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MEDICARE DMEPOS COMPETITIVE BIDDING IMPROVEMENT ACT OF 2015

MARCH 13, 2015.—Ordered to be printed

Mr. RYAN of Wisconsin, from the Committee on Ways and Means, submitted the following

R E P O R T

[To accompany H.R. 284]

[Including cost estimate of the Congressional Budget Office]

The Committee on Ways and Means, to whom was referred the bill (H.R. 284) to amend title XVIII of the Social Security Act to require State licensure and bid surety bonds for entities submitting bids under the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive acquisition program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare DMEPOS Competitive Bidding Improvement Act of 2015".

SEC. 2. REQUIRING BID SURETY BONDS AND STATE LICENSURE FOR ENTITIES SUBMITTING BIDS UNDER THE MEDICARE DMEPOS COMPETITIVE ACQUISITION PROGRAM.

(a) BID SURETY BONDS.—Section 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w–3(a)(1)) is amended by adding at the end the following new subparagraphs:

"(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.".

(b) STATE LICENSURE.—

(1) IN GENERAL.—Section 1847(b)(2)(A) of the Social Security Act (42 U.S.C. 1395w–3(b)(2)(A)) is amended by adding at the end the following new clause:

"(v) The entity meets applicable State licensure requirements.".

(2) CONSTRUCTION.—Nothing in the amendment made by paragraph (1) 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.

(c) GAO REPORT ON BID BOND IMPACT ON SMALL SUPPLIERS.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study that evaluates the effect of the bid surety bond requirement under the amendment made by subsection (a) on the participation of small suppliers in the Medicare DMEPOS competitive acquisition program under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).

(2) REPORT.—Not later than 6 months after the date contracts are first awarded subject to such bid surety bond requirement, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include recommendations for changes in such requirement in order to ensure robust participation by legitimate small suppliers in the Medicare DMEPOS competition acquisition program.

I. SUMMARY AND BACKGROUND

A. PURPOSE AND SUMMARY

The bill, H.R. 284, the Medicare DMEPOS Competitive Bidding Improvement Act of 2015, as reported, would require DMEPOS suppliers that participate in the competitive bidding program to se-

cure a surety bond of no less than $50,000 and no more than $100,000 for each geographic area in which they bid. The bill would also codify in statute a competitive bidding program regulatory requirement that DMEPOS suppliers must meet applicable State licensure requirements. It would promote the participation of suppliers committed to providing beneficiaries with access to DMEPOS products at prices that are conscious of the Medicare program's resources.

B. Background and Need for Legislation

On January 12, 2015, Representative Tiberi and Representative Larson introduced H.R. 284, the Medicare DMEPOS Competitive Bidding Improvement Act of 2015. H.R. 284 would require DMEPOS suppliers that participate in the competitive bidding program to secure a surety bond for each geographic area in which they bid and codify in statute a regulatory requirement that participating DMEPOS suppliers must meet applicable State licensure requirements.

Medicare Part B covers health care products and items that can withstand repeated use and are prescribed by physicians and other professionals for beneficiaries to use in their home. These products, which include wheelchairs and hospital beds, are referred to as DMEPOS. Traditionally, Medicare paid suppliers of DMEPOS products according to a fee schedule based on historical charges. Studies conducted by the Government Accountability Office (GAO), the Inspector General of the Department of Health and Human Services (HHS), and others documented that Medicare was consistently overpaying for many DMEPOS products. As a result, Congress turned to a system where suppliers submit a bid for the amount at which they can supply certain DMEPOS products as a way to establish more rational payment amounts.

In the Balanced Budget Act of 1997 (BBA), Congress required the Secretary of Health and Human Services (the Secretary) to establish a competitive bidding demonstration project in geographic areas likely to reduce expenditures while maintaining access to products.

Based on the results of the BBA demonstration project, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) that required the Secretary to establish a DMEPOS competitive bidding program to be phased-in in successive rounds. The first round included 10 geographic areas, followed by an expansion to 70 additional areas and a national mail order program.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) froze the first round of the DMEPOS competitive bidding program after only a few weeks of operation. Concerned that the Secretary's implementation of the program may have been unfair to suppliers, MIPPA required that the Secretary to, among other things "rebid" the first round and put into place a process to notify suppliers if certain financial information is missing from a bid. MIPPA also established a one-time 9.5 percent reduction to the fee-schedule payment amount for the products that were included in the first round. This fee schedule payment reduction offset the increased spending that resulted from the competitive bidding program's start.

In Public Law 111–148 and Public Law 111–152 (collectively referred to as the Affordable Care Act), Congress required the Secretary the Round 2 competition from 70 additional areas to 91 areas. It also required the Secretary to extend the program, or modify the fee schedule based on competitively bid rates in the non-competitive bidding areas by 2016.

As each round of competitive bidding has awarded suppliers contracts for multiple years, the Secretary has implemented two contract cycles for round 1 and has started the process for the second round 2 cycle. The Secretary has used a consistent process since the initial phase of the program through the round 1 rebid. The Secretary has included DMEPOS products that have a high fee schedule payment amount, are provided frequently, and/or have a high potential to reduce expenditures.

The Secretary established and uses a bidding process that involves a number of steps that include:

- Suppliers submit a bid to supply a product at a price representative of the percentage of the geographic area market they can serve;
- Suppliers must comply with Secretary's regulatory requirement that participants meet applicable State licensure requirements;
- The Secretary arrays eligible bids for a product category and sets a payment amount at the median supplier bid;
- The Secretary offers the median bid payment amount to as many suppliers as needed to meet beneficiary demand, or capacity, in the market. The median bid amount generally results in half of the suppliers receiving a contract amount that is below their bid; and
- If a supplier declines to sign a contract, the Secretary makes an offer to the supplier with the next lowest bid—the payment offered continues to be based on the median bid amount of the suppliers initially offered a contract.

The competitive bidding program has significantly reduced Medicare spending on DMEPOS products, with average payment amount reduction of 45 percent below the fee schedule for the first cycle of Round 2. The reduced per-item payment amount also means that beneficiaries pay less, as the standard 20 percent coinsurance is applied to a smaller amount.

The Committee believes, however, the competitive bidding program can be improved. Some suppliers have rejected a contract offer from the Secretary for a payment amount that exceeds their bid price. The Secretary states that approximately 8 percent of suppliers have rejected a contract offer, with half of those rejecting a payment amount higher than their bid price. A 2014 Government Accountability Office (GAO) report indicates that suppliers have declined over 1,200 individual contracts for products. Under the Secretary's implementation of the program, supplier rejection of contracts above their bid price has the effect of lowering the payment amount made to suppliers who sign an offered contract. Discouraging suppliers from bidding at prices they do not intend to honor improves the program. Further, the Committee believes that the regulatory requirement that suppliers meet applicable State licensure requirements is important to the functioning of the program and should be codified in statute.

C. Legislative History

Background

H.R. 284 was introduced on January 12, 2015, and was referred to the Committee on Energy and Commerce, in addition to the Committee on Ways and Means.

The Chairman's Amendment in the Nature of a Substitute (AINS) to H.R. 284, the Medicare DMEPOS Competitive Bidding Improvement Act of 2015, was made publicly available through the Committee's website on February 25, 2015.

Committee Action

The Committee marked up H.R. 284 on February 26, 2015 and ordered the bill favorably reported to the House of Representatives as amended by a voice vote (with a quorum being present).

Committee Hearings

On May 9, 2012, the Subcommittee on Health had a hearing to examine the impact of the DMEPOS competitive bidding program on Medicare beneficiaries, suppliers, and program expenditures. The Subcommittee heard testimony from the individuals below.

Panel 1:

- Laurence Wilson, Director of the Chronic Care Policy Group, Centers for Medicare and Medicaid Services; and
- Kathleen King, Director, Health Care, Government Accountability Office.

Panel 2:

- Joel D. Marx, Chair, Board of Directors, American Association for Homecare;
- H. Wayne Sale, Chair, Board of Directors, National Association of Independent Medical Equipment Suppliers;
- Dino Martis, President, Ablecare Medical, Inc.; and
- Alfred J. Chiplin, Jr., Senior Policy Attorney, Center for Medicare Advocacy, Inc.

II. EXPLANATION OF THE BILL

PRESENT LAW

Congress requires the Secretary to use a competitive bidding program to sets the Medicare payment amount for certain DMEPOS according to supplier bids as opposed to the traditional fee schedule that is based on historical charges. The Secretary uses a bidding process that involves the following steps:

- Suppliers submit a bid to supply a product at a price representative of the percentage of the geographic area market they can serve;
- Suppliers must comply with Secretary's regulatory requirement that participants meet applicable State licensure requirements;
- The Secretary arrays eligible bids for a product category and sets a payment amount at the median supplier bid;
- The Secretary offers the median bid payment amount to as many suppliers as needed to meet beneficiary demand, or capacity, in the market. The median bid amount generally re-

sults in half of the suppliers receiving a contract amount that is below their bid; and

- If a supplier declines to sign a contract, the Secretary makes an offer to the supplier with the next lowest bid—the payment offered continues to be based on the median bid amount of the suppliers initially offered a contract.

Congress requires that the Secretary take actions to ensure that small suppliers have an opportunity to participate in the competitive bidding program. Through regulation, the Secretary defined small supplier as a supplier that generates gross revenues of $3.5 million or less in annual receipts. The Secretary also established a regulatory target of awarding 30 percent of contracts for each product in each area to small suppliers. The Secretary has generally exceed the target, with small suppliers typically receiving more than 50 percent of contract awards in the rounds that have been implemented.

There is no statutory provision that requires suppliers to meet applicable State licensure requirements to participate in the competitive bidding program, though the Secretary does maintain it as a regulatory requirement.

REASONS FOR CHANGE

The Committee is concerned that some suppliers have rejected contracts offered for payment amounts above their bid price as it lowers the payment amount for suppliers who actually sign contracts. The financial implications of requiring bid bonds would discourage suppliers from submitting bids for prices that they do not intend to honor. The Committee believes that the regulatory requirement that suppliers meet State licensure requirements to participate in the competitive bidding program is important enough to codify it in statute. H.R. 284 would improve the competitive bidding program by promoting participation of suppliers committed to providing access to DMEPOS products at prices that are conscious of the Medicare program's resources.

EXPLANATION OF PROVISION

The bill would require DMEPOS suppliers that participate in the competitive bidding program to secure a surety bond of no less than $50,000 and no more than $100,000 for each geographic area in which they bid. The bill would also codify in statute a competitive bidding program regulatory requirement that DMEPOS suppliers must meet applicable State licensure requirements by establishing it as a criterion to be awarded a contract.

EFFECTIVE DATE

The bill would establish the supplier bid bond requirement for rounds of competitive bidding for which contracts take effect not sooner than 2017 but not later than 2019. The bill establishes the regulatory requirement that suppliers must meet applicable State licensure requirements in statute in a way that would allow the Secretary to continue to use the licensure requirement without disruption.

III. VOTES OF THE COMMITTEE

In compliance with clause 3(b) of rule XIII of the Rules of the House of Representatives, the following statements are made concerning the votes of the Committee on its consideration of H.R. 284. H.R. 284 was ordered favorably reported to the House of Representatives as amended by voice vote (with a quorum being present).

VOTES ON AMENDMENTS

The amendment in the nature of a substitute was agreed to by voice vote.

An amendment by Mr. Tiberi to the AINS to H.R. 284, in which on page 3, lines 8 and 9, strike 'that is offered a contract,' was agreed to by voice vote (with a quorum being present).

IV. BUDGET EFFECTS OF THE BILL

A. Committee Estimate of Budgetary Effects

In compliance with clause 3(d) of rule XIII of the Rules of the House of Representatives, the following statement is made concerning the effects on the budget of the revenue provisions of the bill, H.R. 284 as reported: The Committee agrees with the estimates prepared by the Congressional Budget Office (CBO), which are included below.

B. Statement Regarding New Budget Authority and Tax Expenditures Budget Authority

The bill as reported is in compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives. Further, the bill involves no new or increased tax expenditures and no new budget authority.

C. Cost Estimate Prepared by the Congressional Budget Office

In compliance with clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, requiring a cost estimate prepared by the CBO, the following statement by CBO is provided.

U.S. Congress,
Congressional Budget Office,
Washington, DC, March 11, 2015.

Hon. Paul Ryan,
Chairman, Committee on Ways and Means,
House of Representatives, Washington, DC.

Dear Mr. Chairman: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 284, the Medicare DMEPOS Competitive Bidding Improvement Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Lara Robillard.

Sincerely,

Douglas W. Elmendorf.

Enclosure.

H.R. 284—Medicare DMEPOS Competitive Bidding Improvement Act of 2015

H.R. 284 would impose new requirements on private firms that supply products through Medicare's competitive bidding program for durable medical equipment (DME). CBO estimates that enacting H.R. 284 would increase revenues by about $1 million over the 2015–2025 period. The legislation could affect direct spending, but CBO estimates those effects would not be significant.

Under current law, Medicare pays for some DME (including items like wheelchairs, hospital beds, and oxygen tanks and related supplies) using prices that are set through a two-stage process. In the first stage, firms submit bids to furnish a category of DME items to Medicare beneficiaries in a geographic area. The Medicare program uses those bids to exclude from the second stage the firms that submitted the highest bids. The remaining firms are invited to contract, for a period of three years, to supply that category of DME in that geographic area. The contractual price, or single payment amount (SPA), is the median bid of all the firms that are invited to participate in the second stage. Firms are free to decline to accept the contract.

H.R. 284 would require that firms wishing to bid in a geographic area meet applicable licensure requirements of the state in which they are bidding and obtain a surety bond of between $50,000 and $100,000 from a bonding agency. If the company submitted a bid below the SPA in a geographic area but declined to accept a contract, it would forfeit the bond to the federal government. The estimate assumes those requirements would apply for contracts that go into effect beginning on January 1, 2019; in CBO's judgment, it would take several years to establish the requirements of the bond process through regulations and other program guidance.

CBO is unsure whether under H.R. 284 the bonding agency or the Centers for Medicare and Medicaid Services (CMS), which administers the competitive bidding program, would hold the bond throughout the bidding process. CBO anticipates that these details would be clarified through regulations.

CBO expects that implementing the legislation would not have a significant effect on the prices that CMS establishes for DME items, but that it would result in the forfeiture of a small number of surety bonds. CBO estimates that the revenues from such forfeitures will amount to less than $500,000 in each year, and will total about $1 million over the 2019–2025 period. This estimate assumes enactment in the spring of 2015.

The Statutory Pay-As-You-Go Act of 2010 establishes budget-reporting and enforcement procedures for legislation affecting direct spending or revenues. The net changes in revenues that are subject to those pay-as-you-go procedures are shown in the following table. As noted above, CBO estimates that revenues would rise by less than $500,000 per year.

CBO ESTIMATE OF PAY-AS-YOU-GO EFFECTS FOR H.R. 284, AS ORDERED REPORTED BY THE HOUSE COMMITTEE ON WAYS AND MEANS ON FEBRUARY 26, 2015

	By fiscal year, in millions of dollars—												
	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2015–2020	2015–2025
	NET DECREASE (−) IN THE DEFICIT												
Statutory Pay-As-You-Go Impact	0	0	0	0	0	0	0	0	0	0	0	0	−1

H.R. 284 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act.

The CBO staff contact for this estimate is Lara Robillard. The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

V. OTHER MATTERS TO BE DISCUSSED UNDER THE RULES OF THE HOUSE OF REPRESENTATIVES

A. Committee Oversight Findings and Recommendations

With respect to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives (relating to oversight findings), the Committee concluded that it was appropriate and timely to enact the sections included in the bill, as reported.

On May 9, 2012, the Subcommittee on Health had a hearing to examine the impact of the DMEPOS competitive bidding program on Medicare beneficiaries, suppliers, and program expenditures. During this hearing, the Subcommittee heard testimony that the ability of suppliers to reject contract offers for an amount above their bid is harmful to the competitive bidding program. The Committee believes this bill would promote participation by suppliers committed to providing access to DMEPOS products at reasonable prices.

B. Statement of General Performance Goals and Objectives

In accordance with clause 3(c)(4) of rule XIII of the Rules of the House of Representatives, the performance goals and objectives of the Committee are reflected in the descriptive portions of this report.

C. Duplication of Federal Programs

In compliance with Sec. 3(g)(2) of H. Res. 5 (114th Congress), the Committee states that no provision of the bill establishes or reauthorizes: (1) a program of the Federal Government known to be duplicative of another Federal program, (2) a program included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or (3) a program related to a program identified in the most recent Catalog of Federal Domestic Assistance, published pursuant to the Federal Program Information Act (Public Law 95–220, as amended by Public Law 98–169).

D. Disclosure of Directed Rule Makings

In compliance with Sec. 3(i) of H. Res. 5 (114th Congress), the following statement is made concerning directed rule makings: The

Committee estimates that there may be one directed rule making within the meaning of such section.

E. Information Related to Unfunded Mandates

This information is provided in accordance with section 423 of the Unfunded Mandates Act of 1995 (Pub. L. No. 104–4). The bill does not impose a Federal mandate on the private sector. The bill does not impose a Federal intergovernmental mandate on State, local, or tribal governments.

F. Congressional Earmarks, Limited Tax Benefits, and Limited Tariff Benefits

With respect to clause 9 of rule XXI of the Rules of the House of Representatives, the Committee states that the provisions of the bill do not contain any congressional earmarks, limited tax benefits, or limited tariff benefits within the meaning of the rule.

VI. CHANGES IN EXISTING LAW BY THE BILL, AS REPORTED

With respect to clause 3(e) of rule XIII of the Rules of the House of Representatives, H.R. 876 makes the following changes to current law.

Changes in Existing Law Proposed by the Bill, as Reported

In compliance with clause 3(e)(1)(B) of rule XIII of the Rules of the House of Representatives, changes in existing law proposed by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

Part B—Supplementary Medical Insurance Benefits for the Aged and Disabled

* * * * * * *

COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

Sec. 1847. (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 the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph 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 1841;

(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 1834(a)(13)) for which payment would otherwise be made under section 1834(a), 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 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).

(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) 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 1834(a) and in the case of payment for oxygen under section 1834(a)(5), 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 1834(a).

(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 otherwise 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 1834(a), section 1834(h), or section 1842(s), 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 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 1834(a)(20).

(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 1834(a)(20) 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 1834(a)(20)(F)(i), 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.

(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 1833(b).

(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. 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.

(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 program described in subparagraph (A).

(11) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, 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 1861(d)), and individuals.

(v) The establishment of quality standards under section 1834(a)(20).

(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.

(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 1808(c). 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 1808(c)(2)(C).

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TEXT OF EXISTING LAW AMENDED OR REPEALED BY THE BILL, AS REPORTED

In compliance with clause 3(e)(1)(A) of rule XIII of the Rules of the House of Representatives, the text of each section proposed to be amended or repealed by the bill, as reported, is shown below:

SOCIAL SECURITY ACT

* * * * * * *

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

SEC. 1847. (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 the date of the enactment of this subparagraph are terminated, no payment shall be made under this title on or after the date of the enactment of this subparagraph 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 1841;

(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.

(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 1834(a)(13)) for which payment would otherwise be made under section 1834(a), 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 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).

(B) OTHER EQUIPMENT AND SUPPLIES.—Items and services described in section 1842(s)(2)(D), other than parenteral nutrients, equipment, and supplies.

(C) OFF-THE-SHELF ORTHOTICS.—Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) 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 1834(a) and in the case of payment for oxygen under section 1834(a)(5), 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 1834(a).

(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 otherwise 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 1834(a), section 1834(h), or section 1842(s), 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 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 1834(a)(20).

(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.

(B) TIMELY IMPLEMENTATION OF PROGRAM.—Any delay in the implementation of quality standards under section 1834(a)(20) 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 1834(a)(20)(F)(i), 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.

(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 1833(b).

(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. 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.

(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 program described in subparagraph (A).

(11) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, 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 1861(d)), and individuals.

(v) The establishment of quality standards under section 1834(a)(20).

(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.

(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 1808(c). 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 1808(c)(2)(C).

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