

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS-1561-IFC]

RIN: 0938-AP59

Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements certain provisions of section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) related to the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Competitive Acquisition Program. Specifically, this rule: implements certain MIPPA provisions that delay implementation of Round 1 of the program; requires CMS to conduct a second Round 1 competition (the "Round 1 rebid") in 2009; and mandates certain changes for both the Round 1 rebid and subsequent rounds of the program, including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose to CMS information regarding subcontracting relationships.

DATES: Effective date: These regulations are effective on [OFR--insert 30 days after the date of publication in the **Federal Register**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR--insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1561-IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. Electronically. You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" and enter the filecode to find the document accepting comments.

2. By regular mail. You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1561-IFC,

P.O. Box 8020,

Baltimore, MD 21244-8020.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1561-IFC,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to either of the following addresses:

a. Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201;

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Sabrina Teferi, (410) 786-6884.

Barry Brook, (410) 786-5889.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

A. Legislative and Regulatory History of the DMEPOS Competitive Bidding Program

Medicare pays for most DMEPOS furnished after January 1, 1989 pursuant to fee schedule methodologies set forth in section 1834 of the Social Security Act (the Act), as added by section 4062 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (Pub. L. 100-203). Specifically, sections 1834(a)(1)(A) and (B), and 1834 (h)(1)(A) of the Act provide that Medicare payment for these items is equal to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. We implemented this payment methodology at 42 CFR Part 414, Subpart D of our regulations. Sections 1834(a)(2) through (a)(5) and 1834(a)(7) of the Act, and implementing regulations at §414.200 through §414.232 (with the exception of §414.228), set forth separate payment categories of durable medical equipment (DME) and describe how the fee schedule for each of the following categories is established:

- Inexpensive or other routinely purchased items (section 1834(a)(2) of the Act and §414.220 of the regulations);
- Items requiring frequent and substantial servicing (sections 1834(a)(3) of the Act and §414.222 of the regulations);
- Customized items (section 1834(a)(4) of the Act and §414.224 of the regulations);
- Oxygen and oxygen equipment (section 1834(a)(5) of the Act and §414.226 of the regulations);
- Other items of DME (section 1834(a)(7) of the Act and §414.229 of the regulations).

For a detailed discussion of payment for DMEPOS under fee schedules, see the final rule published in the April 10, 2007 **Federal Register** (72 FR 17992).

Section 1847 of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), requires the Secretary to establish and implement a Medicare DMEPOS Competitive Bidding Program ("Competitive Bidding Program" or "program"). Under the Competitive Bidding Program, Medicare sets payment amounts for selected DMEPOS items and services furnished to beneficiaries in competitive bidding areas (CBAs) based on bids submitted by qualified suppliers and accepted by Medicare. For competitively bid items, these new payment amounts, referred to as "single payment amounts," replace the fee schedule payment methodology. Section 1847(b)(5) of the Act provides that Medicare payment for these competitively bid items and services is made on an assignment-related basis equal to 80 percent of the applicable single payment amount, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts to any entity unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid under the fee schedule methodologies set forth in section 1834(a) of the Act. This requirement guarantees savings to both the Medicare program and beneficiaries under the program. The fee schedule methodologies will continue to set payment amounts for noncompetitively bid DMEPOS items and services. The program also includes provisions to ensure beneficiary access to quality DMEPOS items and services: section 1847 of the Act limits participation in the program to suppliers who have met applicable quality and financial standards and requires the Secretary to maintain beneficiary access to multiple suppliers.

When first enacted by the Congress, section 1847(a)(1)(B) of the Act required the Secretary to phase in the Competitive Bidding Program in a manner so that the competition under the program occurred in 10 of the largest metropolitan statistical areas (MSAs) in 2007. The program was to be expanded into 70 additional MSAs in 2009, and then into additional areas after 2009.

In the May 1, 2006 **Federal Register** (72 FR 25654), we issued a proposed rule that would implement the Competitive Bidding Program for certain DMEPOS items and services and solicited public comment on our proposals. In the April 10, 2007 **Federal Register** (72 FR 17992), we issued a final rule addressing the comments on the proposed rule and establishing the regulatory framework for the Medicare DMEPOS Competitive Bidding Program in accordance with section 1847 of the Act.

Consistent with the requirements of section 1847 of the Act and the competitive bidding regulations, we began implementing the program by conducting the first round of competition in 10 of the largest MSAs in 2007. We limited competition during this first round of the program to DMEPOS items and services included in 10 selected product categories. The bidding window opened on May 15, 2007 and was extended to allow bidders adequate time to prepare and submit their bids. We then evaluated each submission and awarded contracts consistent with the requirements of section 1847(b)(2) of the Act and §414.414. Following the bid evaluation process, we awarded over 329 contracts to qualified suppliers.

We implemented the Competitive Bidding Program on July 1, 2008. Beginning on that date, Medicare coverage for competitively bid DMEPOS items and services furnished in the first 10 competitive bidding areas (CBAs) was limited to items and services furnished by contract and

grandfathered suppliers, and payment to these suppliers was based on the single payment amount, as determined under the competitive bidding regulations. This program was projected to result in a savings of approximately 26 percent annually to the Medicare program and Medicare beneficiaries. We calculated these projections by subtracting the lower single payment amount from the applicable fee schedule amount per CBA per item and then multiplying this amount by the weighted national utilization data. For further discussion of the Competitive Bidding Program and the bid evaluation process, see the final rule published in the April 10, 2007 **Federal Register** (72 FR 17992).

B. The MIPPA and the Medicare DMEPOS Competitive Bidding Program

On July 15, 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) was enacted. Section 154 of the MIPPA amended section 1847 of the Act to make certain limited changes to the Medicare DMEPOS Competitive Bidding Program. Section 154(a) of the MIPPA delays competition under the program and amends section 1847(a)(1)(D)(i) of the Act to terminate the competitive bidding contracts effective June 30, 2008 and prohibit payment based on the contracts. This action effectively reinstates as payment for competitively bid items and services the Medicare fee schedule amounts, as set forth in section 1834 of the Act and 42 CFR part 414, subpart D of our regulations. In light of the amendments, items that had been included in the first round of the Competitive Bidding Program could once again be furnished by any enrolled DMEPOS supplier in accordance with existing Medicare rules. Payments for these items would no longer be made pursuant to competitive bidding contracts at the single payment amount, but instead would be based on the applicable Medicare fee schedule (includes 9.5 percent reduction) amount(s) based on the date of service.

Section 154(a) of the MIPPA requires the Secretary to conduct a second competition to select suppliers for Round 1 in 2009 ("Round 1 rebid"). The Round 1 rebid includes the "same items and services" and is to be conducted in the "same areas" as the 2007 Round 1 competition, with certain limited exceptions. Specifically, the Round 1 rebid must exclude negative pressure wound therapy (NPWT) items and services and exclude Puerto Rico. In addition, section 154(a) of the MIPPA permanently excludes group 3 complex rehabilitative wheelchairs from the Competitive Bidding Program by amending the definition of "items and services" in section 1847(a)(2) of the Act. Suppliers, including suppliers that previously were awarded a competitive bidding contract, will need to submit bids to be considered for a contract under the Round 1 rebid.

Section 154(a) of the MIPPA also delays competition for Round 2 of the competitive bidding program from 2009 to 2011 and subsequent competition under the program from 2009 until after 2011. A competition for a national mail order competitive bidding program may occur after 2010.

The MIPPA mandates certain changes to the bidding process, starting with the Round 1 rebid. Section 154(a) of the MIPPA adds a new paragraph (F) to section 1847(a)(1) of the Act, which sets forth a process for supplier feedback on missing financial documents. Pursuant to this requirement, we will notify suppliers who submit their bids within a specific time period if their bid submission is missing any of the required financial documents. We will allow suppliers to submit missing financial documents within 10 business days after this notice.

Section 154(b) of the MIPPA amends section 1847(b)(3) of the Act to require contract suppliers to notify us of subcontracting relationships they have entered into for the purpose of

furnishing items and services under the competitive bidding program. Contract suppliers must also inform CMS whether each such subcontractor meets the accreditation requirement set forth in section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

Section 154(d) of the MIPPA excludes from the competitive bidding program certain DME furnished by a hospital to the hospital's patients during an admission or on the date of discharge.

In addition to the changes outlined above that we are implementing through this interim final rule with comment period, section 154 of the MIPPA made other changes to the competitive bidding program which include:

- Exclusions of certain areas in subsequent rounds that are not already selected under Rounds 1 and 2;
- Extension of the Program Advisory and Oversight Committee;
- Exemption for Off-the-Shelf Orthotics from Competitive Bidding when provided by Certain Provided; and
- Evaluation of certain Healthcare Common Procedure Coding System (HCPCS) codes.

These provisions are not addressed in this rule, but may be addressed through future rulemaking or subregulatory guidance, as appropriate.

As the following are administrative requirements, they are not addressed in this rule and will be handled by the appropriate agencies:

- A post-award audit by the Office of Inspector General;
- Establishment of a Competitive Acquisition Ombudsman;

- A Government Accountability Office report on the results of the competitive bidding program;

As discussed below, we believe that the changes specifically mandated for the Round 1 rebid are largely self-implementing. The MIPPA delayed the Competitive Bidding Program and requires certain changes in subsequent competitions under the program, but it did not alter the fundamental requirements contained in the competitive bidding program statute and regulations, or revise the methodologies used by us in calculating payment amounts and selecting suppliers under the program. We have therefore chosen to continue to apply the same methodologies to calculate payment and select suppliers, and, except as discussed below, the current competitive bidding regulations published on April 10, 2007 will continue to provide the framework under which we implement the program.

We will implement other changes regarding subsequent rounds of competition through future rulemaking or subregulatory guidance, as appropriate. As noted in the regulatory impact analysis of this rule, the MIPPA mandated a nationwide 9.5 percent reduction in payment for all items and services that were competitively bid during the prior round of competition regardless of any exclusion such as group 3 complex rehabilitative wheelchairs. The 9.5 percent reduction in payment was completed through the standard process for covered item updates rather than through this rule.

II. Provisions of the Interim Final Rule

In this interim final rule, we are revising current provisions at 42 CFR Part 414, Subpart F, to incorporate certain self-implementing MIPPA provisions. To the extent this interim final rule with comment period does not specifically modify regulatory language, the current

regulations, as set forth in the April 10, 2007 final rule, remain unchanged and will govern the Round 1 rebid.

The interim final rule addresses the following changes made by the MIPPA:

General Changes to the DMEPOS Competitive Bidding Program

- Temporary Delay of the Medicare DMEPOS Competitive Bidding Program
- Supplier Feedback on Missing Covered Documents
- Disclosure of Subcontractors and their Accreditation Status under the Competitive

Bidding Program

- Exemption from Competitive Bidding for Certain DMEPOS
- Exclusion of Group 3 Complex Rehabilitative Wheelchairs

Round 1 Changes of the Competitive Bidding Program

- Rebidding of the "same areas" as the previous Round 1, unless otherwise specified.
- Rebidding of the "same items and services" as the previous Round 1, unless otherwise specified.

A. General Changes to the DMEPOS Competitive Bidding Program

1. Temporary Delay of the Medicare DMEPOS Competitive Bidding Program

Section 154(a) of the MIPPA amends section 1847(a)(1) of the Act to delay competition under Rounds 1 and 2 of the Competitive Bidding Program from 2007 and 2009 to 2009 and 2011, respectively. It also delays competition for a national mail order program until after 2010 and competition in additional areas, other than mail order, until after 2011.

We are amending §414.410(a)(1) and (2) to indicate that competition under Round 1 of the competitive bidding program will occur in 2009 and competition under Round 2 of the

program will occur in 2011. In addition, we are revising §414.410(a)(3) to indicate that competition in additional MSAs will occur after 2011 (or, in the case of national mail order for items and services, after 2010) .

2. Supplier Feedback on Missing Covered Documents

Section 1847(b)(2)(A) of the Act prohibits the Secretary from awarding a contract under the program to a supplier unless the supplier meets applicable financial standards specified by the Secretary, taking into account the needs of small providers. We have implemented this requirement at §414.414(d) of the competitive bidding regulations, which requires suppliers to submit, as part of their bids, financial documents specified in the request for bids (RFB).

The RFB issued for the Round 1 rebid will require suppliers to submit the same categories of financial documents as we requested for the previous Round 1 competition. In the previous round of competition, we required suppliers to submit financial documents from the most recent three years. As stated in 42 CFR 414.414(d), the required financial documents will be specified in the RFB. Based on experience from the previous round of competition, we are modifying the required financial documents to lessen the burden on suppliers; instead of 3 years of documentation, we will require only 1 year. We believe that we can determine whether a supplier demonstrates financial soundness by reviewing one year of documentation.

Section 154(a) of the MIPPA adds a new paragraph (F) to section 1847(a)(1) of the Act, which establishes a detailed process by which we must notify suppliers of missing "covered documents" – defined by MIPPA as financial, tax or other documents required to be submitted by a bidder as part of an original bid submission in order to meet required financial standards – if such documents are submitted within a specified time period. The MIPPA details the specific

steps of this process and provides a timeline for each stage of this covered document submission review. We are implementing this provision of the MIPPA consistent with its detailed requirements.

Consistent with section 1847(a)(1)(F) of the Act, in the case of a bid in which one or more covered documents in connection with such a bid has been submitted not later than the covered document review date, we will notify suppliers of each covered document that is missing from the bidder's submission as of the covered document review date. As set out in the Act the "covered document review date" is the later of-- (1) the date that is 30 days before the final date specified by the Secretary for submission of bids; or (2) the date that is 30 days after the first date specified by the Secretary for submission of bids. For example, if a bid window opens on January 1st and closes on April 30th, the "covered document review date" would be the later of: (1) March 31st (30 days before the final date specified by the Secretary); or (2) January 31st (30 days after the first date specified by the Secretary). Therefore, in this case, the "covered document review date" will be March 31st. . Suppliers that submit their financial documents after the covered document review date will not receive notice of any missing financial documents.

Section 1847(a)(1)(F)(i) of the Act requires that we notify bidders of any missing covered documents within 45 days after the covered document review date for the Round 1 rebid. In subsequent rounds of competition, we have 90 days after the covered document review date to provide such notice. For all rounds of competition, bidders that are notified of the missing covered document(s) have 10 business days after the date of notice to submit the missing covered document(s). If a supplier submits the missing covered document(s) within this time

period, we may not reject the supplier's bid on the basis that any covered document is missing or has not been submitted on a timely basis.

Section 1847(a)(1)(F)(iii) of the Act places certain limitations on the covered document review process. First, the covered document review process applies only to the timely submission (prior to the covered document review date) of covered documents. Second, the process does not apply to any determination as to the accuracy or completeness of the covered documents submitted or whether such documents meet applicable financial requirements. Third, the process does not prevent us from rejecting a bid for reasons other than those not described in section 1847(a)(1)(F)(i)(II) of the Act. Fourth, the covered document review process shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

We are revising §414.414(d) by adding paragraphs (2)(i) through (iii) to set forth the required covered document review process. These paragraphs identify the timeframes established by the MIPPA for--

- Suppliers to submit covered documents in order to be eligible to receive notice of any missing covered documents;
- For CMS to review the submitted covered documents and notify bidders of any missing covered documents; and
- For suppliers to submit the missing covered documents.

We are also adding a definition for "covered document" and "covered document review date" to §414.402.

3. Disclosure of Subcontractors and their Accreditation Status under the Competitive Bidding Program

Section 154(b)(2) of the MIPPA adds a new paragraph (C) to section 1847(b)(3) of the Act. This new paragraph requires contract suppliers to disclose information on: (1) each subcontracting arrangement the supplier has in furnishing items and services under the contract; and (2) whether each such subcontractor meets the accreditation requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor. The contract supplier must make this disclosure not later than 10 days after the date a supplier enters into a contract with CMS. If the contract supplier subsequently enters into a subcontracting relationship, the supplier must disclose this information to CMS no later than 10 days after entering into the subcontracting relationship. We will issue subregulatory guidance regarding the need to keep CMS current on all subcontracting relationships.

Section 154(b) of the MIPPA added section 1834(a)(20)(F)(i) to the Act, which mandates that the Secretary require suppliers furnishing items and services under a competitive bidding program on or after October 1, 2009, directly or as a subcontractor for another entity, to submit evidence of accreditation by a CMS-designated accreditation organization. Both contract suppliers and their subcontractors that furnish items and services under the competitive bidding program must do so in accordance with the applicable supplier standards found in Part 424, subpart D and other Federal regulations.

We are amending §414.414(c), redesignating §414.422(f) as §414.422(g) and adding a new §414.422(f) to set forth these requirements for disclosing subcontracting arrangements. We

expect to further address subcontracting relationships and the method for disclosure of the subcontracting relationships in subregulatory guidance.

4. Exemption from Competitive Bidding for Certain DMEPOS

Section 414.404(b) currently exempts from competitive bidding certain DME items when furnished by a physician or treating practitioner to his or her own patients as part of his or her professional services. This exception is limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME. Section 154(d) of the MIPPA amended section 1847(a) of the Act to exclude from the competitive bidding program these same items when they are furnished by hospitals to the hospital's own patients during an admission or on the date of discharge. We are interpreting this exclusion to include only DMEPOS paid for under Part B of the Medicare program because section 1847 does not apply to items that are paid for under Part A. As discussed in the April 10, 2007 final rule, in accordance with §414.404(b)(3) payment for items furnished under the exceptions in §414.404(b) will be made in accordance with §414.408(a).

We are amending §414.402 to include a definition for hospitals. We have also amended §414.404(b)(1) to incorporate the added exemption for hospitals that furnish certain types of competitively bid DME to their own patients during an admission or on the date of discharge from the competitive bidding program. In addition, we amended subparagraph (b)(1)(iii) to address the billing requirements for hospitals under this exemption.

5. Exclusion of Group 3 Complex Rehabilitative Power Wheelchairs

Section 1847(a)(2) of the Act defines the items and services subject to competitive bidding. Section 1847(a)(2)(A) of the Act includes durable medical equipment and supplies as items and services subject to competitive bidding. Section 154(a) of the MIPPA amended this definition to exempt group 3 complex rehabilitative power wheelchairs (and related accessories when furnished in connection with such wheelchairs) from competitive bidding. For Medicare coding, coverage, and payment purposes, power wheelchairs are classified under several groups based on performance and durability test results, patient weight capacity, and equipment handling capabilities. For a description of the components, performance requirements and coding guidelines for group 3 power wheelchairs, see

https://www.dmepdac.com/resources/articles/2006/08_14_06.pdf. Group 2 complex

rehabilitative power wheelchairs will be included in the competitive bidding program because they were not excluded by the MIPPA and thus will continue to be included in the Round 1 competitive bidding program.

We are amending §414.402 to revise the definition of "item" to exclude group 3 complex rehabilitative wheelchairs from the competitive bidding program.

B. Round 1 Changes of the Competitive Bidding Program

1. Rebidding of the "same areas" as the previous Round 1, unless otherwise specified.

Section 1847(a)(1)(D)(i)(II) of the Act, as amended by section 154(a) of the MIPPA, requires us to conduct a Round 1 rebid in 2009. Pursuant to section 1847(a)(1)(D)(i)(II) of the Act, we shall conduct the competition for the Round 1 rebid in a manner "so that it occurs in 2009 with respect to the same items and services and the same areas" as the first Round 1

competition, except as provided by section 1847(a)(1)(D)(i)(III) and (IV) of the Act. Under section 1847(a)(1)(D)(i)(III), as amended by the MIPPA, we must exclude Puerto Rico so that the Round 1 rebid of the competitive bidding program occurs in 9 of the largest MSAs.

Therefore, the Round 1 rebid will occur in the following MSAs:

- Cincinnati – Middletown (Ohio, Kentucky and Indiana)
- Cleveland – Elyria – Mentor (Ohio)
- Charlotte – Gastonia – Concord (North Carolina and South Carolina)
- Dallas – Fort Worth – Arlington (Texas)
- Kansas City (Missouri and Kansas)
- Miami – Fort Lauderdale – Miami Beach (Florida)
- Orlando (Florida)
- Pittsburgh (Pennsylvania)
- Riverside – San Bernardino – Ontario (California)

Section 154(a) of MIPPA mandated that we conduct the round 1 "re-bid" in the "same areas" – except for Puerto Rico – as the previous competition. As stated in the final rule, we identified CBAs in the first round of competition by counties and zip codes to clearly identify the boundaries of a CBA. Therefore, we believe it is reasonable to implement the "same areas" mandate by conducting the round 1 re-bid in those same zip codes. It is possible that certain zip codes may have changed since the first competition. We will therefore review zip code changes made since 2007 and incorporate applicable updates to these zip codes. For example, if a particular zip code has been split into two new zip codes, we will include the new zip codes in

the CBA. We will not add any new zip codes that would expand the geographic area of the CBAs.

Accordingly, we are amending §414.410(a)(1) to reflect the areas for competition set forth in section 1847(a)(1) of the Act, as amended by the MIPPA.

2. Rebidding of the "same items and services" as the previous Round 1, unless otherwise specified.

Section 1847(a)(1)(D)(i)(II) of the Act, as amended by the MIPPA, requires that we conduct the Round 1 rebid competitive bidding program with respect to the "same items and services" as were previously bid in Round 1 except as provided in section 1847(a)(1)(D)(i)(IV) of the Act, which excludes negative pressure wound therapy. The Round 1 rebid will also exclude group 3 complex rehabilitative power wheelchairs as noted previously. Therefore, the Round 1 rebid will include the following categories of items and services:

- Oxygen Supplies and Equipment
- Standard Power Wheelchairs, Scooters, and Related Accessories
- Complex Rehabilitative Power Wheelchairs and Related Accessories (Group 2)
- Mail-Order Diabetic Supplies
- Enteral Nutrients, Equipment and Supplies
- Continuous Positive Airway Pressure (CPAP), Respiratory Assist Devices (RADs), and Related Supplies and Accessories
- Hospital Beds and Related Accessories
- Walkers and Related Accessories
- Support Surfaces (Group 2 mattresses and overlays) in Miami.

In the April 10, 2007 final rule we define an item, in part, as a product included in a competitive bidding program that is identified by a HCPCS code.

Therefore, consistent with our understanding of the MIPPA and the mandate that bidding in the Round 1 rebid occur with respect to the "same items and services" as the previous round of competition, we will conduct the competition for the Round 1 rebid for essentially the same codes for which we bid in 2007. We have made certain adjustments to reflect changes in the HCPCS codes consistent with §414.426. We have made additional exceptions for obsolete codes and codes which, in light of the MIPPA amendments, are no longer separately payable. For example, under the MIPPA, the transfer of title provision was deleted, thus oxygen accessories are no longer separately payable because the supplier maintains ownership of the equipment. The final list of HCPCS codes will be published on the Competitive Bidding Implementation Contractor (CBIC) Web site at <http://www.dmecompetitivebid.com> prior to opening of the bid window.

III. Considerations for Future Rulemaking under the Competitive Bidding Program

We are considering alternatives for the competition of diabetic supplies. This competition will potentially take place sometime after the Round 1 rebid, and will be the subject of a future notice and comment rulemaking. We believe it is consistent with the section 1847(a) of the Act to employ competitive bidding for diabetic supplies in both the mail order and traditional retail markets, in part due to concerns raised about the bifurcation of the method of delivery of diabetic supplies and the difficulty in defining what constitutes "mail order." We welcome public comment on the competition of diabetic supplies.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide for public comment before the provisions of a rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. This process may be waived, however, if an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest. In such cases, the agency must incorporate a statement of this finding and its reasons in the rule issued, or explain that the agency is promulgating interpretive rules, general statements of policy, or rules of agency procedure or practice outside the scope of notice and comment rulemaking.

We do not believe that we need to delay publication of this rule until a notice and comment period is completed. We are conforming the competitive bidding regulations to specific statutory requirements contained in section 154 of MIPPA and informing the public of the procedures and practices the agency will follow to ensure compliance with those statutory provisions. However, to the extent that notice and comment rulemaking would otherwise apply, we find good cause to waive such requirements.

We find it unnecessary to undertake notice and comment rulemaking in this instance in light of the statutory language. We are applying statutory language that is highly detailed and proscriptive, and we believe it is redundant to, in effect, propose a rule to incorporate the words of a provision already contained in the statute. We would not be able to revise the changes to this regulation in response to public comment because this regulation reiterates the statutory language found in MIPPA and because the statute requires implementation to occur in 2009. We are also describing a procedure to ensure compliance with the relevant provisions of the statute. This description is exempt from notice and comment rulemaking as an interpretive rule, general statement of policy, and/or rule of agency procedure or practice. Therefore, under 5 U.S.C. 553(b), we find good cause to waive notice and comment rulemaking procedures for this revision, if such procedures are required at all.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are requesting emergency approval of the information collection requirements contained in this interim final rule with comment period. Please provide comments on these information collection requirements by **[OFR: Please insert 15 days after date of publication]**. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

The need for the information collection and its usefulness in carrying out the proper functions of our agency.

- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

These requirements are not effective until approved by OMB. We are soliciting public comment on the following information collection requirements (ICRs):

A. ICRs Regarding Round 1 Rebid

We previously estimated that the burden associated with Round 1 would be 1,086,164 hours. Our estimate was that on average it would take a supplier 68 hours to complete and submit a bid and that we would receive 15,973 bids. Although we expect the amount of hours to generally remain the same (68 hours) for the round 1 rebid, based on our round 1 experience we anticipate fewer bids. For the 2007 round 1 of the competitive bidding program, we received approximately 6,500 bids. Therefore, the total estimated burden associated with the round 1 rebid is approximately 442,000 hours (68 hours X 6,500).

B. ICRs Regarding Disclosure of Subcontracting Arrangements

Section 414.422(f) states that suppliers entering into a contract with CMS must disclose information on each subcontracting arrangement that the supplier has to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in §424.57, if applicable. Section 414.422(f) also requires that the required disclosure be made no later than 10 days after the date a supplier enters into a contract with CMS or 10 days after a supplier enters into a subcontracting arrangement after entering into a contract with CMS.

The burden associated with the requirements in §414.422(f) are the time and effort necessary to disclose the information to CMS. In the 2007 Round 1 competition, there were 329 winning suppliers. Therefore, we approximate fewer than 400 winning suppliers for the Round 1

rebid. Also, we estimate it will take each of the winning suppliers that use subcontractors on average approximately 1.5 hours to submit information on each subcontracting arrangement to furnish items and services under the contract and whether each subcontractor meets the accreditation requirements in §424.57, if applicable. Those that do not use subcontractors will not have a reporting burden. The total estimated burden associated with these requirements is approximately 600 hours (1.5 hours X 400 winning suppliers).

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the "ADDRESSES" section of this proposed rule; or
2. Mail copies to the address specified in the "ADDRESSES" section of this proposed rule and to the

Office of Information and Regulatory Affairs,

Office of Management and Budget,

725 17th Street, NW, Room 10235,

Washington, DC 20503,

Attn: CMS Desk Officer

Fax (202) 395-6974,

Email: OIRA_submission@omb.eop.gov

VII. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory

Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866, as amended, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The provisions of this rule only implement limited changes to how the program will be implemented and will not result in a change in expenditures of \$100 million or more annually, and is therefore not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

As stated in section I.B. of this preamble, section 154 of the MIPPA amended section 1847 of the Act to make limited changes to the Medicare DMEPOS Competitive Bidding Program. This regulation merely incorporates limited statutory changes to the Medicare DMEPOS Competitive Bidding Program and does not change the fundamental requirements of the program. In addition, a regulatory impact is unnecessary due to previous regulatory action taken when implementing the competitive bidding program, as described in the May 1, 2006 **Federal Register** (72 FR 25654) proposed rule. Specifically, this rule cites the new timeframes for competition to occur under the program. In addition, the rule implements the MIPPA provisions that mandate limited changes that affect competition under the program including a process for providing feedback to suppliers regarding missing financial documentation, requiring

contractors to disclose to CMS information regarding subcontracting relationships, and exempting from competitive bidding certain items and services.

The MIPPA also mandated a 9.5 percent reduction in payment for all items and services that were competitively bid during the round of competition in 2008 regardless of any exclusion such as group 3 complex rehabilitative wheelchairs. The 9.5 percent reduction in payment was completed through the standard process for covered item updates rather than through this rule. Because we are not implementing the 9.5 percent reduction in payment in this rule and the provisions of this rule do not change the fundamentals of this program, and 9.5 percent reduction in payment is not included in this rule, we have determined that a full regulatory impact analysis is unnecessary. Because the statute rather than the regulation is imposing a 9.5 reduction in payment, this rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of section 604 of the RFA, small entities include small businesses, non-profit organizations and government agencies. Individuals and States are not included in the definition of a small entity. Based on data from the Small Business Administration (SBA), we estimate that 85 percent of suppliers of the items and services affected by this rule would be defined as small entities with total revenues of \$6.5 million or less in any 1 year. This regulation merely codifies the MIPPA provisions, so there are no options for regulatory relief for small suppliers. The RFA therefore does not require that we analyze regulatory options for small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes

of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this rule will not have a significant impact on a substantial number of small entities and on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any year by State, local or tribal governments, in the aggregate, or by the private sector, of \$100 million. The \$100 million in 1995 dollars is updated annually for inflation and the current expenditure threshold is approximately \$130 million. This rule will not have an effect on the governments mentioned, and the private sector costs would be less than the \$130 million per year threshold. Hence, the Unfunded Mandates Reform Act of 1995 would not apply.

Lastly, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule will not have a significant effect on the rights, roles and responsibilities of States.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare Reporting and recordkeeping requirements

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 414 PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

Subpart F--Competitive Bidding for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

2. Section 414.402 is amended by--

A. Revising the introductory text of paragraph (1) of the definition of "item."

B. Adding the definitions of "covered document", "covered document review date" and "hospital".

§414.402 Definitions.

* * * * *

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 the required financial standards.

Covered document review date means the later of--

- (1) The date that is 30 days before the final date for the closing of the bid window; or
- (2) The date that is 30 days after the opening of the bid window.

Hospital has the same meaning as in section 1861(e) of the Act.

Item * * *

(1) Durable medical equipment (DME) other than class III devices under the Federal Food, Drug and Cosmetic Act, as defined in §414.202 of this part and group 3 complex rehabilitative wheelchairs and further classified into the following categories:

* * * * *

3. Section 414.404 is amended by revising paragraphs (b)(1) introductory text, (b)(1)(ii), and (b)(1)(iii) to read as follows:

§ 414.404 Scope and applicability.

* * * * *

(b) * * *

(1) Physicians, treating practitioners, and hospitals may furnish certain types of competitively bid durable medical equipment without submitting a bid and being awarded a contract under this subpart, provided that all of the following conditions are satisfied:

* * * * *

(ii) The items are furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service or by a hospital to its own patients during an admission or on the date of discharge.

(iii) The items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

* * * * *

4. Section 414.408 is amended by revising paragraph (e)(2)(iv) to read as follows:

§ 414.408 Payment rules.

* * * * *

(e) * * *

(2) * * *

(iv) A physician, treating practitioner, physical therapist in private practice, occupational therapist in private practice, or hospital may furnish an item in accordance with §414.404(b) of this subpart.

* * * * *

5. Section 414.410 is amended by revising paragraph (a) as follows:

§ 414.410 Phased-in implementation of competitive bidding programs.

(a) Phase-in of competitive bidding programs. CMS phases in competitive bidding programs so that competition under the programs occurs –

(1) In CY 2009, in Cincinnati – Middletown (Ohio, Kentucky and Indiana), Cleveland - Elyria – Mentor (Ohio), Charlotte – Gastonia – Concord (North Carolina and South Carolina), Dallas – Fort Worth – Arlington (Texas), Kansas City (Missouri and Kansas), Miami – Fort Lauderdale – Miami Beach (Florida), Orlando (Florida), Pittsburgh (Pennsylvania), and Riverside – San Bernardino – Ontario (California).

(2) In CY 2011, the additional 70 MSAs selected by CMS as of June 1, 2008.

(3) After CY 2011, additional CBAs (or, in the case of national mail order for items and services, after CY 2010).

* * * * *

6. Section 414.414 is amended by revising paragraph (c) and (d) as follows:

§414.414 Conditions for awarding contracts.

* * * * *

(c) Quality standards and accreditation. Each supplier furnishing items and services directly or as a subcontractor must meet applicable quality standards developed by CMS in accordance with section 1834(a)(20) of the Act and be accredited by a CMS-approved organization that meets the requirements of §424.58 of this subchapter, unless a grace period is specified by CMS.

(d) Financial standards.

(1) General rule. Each supplier must submit along with its bid the applicable covered documents (as defined in §414.402) specified in the request for bids.

(2) Process for reviewing covered documents.

(i) Submission of covered documents for CMS review. To receive notification of whether there are missing covered documents, the supplier must submit its applicable covered documents by the later of the following covered document review dates:

(A) The date that is 30 days before the final date for the closing of the bid window; or

(B) The date that is 30 days after the opening of the bid window.

(ii) CMS feedback to a supplier with missing covered documents.

(A) For Round 1 bids. CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents.

(B) For subsequent Round bids. CMS has 90 days after the covered document review date to provide notify suppliers of any missing covered documents.

(iii) Submission of missing covered documents. Suppliers notified by CMS of missing covered documents have 10 business days after the date of such notice to submit the missing

documents. CMS does not reject the supplier's bid on the basis that the covered documents are late or missing if all the applicable missing covered documents identified in the notice are submitted to CMS not later than 10 business days after the date of such notice.

* * * * *

6. Section 414.422 is amended by--

- A. Redesignating paragraph (f) as paragraph (g).
- B. Adding a new paragraph (f).

The addition reads as follows:

§ 414.422 Terms of contracts

* * * * *

(f) Disclosure of subcontracting arrangements.

(1) Initial disclosure. Not later than 10 days after the date a supplier enters into a contract under this section the supplier must disclose information on both of the following:

(i) Each subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether each subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act if applicable to such subcontractor.

(2) Subsequent disclosure. Not later than 10 days after the date a supplier enters into a subcontracting arrangement subsequent to contract award with CMS, the supplier must disclose information on both of the following:

(i) The subcontracting arrangement that the supplier has in furnishing items and services under the contract.

(ii) Whether the subcontractor meets the requirement of section 1834(a)(20)(F)(i) of the Act, if applicable to such subcontractor.

* * * * *

CMS-1561-IFC

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance;
and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: November 13, 2008.

Kerry Weems,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Approved: December 5, 2008

Michael O. Leavitt,

Secretary.

BILLING CODE: 4120-01-P

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