

114TH CONGRESS
1ST SESSION

H. R. 4185

To make adjustments, including by amending title XVIII of the Social Security Act, relating to competitive bidding program and durable medical equipment under the Medicare program, to amend such title to establish a DMEPOS market pricing program demonstration project, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 8, 2015

Mr. TOM PRICE of Georgia (for himself, Mrs. McMORRIS RODGERS, Mrs. BLACKBURN, Ms. DUCKWORTH, Mr. LOEBSACK, Mr. RYAN of Ohio, Mr. ROE of Tennessee, Mrs. NOEM, Mr. KING of New York, Mr. ZINKE, Mr. TIPTON, Mr. BLUM, Mr. CRAMER, Mr. MCCLINTOCK, Mr. KEATING, Mr. DUNCAN of Tennessee, Mrs. ELLMERS of North Carolina, Mr. HARPER, and Mr. AUSTIN SCOTT of Georgia) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To make adjustments, including by amending title XVIII of the Social Security Act, relating to competitive bidding program and durable medical equipment under the Medicare program, to amend such title to establish a DMEPOS market pricing program demonstration project, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Protecting Access
3 through Competitive-pricing Transition Act of 2015” or
4 as the “PACT Act of 2015”.

5 **SEC. 2. REVISION OF PAYMENTS FOR DURABLE MEDICAL**
6 **EQUIPMENT UNDER THE MEDICARE PRO-**
7 **GRAM.**

8 (a) TRANSITION TO IMPLEMENTATION OF FEE
9 SCHEDULE PAYMENT ADJUSTMENTS USING INFORMA-
10 TION FROM COMPETITIVE BIDDING PROGRAMS.—Section
11 1834(a)(1) of the Social Security Act (42 U.S.C.
12 1395m(a)(1)) is amended by adding at the end the fol-
13 lowing new subparagraph:

14 “(J) TRANSITION TO IMPLEMENTATION OF
15 PAYMENT ADJUSTMENTS USING INFORMATION
16 FROM COMPETITIVE BIDDING PROGRAMS.—

17 “(i) IN GENERAL.—In implementing
18 subparagraph (F) and paragraphs (1) and
19 (2) of section 414.210(g) of title 42, Code
20 of Federal Regulations, with respect to
21 items and services furnished on or after
22 January 1, 2016, and before January 1,
23 2019, the fee schedule amount that would
24 otherwise be determined for each area
25 under this section shall be adjusted to the
26 lesser of—

1 “(I) 130 percent of the regional
2 price determined under clause (i) of
3 such paragraph (1) for the State in
4 which such area is located (or, in the
5 case of an area located within the Dis-
6 trict of Columbia, for such District);
7 or

8 “(II) the fee schedule amount
9 that would otherwise be determined
10 for such area under this section (with-
11 out the application of subsection
12 (a)(1)(F) of such section) on January
13 1, 2015, updated by the covered item
14 update described in paragraph
15 (14)(L) for the year in which the
16 items and services to which such fee
17 schedule applies are furnished.

18 “(ii) PHASE-IN.—The adjustment de-
19 scribed in clause (i) shall be implemented
20 over a two-year period and in a manner
21 that phases in such adjustment in equal
22 increments in each year of such two-year
23 period, with such adjustment being fully
24 implemented with respect to items and
25 services furnished in 2017.”.

1 (b) BID CEILING FOR COMPETITIVE ACQUISITION
 2 FOR DURABLE MEDICAL EQUIPMENT UNDER THE MEDI-
 3 CARE PROGRAM.—Section 1847(b)(5) of the Social Secu-
 4 rity Act (42 U.S.C. 1395w–3(b)(5)) is amended—

5 (1) in subparagraph (A)—

6 (A) by inserting “, subject to subpara-
 7 graph (E),” after “subsection (a)(2)”; and

8 (B) by inserting “, subject to subpara-
 9 graph (E),” after “Based on such bids”; and

10 (2) by adding at the end the following new sub-
 11 paragraph:

12 “(E) BID CEILING FOR DURABLE MEDICAL
 13 EQUIPMENT.—

14 “(i) IN GENERAL.—Payment under
 15 this section for applicable covered items
 16 may not exceed the amount that would
 17 otherwise be paid for such items under sec-
 18 tion 1834 (without the application of sub-
 19 section (a)(1)(F) of such section) on Janu-
 20 ary 1, 2015, updated by the covered item
 21 update described in section 1834(a)(14)(L)
 22 for the year in which such covered item is
 23 furnished.

24 “(ii) APPLICATION TO NEW COVERED
 25 ITEMS.—The Secretary shall establish a

process for purposes of applying clause (i) with respect to applicable covered items for which no amount would otherwise be paid under section 1834 (without the application of subsection (a)(1)(F) of such section) on January 1, 2015.

“(iii) APPLICABLE COVERED ITEMS DEFINED.—For purposes of this subparagraph, the term ‘applicable covered items’ means covered items (as defined in section 1834(a)(13)) for which payment would otherwise be made under section 1834(a) that are furnished with respect to competitive bid contracts that begin on or after January 1, 2017.”.

(c) REQUIREMENT IN DETERMINING ADJUSTMENTS USING INFORMATION FROM COMPETITIVE BIDDING PROGRAMS.—Section 1834(a)(1)(G) of the Social Security Act (42 U.S.C. 1395m(a)(1)(G)) is amended by adding at the end the following new sentence: “In the case of items and services furnished on or after January 1, 2019, in making any adjustments under clause (ii) or (iii) of subparagraph (F), the Secretary shall take into account the average travel distance and cost associated with furnishing items and services in a competitive acquisition area, the average

1 volume of items and services furnished by providers in
 2 such an area, the clearing price of items and services, and
 3 the number of providers in competitive acquisition areas
 4 compared to the number of providers in noncompetitive
 5 acquisition areas. In implementing the preceding sentence,
 6 the Secretary shall solicit and take into account stake-
 7 holder input.”.

8 **SEC. 3. ESTABLISHMENT OF DMEPOS MARKET PRICING**
 9 **PROGRAM DEMONSTRATION PROJECT.**

10 (a) IN GENERAL.—Part B of title XVIII of the Social
 11 Security Act is amended by inserting after section 1847B
 12 (42 U.S.C. 1395w–3b) the following new section:

13 “DMEPOS MARKET PRICING PROGRAM DEMONSTRATION
 14 PROJECT

15 “SEC. 1847C.

16 “(a) ESTABLISHMENT.—

17 “(1) IN GENERAL.—The Secretary shall estab-
 18 lish and implement a six-year market pricing pro-
 19 gram demonstration project (in this section referred
 20 to as the ‘demonstration project’) under which three
 21 auctions are conducted in eligible auction areas (as
 22 defined in paragraph (3)) throughout the United
 23 States for the furnishing of market-priced items and
 24 services (as defined in subsection (b)) for which pay-
 25 ment is made under this part. Each such auction
 26 shall, in accordance with subsection

(c)(3)(D)(ii)(IV), be with respect to a contract period of two years for each lead product.

“(2) IMPLEMENTATION TIMELINE.—The demonstration project shall be carried out in accordance with the following timeline:

“(A) CONTRACTING WITH AUCTION EXPERT AND MARKET MONITOR.—Not later than 3 months after the date of the enactment of this section, the Secretary shall contract with the auction expert contracted with under subsection (f)(1) (hereinafter referred to as the ‘auction expert’) and market monitor contracted with under such subsection (hereinafter referred to as the ‘market monitor’).

“(B) INITIAL DESIGN OF AUCTION.—Not later than 5 months after such date of enactment, the development of the initial auction design under subsection (c)(2)(B)(i) shall be completed.

“(C) AUCTION DESIGN CONFERENCE.—Not later than 6 months after such date of enactment, the Secretary shall hold the auction design conference under subsection (c)(2)(C).

“(D) FINALIZING AUCTION DETAILS.—Not later than 7½ months after such date of enact-

1 ment, the Secretary shall promulgate, through
2 the expedited rulemaking process under sub-
3 section (c)(2)(D), the procedures to be used for
4 auctions under the demonstration project.

5 “(E) CONDUCT OF FIRST AUCTION.—Not
6 later than 11 months after such date of enact-
7 ment, the first auction under the demonstration
8 project shall occur under subsection (c)(3).

9 “(F) AWARDING CONTRACTS UNDER FIRST
10 AUCTION.—Not later than 1 year after such
11 date of enactment, contracts under such first
12 auction shall be awarded.

13 “(3) ELIGIBLE AUCTION AREAS.—

14 “(A) DEFINITION.—

15 “(i) IN GENERAL.—In this section,
16 subject to clause (ii), the term ‘eligible
17 auction area’ means, with respect to an
18 auction under this section, a county, aggre-
19 gation of counties, or part of one or more
20 counties specified by the Secretary for pur-
21 poses of such auction, in accordance with
22 this paragraph.

23 “(ii) SPECIAL RULE FOR DIABETIC
24 SUPPLIES.—In applying this section with
25 respect to the product category described

1 in subsection (b)(11), the term ‘eligible
2 auction area’ means, with respect to an
3 auction under this section, a State speci-
4 fied by the Secretary for purposes of such
5 auction, in accordance with subparagraph
6 (B)(iii).

7 “(B) SPECIFICATION OF ELIGIBLE AUC-
8 TION AREAS.—For purposes of this section, the
9 Secretary shall specify eligible auction areas in
10 accordance with the following:

11 “(i) MARKET AREAS MUST REFLECT
12 ECONOMIC INTERDEPENDENCY.—The Sec-
13 retary shall choose counties, aggregations
14 of counties, or parts of counties in such a
15 manner as to provide for auction areas
16 that form economically interdependent
17 areas (as reflected in standard econometric
18 market models). For purposes of specifying
19 eligible auction areas in accordance with
20 the preceding sentence, the Secretary may
21 subdivide a large county to take into ac-
22 count population and geographic size.

23 “(ii) ROUND 2 RECOMPETE COMPETI-
24 TIVE BIDDING AREAS.—The Secretary
25 shall specify at least 10 eligible auction

1 areas that constituted Round 2 Recompete
2 competitive bidding areas under section
3 1847. To the extent possible, areas se-
4 lected for the demonstration project should
5 represent a variety of economic markets
6 (as reflected in standard econometric mar-
7 ket models).

8 “(iii) MAIL ORDER DIABETIC SUP-
9 PLIES.—For purposes of subparagraph
10 (A)(ii), with respect to the product cat-
11 egory described in subsection (b)(11), the
12 Secretary shall specify two States as eligi-
13 ble auction areas for mail order diabetic
14 supplies. Such two States, combined, shall
15 represent at least 7 percent of the total
16 population of individuals who are either en-
17 titled to benefits under part A or enrolled
18 under part B (as determined based upon
19 the most recent available data).

20 “(4) APPLICATION OF CERTAIN POLICIES AP-
21 PPLICABLE TO COMPETITIVE ACQUISITION PRO-
22 GRAMS.—The following provisions of subsection
23 (a)(1) of section 1847 shall apply to the demonstra-
24 tion project in the same manner as such provisions

1 apply to competitive acquisition programs under
2 such section except as otherwise provided:

3 “(A) Subparagraph (C) (relating to waiver
4 of certain provisions).

5 “(B) Subparagraph (E) (relating to
6 verification by OIG), except that the assessment
7 shall be of market pricing and subsequent pric-
8 ing determinations that are the basis for auc-
9 tion prices and single payment amounts for
10 items and services in eligible auction areas and
11 shall be conducted in the first two years of the
12 demonstration project and may continue in sub-
13 sequent years of the project.

14 “(C) Subparagraph (F) (relating to feed-
15 back on missing financial documentation), ex-
16 cept that any reference to a round of a program
17 is deemed a reference to a year of the dem-
18 onstration project.

19 “(b) MARKET-PRICED ITEMS AND SERVICES DE-
20 FINED.—In this section, the term ‘market-priced items
21 and services’ means items and services in each of the fol-
22 lowing categories (each of which in this section referred
23 to as a ‘product category’):

24 “(1) Oxygen supplies and equipment.

1 “(2) Standard power wheelchairs, power scoot-
2 ers, and related accessories.

3 “(3) Manual wheelchairs.

4 “(4) Enteral nutrients, equipment, and sup-
5 plies.

6 “(5) Continuous positive airway pressure de-
7 vices, respiratory assistive devices, and related sup-
8 plies.

9 “(6) Hospital beds and related accessories.

10 “(7) Walkers and related accessories.

11 “(8) Support services (Group 2 mattresses and
12 overlays).

13 “(9) Negative pressure wound therapy pumps
14 and related supplies and accessories.

15 “(10) Off-the-shelf orthotics described in sub-
16 paragraph (C) of section 1847(a)(2) to the extent
17 they are included pursuant to such subparagraph in
18 items and services described under such section and
19 included in a competitive bidding program in a com-
20 petitive acquisition area under section 1847(a).

21 “(11) Mail order diabetic supplies.

22 “(12) Other items and services (other than
23 those items and services specified in paragraph (2))
24 that could have been subject to participation in com-

1 petitive acquisition programs under section
2 1847(a)(1).

3 “(c) DEMONSTRATION PRICING PROJECT REQUIRE-
4 MENTS.—

5 “(1) IN GENERAL.—The Secretary shall estab-
6 lish, through the process described in paragraph (2),
7 an auction design for each auction that meets the
8 requirements of paragraph (3), and shall ensure that
9 the first auction under the demonstration project
10 will be conducted for all eligible auction areas speci-
11 fied under subsection (a)(3) not later than the date
12 specified in subsection (a)(2)(E).

13 “(2) AUCTION DESIGN PROCESS; STAKEHOLDER
14 INPUT.—

15 “(A) TRANSPARENT PROCESS RE-
16 QUIRED.—In establishing the auction design de-
17 scribed in paragraph (1), the Secretary shall
18 utilize an open and transparent process that in-
19 volves all eligible participants described in sub-
20 paragraph (C)(ii), including through the auc-
21 tion design conference and other outreach ef-
22 forts.

23 “(B) INITIAL AUCTION DESIGN.—The auc-
24 tion expert shall, with respect to an auction and
25 consistent with subsection (a)(2)(B), develop an

1 auction design (referred to in this section as the
2 ‘initial auction design’) that shall propose for
3 such auction eligible auction areas, lead prod-
4 ucts for each product category, weights to be
5 assigned to products under paragraph
6 (3)(B)(iv), and proposed rules for the conduct
7 of the auction.

8 “(C) AUCTION DESIGN CONFERENCE.—

9 “(i) IN GENERAL.—The Secretary
10 shall, consistent with subsection (a)(2)(C),
11 convene a design conference (in this para-
12 graph referred to as the ‘design con-
13 ference’) for the auction process for each
14 auction under this section. The auction ex-
15 pert shall chair the conference and the
16 market monitor shall participate in the
17 conference (including as described in
18 clause (v)).

19 “(ii) PARTICIPANTS.—The partici-
20 pants at the design conference shall in-
21 clude at least the following:

22 “(I) MANUFACTURERS, SUP-
23 PLIERS AND TRADE ASSOCIATIONS OF
24 DMEPOS.—Representatives of manu-
25 facturers, suppliers, and trade asso-

1 ciations of market-priced items and
2 services.

3 “(II) BENEFICIARIES.—Rep-
4 resentatives of individuals enrolled
5 under this part.

6 “(III) CMS.—The Administrator
7 of the Centers for Medicare & Med-
8 icaid Services and other appropriate
9 Federal personnel.

10 “(iii) PURPOSE OF CONFERENCE.—
11 The purpose of the design conference shall
12 be to review the initial auction design for
13 the establishment of an efficient auction
14 consistent with best practices and actuarial
15 science and to provide stakeholders the op-
16 portunity to provide feedback on the initial
17 auction design.

18 “(iv) AUCTION EXPERT RESPONSIBIL-
19 ITIES AT CONFERENCE.—With respect to
20 the design conference, the auction expert
21 shall—

22 “(I) provide a demonstration of
23 the initial auction design;

24 “(II) lead a mock auction based
25 upon such initial auction design in

1 which the attendees will participate
2 and offer comments and suggestions
3 for improvement;

4 “(III) invite input from suppliers
5 as to the relationship between, with
6 respect to a product category, the lead
7 product in such product category and
8 the value of other products in the
9 same product category as such lead
10 product (and may establish working
11 committees on major issues related to
12 such relationship); and

13 “(IV) invite input from small
14 suppliers as to the ways in which such
15 initial auction design can be improved
16 to ensure that small suppliers have
17 the opportunity to participate in the
18 auction.

19 “(v) MARKET MONITOR RESPONSIBIL-
20 ITIES AT CONFERENCE.—With respect to
21 the design conference, the market monitor
22 shall provide a presentation on the respon-
23 sibilities of the market monitor throughout
24 the year and comment on key aspects of

1 the initial auction design and their pur-
2 pose.

3 “(vi) INTERNET ACCESSIBILITY OF
4 CONFERENCE.—The design conference
5 shall be recorded and made available on an
6 Internet Web site (through simultaneous
7 Web cast or otherwise).

8 “(D) AUCTION DESIGN PROPOSED
9 THROUGH EXPEDITED RULEMAKING.—

10 “(i) SUBMISSION TO SECRETARY.—
11 The auction expert shall, with respect to
12 an auction and in accordance with the
13 timeline described in subsection (a)(2),
14 submit to the Secretary an auction design
15 for the auction (referred to in this section
16 as the ‘revised auction design’) that takes
17 into account the feedback on the initial
18 auction design provided at the auction con-
19 ference for such auction.

20 “(ii) PUBLICATION AND PROPOSAL.—
21 Upon receiving the submission of the re-
22 vised auction design for an auction by the
23 auction expert pursuant to clause (i), the
24 Secretary shall—

1 “(I) make such modifications to
2 such revised auction design as are
3 necessary to ensure that the such auc-
4 tion design meets the requirements
5 described in clause (viii);

6 “(II) make such other modifica-
7 tions to such revised auction design as
8 the Secretary determines appropriate;
9 and

10 “(III) publish and propose a rule
11 for implementing such auction design
12 for such auction, as modified pursu-
13 ant to subclauses (I) and (II),
14 through an expedited rulemaking
15 process.

16 “(iii) SUBMISSION OF COMMENTS TO
17 AUCTION EXPERT AND MARKET MON-
18 ITOR.—The Secretary shall submit com-
19 ments received on an auction design pub-
20 lished under clause (ii)(III) to the auction
21 expert and the market monitor to consider
22 for modification of such auction design.

23 “(iv) REVIEW OF COMMENTS BY AUC-
24 TION EXPERT AND MARKET MONITOR.—
25 The market monitor and auction expert

1 shall review such comments and, within
2 one month of the receipt of such comments
3 pursuant to clause (iii), shall each provide
4 public comment on such comments.

5 “(v) DETERMINATION OF CHANGES
6 TO AUCTION DESIGN.—Taking into consid-
7 eration the comments submitted to the
8 auction expert and market monitor pursu-
9 ant to clause (iii), such auction expert shall
10 determine if any changes should be made
11 in the auction design published under
12 clause (ii)(III) for an auction in response
13 to such comments. If the auction expert
14 determines that changes should be made in
15 such design in response to such comments,
16 the auction expert shall submit to the Sec-
17 retary an auction design (referred to in
18 this section as the ‘further revised auction
19 design’) for such auction.

20 “(vi) ADOPTION AND PUBLICATION OF
21 AUCTION DESIGN.—The Secretary shall
22 adopt as the auction design to be used for
23 purposes of an auction conducted under
24 the demonstration project either—

1 “(I) the further revised auction
2 design for such auction, modified as
3 necessary by the Secretary to ensure
4 that such auction design meets the re-
5 quirements described in clause (viii)
6 (and, if such design is so established,
7 shall publish by rule such design); or

8 “(II) the auction design pub-
9 lished under clause (ii)(III) for such
10 auction (and, if such design is so se-
11 lected despite a further revised auc-
12 tion design having been submitted to
13 the Secretary under clause (v), shall
14 notify the auction expert and market
15 monitor of, and publish in the Federal
16 Register, the reasons for electing to
17 establish the revised auction design
18 instead of the further revised auction
19 design).

20 “(vii) EXPEDITED RULEMAKING
21 PROCESS DEFINED.—In this subparagraph,
22 the term ‘expedited rulemaking process’
23 means a process of publication of the re-
24 vised auction design (and, as applicable,
25 the further revised auction design) and so-

1 licitation of public comments on such de-
2 sign. The provisions of section 1871(b)(1)
3 shall not apply to such process.

4 “(viii) REQUIREMENTS DESCRIBED.—
5 For purposes of this paragraph, the re-
6 quirements described in this clause are re-
7 quirements that, with respect to an auction
8 design—

9 “(I) the rates of payment under
10 such auction design do not result in a
11 diminution of access to market-priced
12 items and services for individuals enti-
13 tled to benefits under part A or en-
14 rolled under part B in the eligible
15 auction areas in which the demonstra-
16 tion project is conducted or of the
17 quality of such items and services that
18 are furnished to such individuals in
19 such areas;

20 “(II) the lead product proposed
21 in such auction design for each prod-
22 uct category has been selected to be
23 so proposed based upon the historical
24 price and utilization of the product
25 under this part; and

1 “(III) the weights assigned under
2 paragraph (3)(B)(iv) to products that
3 are not lead products take into consid-
4 eration input provided on such
5 weights by providers at the design
6 conference for the applicable auction.

7 “(3) CONDUCT OF AUCTION.—

8 “(A) IN GENERAL.—The market monitor
9 shall, consistent with subsection (a)(2)(E) and
10 in accordance with the auction design adopted
11 under paragraph (2)(D), conduct auctions (each
12 in this section referred to as a ‘market-priced
13 auction’) among potential bidders that are iden-
14 tified as eligible bidders under subparagraph
15 (B)(ii) by carrying out the activities described
16 in subparagraph (B) and subparagraph (C)(i)
17 and such other activities as specified by the
18 Secretary.

19 “(B) MARKET MONITOR ACTIONS BEFORE
20 AUCTION DATE.—In conducting a market-priced
21 auction, the market monitor shall (subject, as
22 appropriate, to review by the Secretary), on a
23 date that is prior to the date of such auction,
24 carry out the following:

1 “(i) DETAIL AUCTION RULES.—Detail
2 auction rules and processes that are con-
3 sistent with the auction design adopted
4 under paragraph (2)(D). The rules and
5 processes described in the preceding sen-
6 tence shall, with respect to an auction, in-
7 clude the following:

8 “(I) The requirements that an
9 entity must meet in order to be con-
10 sidered an eligible bidder under sub-
11 paragraph (E)(ii) for purposes of such
12 auction.

13 “(II) Processes through which it
14 will be determined for such auction,
15 as a function of bids submitted by eli-
16 gible bidders at such auction, the eli-
17 gible bidders for lead products that
18 are to be awarded contracts under
19 this section and the prices for all
20 products that are in the same product
21 category as such lead product.

22 “(III) Performance obligations of
23 such eligible bidders that are awarded
24 such contracts, guarantee require-
25 ments applied under the demonstra-

tion program, and penalties that will apply in the case of such an eligible bidder that is awarded such a contract and that fails satisfy the terms of such contract or such requirements.

“(ii) IDENTIFY ELIGIBLE BIDDERS.—

Review all applications for potential bidders seeking to be eligible bidders in the auction and identify, for purposes of such auction, the eligible bidders (as defined in subparagraph (E)(ii)) by eligible auction area.

“(iii) SPECIFY TARGET CAPACITY FOR

ELIGIBLE BIDDERS.—Specify, with respect to each eligible bidder for such auction, a target percentage for a product category that represents the percentage of the projected market for such product in an eligible auction area and contract period that it is estimated that the eligible bidder would have the capacity to serve. Each such target percentage shall be determined as follows:

“(I) In the case of an eligible

bidder with historic capacity in an

1 auction area with respect to the lead
2 product in such product category, the
3 target percentage shall be determined
4 based on the historic capacity for such
5 bidder for such product.

6 “(II) In the case of an eligible
7 bidder that has no historic capacity in
8 an auction area with respect to such
9 lead product, the target percentage
10 shall be 1 percent of the projected
11 market for such product.

12 “(iv) SET PRODUCT WEIGHTS.—

13 “(I) IN GENERAL.—Assign to
14 each product (categorized by the
15 health care common procedure coding
16 system code) that is in the same prod-
17 uct category as a lead product a
18 weight that is expressed as a number.

19 “(II) WEIGHT AMOUNT FOR
20 LEAD PRODUCT.—With respect to a
21 product category described in clause
22 (i), the lead product in such product
23 category shall, for purposes of such
24 clause, be assigned a weight of 1.0.

1 “(C) AUCTION.—In conducting a market-
2 priced auction, the market monitor or Secretary
3 (as applicable) shall, during such auction, carry
4 out the following:

5 “(i) ESTABLISHMENT OF CLEARING
6 PRICE.—The market monitor (subject, as
7 appropriate, to review by the Secretary)
8 shall establish a clearing price for each
9 lead product selected under subparagraph
10 (A) for each eligible area. Such clearing
11 price shall, subject to clause (iii) and with
12 respect to a lead product, be equal to the
13 price (referred to in this clause as the ‘tar-
14 get price’) specified in the bid submitted
15 by an eligible bidder with respect to such
16 product and such area that, in conjunction
17 with all bids submitted by eligible bidders
18 for such product and such area that speci-
19 fy prices that are less than such target
20 price, will provide for the total projected
21 volume determined by the Secretary to be
22 needed to fulfill demand for such product
23 under this title in such area (as deter-
24 mined through the use of target percent-

ages specified under subparagraph
(B)(iii)).

“(ii) AWARDING OF CONTRACTS.—

“(I) IN GENERAL.—The Secretary shall award, pursuant to an auction for a contract period and eligible auction area, a contract for products in a product category to each eligible bidder whose bid submitted for the lead product in such product category for such area is at or below the clearing price established for such lead product and area pursuant to clause (i).

“(II) MANDATORY ACCEPTANCE OF CONTRACT.—An eligible bidder that has been awarded a contract under subclause (I) based on a bid described in such subclause by such bidder shall be treated, upon the conclusion of the auction with respect to which such contract is awarded, as having agreed to and accepted the contract, including the requirements described in subclauses (III) and (IV),

1 based on the price of items included
2 in such bid.

3 “(III) VOLUME OF PRODUCTS
4 UNDER CONTRACT.—A contract
5 awarded to an eligible bidder under
6 subclause (I) with respect to market-
7 priced items and services in a product
8 category for an eligible auction area
9 and contract period shall include a re-
10 quirement that such bidder will fur-
11 nish such items and services in suffi-
12 cient quantities to meet the needs of
13 individuals for such items and services
14 in the eligible auction area during
15 such period. An eligible bidder shall
16 not satisfy the sufficient quantities re-
17 quirement described in the preceding
18 sentence unless the bidder furnishes
19 the percentage of the market for such
20 item or service in such area that is
21 equal to the target percentage speci-
22 fied for such bidder for the lead prod-
23 uct for such category under subpara-
24 graph (B)(iii) or, if lesser, the per-
25 centage of such market in such area

1 and period that seeks such item or
2 service from such bidder.

3 “(IV) DURATION OF CON-
4 TRACT.—A contract awarded under
5 subclause (I) shall be valid for 2
6 years.

7 “(iii) RULE IF TOTAL BIDS INAD-
8 EQUATE TO FULFILL DEMAND.—In the
9 case that the capacity represented by all
10 bids submitted by eligible bidders for a
11 lead product for an eligible area does not
12 provide for the total projected volume de-
13 termined by the Secretary to be needed to
14 fulfill demand for such product under this
15 title in such area, the Secretary shall—

16 “(I) establish a clearing price for
17 such lead product and area that is
18 equal to the initial bid price estab-
19 lished at such auction by the market
20 monitor for such product and area
21 and, pursuant to clause (ii)(I), award
22 contracts to all eligible bidders for
23 such lead product and area whose bid
24 submitted for such product and area
25 is at or below such price;

1 “(II) announce the remaining ag-
 2 gregate supply needed for such prod-
 3 uct and area in order to fulfill de-
 4 mand for such product under this title
 5 in such area; and

6 “(III) conduct among eligible
 7 bidders an additional auction round,
 8 in such manner as is specified by the
 9 Secretary, to fulfill such remaining
 10 supply.

11 “(D) ANNOUNCEMENT OF INFORMATION
 12 AFTER AUCTION.—Immediately after a market-
 13 priced auction is completed, the Secretary shall
 14 publish on the Internet Web site of the Centers
 15 for Medicare & Medicaid Services and in the
 16 Federal Register the following:

17 “(i) A list of eligible bidders awarded
 18 contracts under such auction.

19 “(ii) The price determined at such
 20 auction for each product in a product cat-
 21 egory that is subject to the auction.

22 “(E) BID-RELATED TERMS DEFINED.—For
 23 purposes of this section:

24 “(i) The term ‘bid’ means, with re-
 25 spect to a lead product in a product cat-

1 egory that is subject to a market-priced
2 auction under the demonstration project,
3 an offer made at the auction by an eligible
4 bidder to furnish a lead product in a vol-
5 ume specified in such bid for a particular
6 price and time period for one or more eligi-
7 ble auction areas.

8 “(ii) The term ‘eligible bidder’ means,
9 with respect to an auction and an eligible
10 auction area and lead product, a supplier
11 that—

12 “(I) applies to the Secretary to
13 participate in such auction with re-
14 spect to such area and lead product;

15 “(II) is identified by the Sec-
16 retary as a supplier of a market-
17 priced item or service that is the sub-
18 ject of a market-priced auction in an
19 eligible auction area;

20 “(III) would meet the licensure
21 and performance guarantee require-
22 ments under section 1847(a)(1)(G) if
23 such requirements applied for pur-
24 poses of auctions conducted under the
25 demonstration project in the same

1 manner that they apply with respect
2 to such section; and

3 “(IV) meets such other licensure,
4 bid-bond, and other requirements as
5 the Secretary may specify.

6 “(4) MONITORING ACCESS AND QUALITY.—

7 “(A) IN GENERAL.—The Secretary, in con-
8 sultation with the market monitor, shall mon-
9 itor the performance of eligible bidders that are
10 awarded contracts under paragraph (3)(C)(ii)
11 and the effects of the demonstration project to
12 ensure compliance with the requirements of this
13 section, including the requirements and obliga-
14 tions established in the auction design adopted
15 under paragraph (2)(D)(v).

16 “(B) PROVIDE TRANSPARENCY OF INFOR-
17 MATION.—The market monitor shall make pub-
18 licly available the number of suppliers providing
19 market-priced items and services in an eligible
20 auction area during each year of the operation
21 of the demonstration project.

22 “(C) ENFORCEMENT.—If the Secretary,
23 after consultation with the market monitor, de-
24 termines that there has been a material failure
25 of an eligible bidder that has been awarded a

1 contract under paragraph (3)(C)(ii) to comply
2 with such requirements, the Secretary, after
3 consultation with the market monitor, shall im-
4 plement, consistent with subparagraph (D), en-
5 forcement measures, which may include the ter-
6 mination of a contract awarded under para-
7 graph (3)(C)(ii).

8 “(D) ENFORCEMENT MEASURES.—

9 “(i) WARNING LETTERS AND OPPOR-
10 TUNITY FOR CORRECTIVE ACTION.—The
11 Secretary shall provide for the following
12 before terminating, pursuant to subpara-
13 graph (B), a contract awarded under para-
14 graph (3)(C)(ii):

15 “(I) WARNING LETTER.—The
16 Secretary shall issue a formal warning
17 letter at least 90 days before the date
18 on which the Secretary terminates
19 such contract. The warning letter
20 shall describe the reason (or reasons)
21 for the termination.

22 “(II) OPPORTUNITY FOR COR-
23 RECTIVE ACTION.—The Secretary
24 shall provide an opportunity for the
25 supplier to take corrective action to

1 come into compliance with the con-
2 tract and avoid termination of the
3 contract.

4 “(ii) ADDITIONAL CONSEQUENCES OF
5 TERMINATION.—In the case of a termi-
6 nation of such a contract with an eligible
7 bidder, the Secretary may require for-
8 feiture of amounts submitted as a bid and
9 performance bond pursuant to section
10 1847(a)(1)(G)(ii).

11 “(d) APPLICATION OF COMPETITIVE ACQUISITION
12 PROGRAM PROVISIONS.—In implementing the demonstra-
13 tion project under this section, the provisions of section
14 1847(b) shall be applied as follows:

15 “(1) Paragraph (3) shall apply, except that, for
16 purposes of contracts awarded under the demonstra-
17 tion project, subparagraph (B) of such paragraph
18 shall be applied by substituting ‘2 years’ for ‘3
19 years’.

20 “(2) Paragraph (4) shall apply.

21 “(3) Paragraph (5) shall apply, except that—

22 “(A) the reference in subparagraph (A) of
23 such paragraph to subsection (a)(2) is deemed
24 a reference to subsection (b) of this section; and

1 “(B) the reference in subparagraph (B)(i)
2 of such paragraph to subparagraph (A) is
3 deemed a reference to subsection (a) of this sec-
4 tion.

5 “(4) Paragraph (7) shall not apply.

6 “(5) Paragraph (8) shall apply.

7 “(6) Paragraph (9) shall apply, except that
8 such paragraph shall be applied as if a reference to
9 a bidding program includes a reference to the dem-
10 onstration project.

11 “(7) Paragraph (10) shall apply, except that
12 such paragraph shall be applied as if a reference to
13 a competitive acquisition program includes a ref-
14 erence to the demonstration project.

15 “(8) Paragraph (11) shall not apply, except
16 that—

17 “(A) the pendency of any claim for review
18 under this section shall not delay any auction
19 conducted pursuant to this section; and

20 “(B) there shall be no administrative or ju-
21 dicial review of any claim to enjoin the oper-
22 ation of a market-priced auction conducted dur-
23 ing the first round of the demonstration
24 project.

1 “(e) TRANSPARENCY REQUIREMENTS FOR DEM-
2 ONSTRATION PROJECT.—In implementing the demonstra-
3 tion project, the Secretary shall provide for the publica-
4 tion, on an Internet Web site operated by the Secretary,
5 of the following information with respect to an auction:

6 “(1) The qualifications necessary to be an eligi-
7 ble bidder.

8 “(2) The standards developed for purposes of
9 subsection (c)(2)(B)(ii)(II).

10 “(3) The calculation of the total market capac-
11 ity of an eligible auction area for purposes of speci-
12 fying the target percentage under subsection
13 (c)(3)(B)(iii) for eligible bidders in the auction for
14 such area.

15 “(4) The process for soliciting and accepting
16 bids for purposes of subsection (c)(3)(D)(ii).

17 “(5) For purposes of such subsection—

18 “(A) the number of eligible bidders at the
19 auction;

20 “(B) the number of eligible bidders at the
21 auction that were awarded a contract under
22 such subsection at the auction; and

23 “(C) with respect to prospective bidders at
24 the auction that were determined by the Sec-
25 retary not to be eligible bidders—

1 “(i) the specific reasons for such de-
2 termination; and

3 “(ii) a means and process by which
4 such prospective bidders may appeal, or
5 otherwise obtain a review of, such deter-
6 mination.

7 “(6) The calculation of and compliance with the
8 requirement of section 1847(b)(6)(D), as made ap-
9 plicable to the demonstration project by subsection
10 (d).

11 “(f) RELIANCE ON AUCTION EXPERT AND MARKET
12 MONITOR IN ESTABLISHING AND OPERATING MARKET-
13 PRICING DEMONSTRATION PROJECT; ADVISORY COM-
14 MITTEE REPORT AND MONITORING.—

15 “(1) AUCTION EXPERT AND MARKET MON-
16 ITOR.—

17 “(A) IN GENERAL.—The Secretary shall,
18 consistent with subsection (a)(2)(A) and
19 through the Office of the Assistant Secretary
20 for Planning and Evaluation, enter into a con-
21 tract with an individual to serve as the auction
22 expert and a contract with an individual to
23 serve as a market monitor to assist in the de-
24 sign, development, implementation and func-
25 tioning of the auctions to be conducted pursu-

ant to subsection (c). Under each such contract, the auction expert and market monitor shall report and be accountable to the Secretary in the manner described in this section.

“(B) SELECTION OF AUCTION EXPERT AND MARKET MONITOR; TERM; ACCESS TO INFORMATION.—

“(i) COMPETITIVE PROCESS.—The selection of the individual to serve as the auction expert and as a market monitor under subparagraph (A) shall be undertaken through a competitive process.

“(ii) DISQUALIFICATIONS.—An individual may not be selected as the auction expert if such individual—

“(I) is a current or former employee of the Centers for Medicare & Medicaid Services;

“(II) is a current or former contractor for the Centers for Medicare & Medicaid Services that participated in the implementation of the competitive acquisition program under section 1847(a);

1 “(III) does not have significant
2 experience in implementing auctions
3 of similar complexity in Government
4 programs; or

5 “(IV) does not have appropriate
6 educational credentials.

7 “(iii) ACCESS TO INFORMATION.—The
8 Secretary shall make available to the auc-
9 tion expert and the market monitor all ap-
10 plicable information (including confidential
11 information) on the relevant markets
12 throughout the duration of the demonstra-
13 tion project.

14 “(iv) TERM OF CONTRACT.—The con-
15 tract for the auction expert and for the
16 market monitor under this paragraph shall
17 be for a period of 6 years.

18 “(2) REPORTS.—

19 “(A) SEMIANNUAL REPORTS TO SEC-
20 RETARY.—The market monitor shall provide to
21 the Secretary semiannual reports in the initial
22 two years of the demonstration project and an-
23 nual reports in each subsequent year of the
24 demonstration project on the development and

1 operations of the demonstration project. In each
2 report, the market monitor shall—

3 “(i) identify potential problems with
4 the demonstration project; and

5 “(ii) recommend solutions to potential
6 problems so identified.

7 “(B) ANNUAL REPORT.—The market mon-
8 itor shall submit to the Committees on Ways
9 and Means and Energy and Commerce of the
10 House of Representatives and the Committee
11 on Finance of the Senate an annual report on
12 the operation and functioning of the demonstra-
13 tion project. Each such report shall include in-
14 formation on—

15 “(i) potential problems with the
16 project;

17 “(ii) recommended solutions to prob-
18 lems identified pursuant to clause (i);

19 “(iii) the appropriateness of HCPCS
20 codes selected for auctions;

21 “(iv) an evaluation on the ability of
22 individuals eligible for benefits under this
23 part to obtain items and services subject to
24 the demonstration project;

1 “(v) any adverse health effects result-
2 ing from implementation of the project;

3 “(vi) any material deterioration in the
4 quality of items and services provided
5 under the project;

6 “(vii) the costs of any preventable or
7 prolonged hospitalizations due to lack of
8 timely access to market-priced items and
9 services; and

10 “(viii) any negative business con-
11 sequences to the supplier of any market-
12 priced items and services occurring as a re-
13 sult of errors made in the conduct of the
14 project.”.

15 (b) LICENSURE REQUIREMENTS AND FINANCIAL AS-
16 SURANCES UNDER COMPETITIVE BIDDING.—Section
17 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w-
18 3(a)(1)) is amended by adding at the end the following
19 new subparagraphs:

20 “(G) REQUIRING STATE LICENSURE AND
21 PERFORMANCE GUARANTEES FOR BIDDING EN-
22 TITIES.—With respect to rounds of competi-
23 tions beginning under this subsection on or
24 after the date of enactment of this subpara-
25 graph, the Secretary may not accept a bid from

1 an entity for an area unless, as of the deadline
2 for bid submission—

3 “(i) the entity meets applicable State
4 licensure requirements for such area for all
5 items in such bid for a product category;
6 and

7 “(ii) the entity has submitted a cash
8 deposit as a bid and performance bond in
9 an amount determined by the Secretary
10 after consultation with the auction expert,
11 except that the Secretary may, in the Sec-
12 retary’s sole discretion, accept a letter of
13 credit from a financial institution accept-
14 able to the Secretary in lieu of the cash de-
15 posit required to be submitted under this
16 clause.

17 “(H) TREATMENT OF BID AND PERFORM-
18 ANCE BONDS SUBMITTED.—

19 “(i) FOR SUCCESSFUL BIDDERS.—The
20 Secretary shall retain as a performance
21 guarantee the deposit submitted by a sup-
22 plier that is selected at an auction con-
23 ducted pursuant to subparagraph (G)(ii)
24 and such deposit—

1 “(I) shall be returned to the enti-
 2 ty within 90 days of the date of com-
 3 pletion of the contract; or

4 “(II) shall be retained by the
 5 Secretary if the contract is terminated
 6 before the expiration of the contract.

7 “(ii) UNSUCCESSFUL BIDDERS.—If a
 8 bidding entity submits a bid that is not ac-
 9 cepted for an area, the bid and perform-
 10 ance deposit submitted for the entity for
 11 such area shall be returned within 90 days
 12 of the date of notice of nonacceptance.”.

13 (c) CLARIFICATION ABOUT INDIVIDUAL SELF-AD-
 14 JUSTMENT FOR OFF-THE-SHELF ORTHOTICS.—

15 (1) IN GENERAL.—Section 1847(a)(2)(C) of the
 16 Social Security Act (42 U.S.C. 1395w–3(a)(2)(C)) is
 17 amended—

18 (A) by inserting “furnished to an indi-
 19 vidual” after “section 1861(s)(9)”;

20 (B) by inserting after “minimal self-adjust-
 21 ment” the following: “by that individual (and
 22 not by another person)”; and

23 (C) by striking “to fit to the individual”
 24 and inserting “to fit to that individual”.

1 (2) EFFECTIVE DATE.—The amendments made
2 by paragraph (1) shall apply to off-the-shelf
3 orthotics (as defined in section 1847(a)(2)(C) of the
4 Social Security Act (42 U.S.C. 1395w–3(a)(2)(C)),
5 as amended by paragraph (1)) furnished in rounds
6 of competitive bidding under section 1847 of such
7 Act (42 U.S.C. 1395w–3) initiated on or after such
8 date, as soon as practicable after the date of the en-
9 actment of this Act, as the Secretary of Health and
10 Human Services determines appropriate. Such
11 amendments only apply to the demonstration project
12 under section 1847C of such Act, as added by sub-
13 section (a), if the Secretary implements competitive
14 bidding for such off-the-shelf orthotics under the
15 competitive bidding program under such section
16 1847.

○