committee shall terminate on December 31, 2011.

(d) Report

Not later than July 1, 2011, the Secretary shall submit to Congress a report on the programs under this section. The report shall include information on savings, reductions in cost-sharing, access to and quality of items and services, and satisfaction of individuals.

(e) Repealed. Pub. L. 110–275, title I, § 145(a)(1), July 15, 2008, 122 Stat. 2547

(f) Competitive acquisition ombudsman

The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1395b–9(c) of this title. The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1395b–9(c)(2)(C) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added Pub. L. 105–33, title IV, § 4319(a), Aug. 5, 1997, 111 Stat. 392; amended Pub. L. 106–113, div. B, § 1000(a)(6) [title III, § 321(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–366; Pub. L. 108–173, title III, § 302(b)(1), Dec. 8, 2003, 117 Stat. 2224; Pub. L. 110–275, title I, §§ 145(a)(1), 154(a)(1), (b)(2), (3), (c)(2)(A), (B), (d)(1), (3), (4), July 15, 2008, 122 Stat. 2547, 2560, 2565–2568; Pub. L. 111–148, title VI, § 6410(a), Mar. 23, 2010, 124 Stat. 773; Pub. L. 114–10, title V, § 522(a), (b)(1), Apr. 16, 2015, 129 Stat. 176, 177; Pub. L. 114–255, div. A, title V, § 5004(b)(1), Dec. 13, 2016, 130 Stat. 1191; Pub. L. 115–123, div. E, title IV, § 50414(a), (b), Feb. 9, 2018, 132 Stat. 221, 222; Pub. L. 116–94, div. N, title I, § 106(a), Dec. 20, 2019, 133 Stat. 3101.)

Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (a)(2)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§ 301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Advisory Committee Act, referred to in subsec. (c)(4), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

PRIOR PROVISIONS

A prior section 1395w–3, act Aug. 14, 1935, ch. 531, title XVIII, § 1847, as added July 1, 1988, Pub. L. 100–360, title II, § 202(j), 102 Stat. 719; amended Oct. 13, 1988, Pub. L. 100–485, title VI, § 608(d)(5)(I), 102 Stat. 2414, provided for appointment of Prescription Drug Payment Review Commission by Director of Congressional Office of Technology Assessment, prior to repeal by Pub. L. 101–234, title II, § 201(a), (c), Dec. 13, 1989, 103 Stat. 1981, effective Jan. 1, 1990.

AMENDMENTS

2019—Subsec. (a)(2)(A). Pub. L. 116–94 inserted '', complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes)'' after ''group 3 or higher'' and substituted ''such complex rehabilitative power wheelchairs, complex rehabilitative manual wheelchairs, and certain manual wheelchairs'' for ''such wheelchairs''.

2018—Subsec. (b)(10)(A). Pub. L. 115–123, § 50414(a)(1)(A), substituted ''With respect to bids to furnish such types of products on or after January 1, 2019, the volume for such types of products shall be determined by the Secretary through the use of multiple sources of data (from mail order and non-mail order Medicare markets), including market-based data measuring sales of diabetic testing strip products that are not exclusively sold by a single retailer from such markets.'' for ''The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.''

Subsec. (b)(10)(C) to (E). Pub. L. 115–123, § 50414(a)(1)(B), added subpars. (C) to (E).

Subsec. (b)(11), (12). Pub. L. 115–123, § 50414(b), added par. (11) and redesignated former par. (11) as (12).

2016—Subsec. (a)(2)(A). Pub. L. 114–255 substituted '', excluding certain'' for ''and excluding certain'' and

inserted before period at end '', and excluding drugs and biologicals described in section 1395u(*o*)(1)(D) of this title''.

2015—Subsec. (a)(1)(G), (H). Pub. L. 114–10, § 522(a), added subpars. (G) and (H).

Subsec. (b)(2)(A)(v). Pub. L. 114–10, § 522(b)(1), added cl. (v).

2010—Subsec. (a)(1)(B)(i)(II). Pub. L. 111–148, § 6410(a)(1), substituted ''91'' for ''70''.

Subsec. (a)(1)(D)(ii)(II), (III). Pub. L. 111–148, § 6410(a)(2), added subcl. (II) and redesignated former subcl. (II) as (III).

2008—Subsec. (a)(1)(B)(i). Pub. L. 110–275, § 154(a)(1)(A)(i), inserted ''consistent with subparagraph (D)'' after ''in a manner'' in introductory provisions.

Subsec. (a)(1)(B)(i)(II). Pub. L. 110–275, § 154(a)(1)(A)(ii), substituted ''an additional 70'' for ''80'' and ''in 2011'' for ''in 2009''.

Subsec. (a)(1)(B)(i)(III). Pub. L. 110–275, § 154(a)(1)(A)(iii), substituted ''after 2011 (or, in the case of national mail order for items and services, after 2010)'' for ''after 2009''.

Subsec. (a)(1)(D) to (F). Pub. L. 110–275, § 154(a)(1)(A)(iv), added subpars. (D) to (F).

Subsec. (a)(2)(A). Pub. L. 110–275, § 154(a)(1)(B), which directed amendment of par. (2)(A) of subsec. (a)(1) by inserting ''and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs)'' before period at end, was executed by making the insertion in subsec. (a)(2)(A), to reflect the probable intent of Congress.

Subsec. (a)(7). Pub. L. 110–275, § 154(d)(1), added par. (7).

Subsec. (b)(3)(C). Pub. L. 110–275, § 154(b)(2), added subpar. (C).

Subsec. (b)(10). Pub. L. 110–275, § 154(d)(3)(B), added par. (10). Former par. (10) redesignated (11).

Subsec. (b)(11). Pub. L. 110–275, § 154(d)(3)(A), redesignated par. (10) as (11).

Subsec. (b)(11)(C). Pub. L. 110–275, § 154(d)(4)(A), inserted ''and the identification of areas under subsection (a)(1)(D)(iii)'' after ''(a)(1)(A)''.

Subsec. (b)(11)(D). Pub. L. 110–275, § 154(d)(4)(B), inserted ''and implementation of subsection (a)(1)(D)'' after ''(a)(1)(B)''.

Subsec. (b)(11)(G). Pub. L. 110–275, § 154(d)(4)(C)–(E), added subpar. (G).

Subsec. (c)(5). Pub. L. 110–275, § 154(c)(2)(A), substituted ''December 31, 2011'' for ''December 31, 2009''.

Subsec. (d). Pub. L. 110–275, § 154(c)(2)(B), substituted ''July 1, 2011'' for ''July 1, 2009''.

Subsec. (e). Pub. L. 110–275, § 145(a)(1), struck out subsec. (e) which related to a demonstration project on the application of competitive acquisition to clinical diagnostic laboratory tests, terms and conditions of the project, and reporting requirement.

Subsec. (f). Pub. L. 110–275, § 154(b)(3), added subsec. (f).

2003—Pub. L. 108–173 amended section catchline and text generally, substituting provisions relating to competitive acquisition of certain items and services for provisions relating to demonstration projects for competitive acquisition of items and services.

1999—Subsec. (b)(2). Pub. L. 106–113 inserted ''and'' after ''specified by the Secretary''.

Statutory Notes and Related Subsidiaries

Effective Date of 2008 Amendment

Amendment by section 154 of Pub. L. 110–275 effective June 30, 2008, see section 154(e) of Pub. L. 110–275, set out as a note under section 1395m of this title.

Effective Date of 1999 Amendment

Amendment by Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, § 321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

Construction of 2015 Amendment

Pub. L. 114–10, title V, § 522(b)(2), Apr. 16, 2015, 129 Stat. 177, provided that: ''Nothing in the amendment made by paragraph (1) [amending this section] shall be construed as affecting the authority of the Secretary of Health and Human Services to require State licensure of an entity under the Medicare competitive acquisition program under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) before the date of the enactment of this Act [Apr. 16, 2015].''

Non-Application of Medicare Fee Schedule Adjustments for Wheelchair Accessories and Seat and Back Cushions When Furnished in Connection With Complex Rehabilitative Manual Wheelchairs

Pub. L. 116–94, div. N, title I, § 106(b), Dec. 20, 2019, 133 Stat. 3101, provided that:

''(1) In general.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall not, during the period beginning on January 1, 2020, and ending on June 30, 2021, use information on the payment determined under the competitive acquisition programs under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) to adjust the payment amount that would otherwise be recognized under section 1834(a)(1)(B)(ii) of such Act (42 U.S.C. 1395m(a)(1)(B)(ii)) for wheelchair accessories (including seating systems) and seat and back cushions when furnished in connection with complex rehabilitative manual wheelchairs (as determined by the Secretary), and certain manual wheelchairs (identified, as of October 1, 2018, by HCPCS codes E1235, E1236, E1237, E1238, and K0008 or any successor to such codes).

''(2) Implementation.—Notwithstanding any other provision of law, the Secretary may implement this subsection by program instruction or otherwise.''

Implementation of 2018 Amendment

Pub. L. 115–123, div. E, title IV, § 50414(c), Feb. 9, 2018, 132 Stat. 223, provided that:

''(1) Implementation.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, and amendments made by, this section [amending this section] by program instruction or otherwise.

''(2) Non-application of the paperwork reduction act.—Chapter 35 of title 44, United States Code (commonly referred to as the 'Paperwork Reduction Act of 1995'), shall not apply to this section or the amendments made by this section.''

GAO Report on Impact of Competitive Acquisition on Suppliers

Pub. L. 108–173, title III, § 302(b)(3), Dec. 8, 2003, 117 Stat. 2230, as amended by Pub. L. 110–275, title I, § 154(c)(1), July 15, 2008, 122 Stat. 2565, provided that:

''(A) Study.—The Comptroller General of the United States shall conduct a study on the impact of competitive acquisition of durable medical equipment under section 1847 of the Social Security Act [42 U.S.C. 1395w–3], as amended by paragraph (1) and as amended by section 2 of the Medicare DMEPOS Competitive Acquisition Reform Act of 2008 [probably should refer to section 154 of the Medicare Improvements for Patients and Providers Act of 2008, Pub. L. 110–275], on suppliers and manufacturers of such equipment and on patients. Such study shall specifically examine the impact of such competitive acquisition on access to, and quality of, such equipment and service related to such equipment and the topics specified in subparagraph (C).

''(B) Report.—Not later than 1 year after the first date that payments are made under section 1847 of the Social Security Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A) and shall include in the report such

recommendations as the Comptroller General determines appropriate.

''(C) TOPICS.—The topics specified in this subparagraph, for the study under subparagraph (A) concerning the competitive acquisition program, are the following:

''(i) Beneficiary access to items and services under the program, including the impact on such access of awarding contracts to bidders that—

''(I) did not have a physical presence in an area where they received a contract; or

''(II) had no previous experience providing the product category they were contracted to provide.

''(ii) Beneficiary satisfaction with the program and cost savings to beneficiaries under the program.

''(iii) Costs to suppliers of participating in the program and recommendations about ways to reduce those costs without compromising quality standards or savings to the Medicare program.

''(iv) Impact of the program on small business suppliers.

''(v) Analysis of the impact on utilization of different items and services paid within the same Healthcare Common Procedure Coding System (HCPCS) code.

''(vi) Costs to the Centers for Medicare & Medicaid Services, including payments made to contractors, for administering the program compared with administration of a fee schedule, in comparison with the relative savings of the program.

''(vii) Impact on access, Medicare spending, and beneficiary spending of any difference in treatment for diabetic testing supplies depending on how such supplies are furnished.

''(viii) Such other topics as the Comptroller General determines to be appropriate.''

REPORT ON ACTIVITIES OF SUPPLIERS

Pub. L. 108–173, title III, §302(e), Dec. 8, 2003, 117 Stat. 2233, as amended by Pub. L. 110–275, title I, §154(c)(2)(C), July 15, 2008, 122 Stat. 2566, provided that: ''The Inspector General of the Department of Health and Human Services shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act [42 U.S.C. 1395w–3], as amended by subsection (a) [probably should be (b)(1)], are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability. Not later than July 1, 2011, the Inspector General shall submit to Congress a report on such study.''

STUDY BY GAO

Pub. L. 105–33, title IV, §4319(c), Aug. 5, 1997, 111 Stat. 394, provided that: ''The Comptroller of the United States shall study the effectiveness of the establishment of competitive acquisition areas under section 1847(a) of the Social Security Act [42 U.S.C. 1395w–3(a)], as added by this section.''

§ 1395w–3a. Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395u(*o*)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(ii) of section 1395w–3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e), the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008;

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D)), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 1396r–8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable.

(B) Unit defined

In this section, the term ''unit'' means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.

(3) Multiple source drug

For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1396r–8(b)(3)(A)(iii) of this title or subsection (f)(2), as applicable, determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer's average sales price (as defined in subsection (c)); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.