

**SEC. 154. DELAY IN AND REFORM OF MEDICARE DMEPOS COMPETITIVE ACQUISITION PROGRAM.**

(a) Temporary Delay and Reform-

(1) IN GENERAL- Section 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w-3(a)(1)) is amended--

(A) in paragraph (1)--

(i) in subparagraph (B)(i), in the matter before subclause (I), by inserting `consistent with subparagraph (D)' after `in a manner';

(ii) in subparagraph (B)(i)(II), by striking `80' and `in 2009' and inserting `an additional 70' and `in 2011', respectively;

(iii) in subparagraph (B)(i)(III), by striking `after 2009' and inserting `after 2011 (or, in the case of national mail order for items and services, after 2010)'; and

(iv) by adding at the end the following new subparagraphs:

`(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; and

`(II) 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.'; and

(B) in paragraph (2)(A), by inserting before the period at the end the following: `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)'.

(2) BUDGET NEUTRAL OFFSET-

(A) IN GENERAL- Section 1834(a)(14) of such Act (42 U.S.C. 1395m(a)(14)) is amended--

(i) by striking `and' at the end of subparagraphs (H) and (I);

(ii) by redesignating subparagraph (J) as subparagraph (M); and

(iii) by inserting after subparagraph (I) the following new subparagraphs:

`(J) for 2009--

`(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1847(a)(1)(B)(i)(I) before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, - 9.5 percent; or

`(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;

`(K) for 2010, 2011, 2012, and 2013, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year;

`(L) for 2014--

`(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, plus 2.0 percentage points; or

`(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013; and'.

(B) CONFORMING TREATMENT FOR CERTAIN ITEMS AND SERVICES- The second sentence of section 1842(s)(1) of such Act (42 U.S.C. 1395u(s)(1)) is amended by striking `except that' and all that follows and inserting the following: `except that for items and services described in paragraph (2)(D)--

`(A) for 2009 section 1834(a)(14)(J)(i) shall apply under this paragraph instead of the percentage increase otherwise applicable; and

`(B) for 2014, if subparagraph (A) is applied to the items and services and there has not been a payment adjustment under paragraph (3)(B) for the items and services for any previous year, the percentage increase computed under section 1834(a)(14)(L)(i) shall apply instead of the percentage increase otherwise applicable.'.

(3) CONFORMING DELAY- Subsections (a)(1)(F) and (h)(1)(H) of section 1834 of the Social Security Act (42 U.S.C. 1395m) are each amended by striking `January 1, 2009' and inserting `January 1, 2011'.

(4) CONSIDERATIONS IN APPLICATION- Section 1834 of such Act (42 U.S.C. 1395m) is amended--

(A) in subsection (a)(1)--

(i) in subparagraph (F), by inserting `subject to subparagraph (G),' before `that are included'; and

(ii) by adding at the end the following new subparagraph:

`(G) USE OF INFORMATION ON COMPETITIVE BID RATES- The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.'; and

(B) in subsection (h)(1)(H), by inserting `subject to subsection (a)(1)(G),' before `that are included'.

(b) Quality Standards-

(1) APPLICATION OF ACCREDITATION REQUIREMENT-

(A) IN GENERAL- Section 1834(a)(20) of the Social Security Act (42 U.S.C. 1395m(a)(20)) is amended--

(i) in subparagraph (E), by inserting `including subparagraph (F),' after `under this paragraph,'; and

(ii) by adding at the end the following new subparagraph:

`(F) APPLICATION OF ACCREDITATION REQUIREMENT- In implementing quality standards under this paragraph--

`(i) subject to clause (ii), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards; and

`(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services--

`(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

`(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.'.

(B) CONSTRUCTION- Section 1834(a)(20)(F)(ii) of the Social Security Act, as added by subparagraph (A), shall not be construed as preventing the Secretary of Health and Human Services from implementing the first round of competition under section 1847 of such Act on a timely basis.

(2) DISCLOSURE OF SUBCONTRACTORS UNDER COMPETITIVE ACQUISITION PROGRAM- Section 1847(b)(3) of such Act (42 U.S.C. 1395w-3(b)(3)) is amended by adding at the end the following new subparagraph:

`(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).'

(3) COMPETITIVE ACQUISITION OMBUDSMAN- Such section is further amended by adding at the end the following new subsection:

`(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).'

(c) Change in Reports and Deadlines-

(1) GAO REPORT- Section 302(b)(3) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended--

(A) in subparagraph (A)--

(i) by inserting 'and as amended by section 2 of the Medicare DMEPOS Competitive Acquisition Reform Act of 2008' after 'as amended by paragraph (1)'; and

(ii) by inserting before the period at the end the following: 'and the topics specified in subparagraph (C)';

(B) in subparagraph (B), by striking 'Not later than January 1, 2009,' and inserting 'Not later than 1 year after the first date that payments are made under section 1847 of the Social Security Act,'; and

(C) by adding at the end the following new subparagraph:

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

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

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

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

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

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

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

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

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

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

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

(2) DELAY IN OTHER DEADLINES-

(A) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE- Section 1847(c)(5) of the Social Security Act (42 U.S.C. 1395w-3(c)(5)) is amended by striking `December 31, 2009' and inserting `December 31, 2011'.

(B) SECRETARIAL REPORT- Section 1847(d) of such Act (42 U.S.C. 1395w-3(d)) is amended by striking `July 1, 2009' and inserting `July 1, 2011'.

(C) IG REPORT- Section 302(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended by striking `July 1, 2009' and inserting `July 1, 2011'.

(3) EVALUATION OF CERTAIN CODE- The Secretary of Health and Human Services shall evaluate the existing Health Care Common Procedure Coding System (HCPCS) codes for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such codes. In carrying out such evaluation, the Secretary shall use an existing process, administered by the Durable Medical Equipment Medicare Administrative Contractors, for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.

(d) Other Provisions-

(1) EXEMPTION FROM COMPETITIVE ACQUISITION FOR CERTAIN OFF-THE-SHELF ORTHOTICS- Section 1847(a) of the Social Security Act (42 U.S.C. 1395w-3(a)) is amended by adding at the end the following new paragraph:

`(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.'

(2) CORRECTION IN FACE-TO-FACE EXAMINATION REQUIREMENT- Section 1834(a)(1)(E)(ii) of such Act (42 U.S.C. 1395m(a)(1)(E)(ii)) is amended by striking `1861(r)(1)' and inserting `1861(r)'.

(3) SPECIAL RULE IN CASE OF NATIONAL MAIL-ORDER COMPETITION FOR DIABETIC TESTING STRIPS- Section 1847(b) of such Act (42 U.S.C. 1395w-3(b)) is amended--

(A) by redesignating paragraph (10) as paragraph (11); and

(B) by inserting after paragraph (9) the following new paragraph:

`(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 acquisition program described in subparagraph (A).'

(4) OTHER CONFORMING AMENDMENTS- Section 1847(b)(11) of such Act, as redesignated by paragraph (3), is amended--

(A) in subparagraph (C), by inserting `and the identification of areas under subsection (a)(1)(D)(iii)' after `(a)(1)(A)';

(B) in subparagraph (D), by inserting `and implementation of subsection (a)(1)(D)' after `(a)(1)(B)';

(C) in subparagraph (E), by striking `or' at the end;

(D) in subparagraph (F), by striking the period at the end and inserting `; or'; and

(E) by adding at the end the following new subparagraph:

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

(5) FUNDING FOR IMPLEMENTATION- In addition to funds otherwise available, for purposes of implementing the provisions of, and amendments made by, this section, other than the amendment made by subsection (c)(1) and other than section 1847(a)(1)(E) of the Social Security Act, the Secretary of Health and Human Services shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) to the Centers for Medicare & Medicaid Services Program Management Account of \$20,000,000 for fiscal year 2008, and \$25,000,000 for each of fiscal years 2009 through 2012. Amounts transferred under this paragraph for a fiscal year shall be available until expended.

(e) Effective Date- The amendments made by this section shall take effect as of June 30, 2008.