

## MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: July 28, 2008

RE: The “Medicare Improvements for Patients and Providers Act of 2008”:  
Delay and Reform of the Medicare DMEPOS Competitive Bidding Program

### I. INTRODUCTION

On July 15, 2008, the House and Senate overrode President Bush’s veto of H.R. 6331, the “Medicare Improvements for Patients and Providers Act of 2008” (“MIPPA”).<sup>1</sup> Among many other things, MIPPA delays and reforms the Centers for Medicare & Medicaid Services’ (“CMS”) controversial competitive bidding program for certain categories of durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”), which had already gone into effect in 10 geographic areas on July 1, 2008. Specifically, MIPPA:

- Terminates contracts awarded under round one, requires CMS to rebid those areas in 2009, and delays bidding for round two until 2011;
- Finances the delay by cutting fee schedule payments for all items covered by round one of the bidding program by 9.5 percent nationwide beginning January 1, 2009, followed by a 2 percent increase (in addition to regular inflation updates) in 2014, except where bidding is in effect or CMS has otherwise adjusted rates;
- Adds a series of procedural improvements to the bidding process, including a requirement that CMS notify bidders in the case of certain missing financial documentation; and
- Addresses quality by, among other things: requiring subcontractor accreditation; excluding complex rehabilitation wheelchairs and negative pressure wound therapy from bidding;; exempting certain rural and low-population areas from bidding; and requiring CMS to issue regulations before using its authority to adjust prices in non-bid areas.

These provisions are effective June 30, 2008, unless otherwise noted.

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<sup>1</sup> Pub. L. No. 110-275 (July 15, 2008). Additional details regarding the legislation are available on the House Ways and Means Committee web site, <http://waysandmeans.house.gov/MoreInfo.asp?section=45>.

CMS has instructed suppliers that as a result of the new law, items that had been included in the first round of the DMEPOS competitive bidding program can be furnished by any enrolled DMEPOS supplier in accordance with existing Medicare rules, and Medicare will pay for DMEPOS items in bidding areas using the standard DMEPOS fee schedule amounts, retroactive to June 30, 2008. Nevertheless, given that the program was in effect for two weeks before the legislation was enacted, certain operational and legal questions have been raised.

This memorandum provides a summary of the DMEPOS bidding provisions of the new law and discusses CMS guidance issued to date. We would be pleased to answer any further questions you may have.

## **II. BACKGROUND ON DMEPOS COMPETITIVE BIDDING**

### **A. Statutory Background**

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”) required the Secretary of the Department of Health and Human Services (“HHS”) to implement competitive acquisition programs for DMEPOS beginning in 2007. Eligible products included: (1) DME (including DME used with infusion and drugs, other than inhalation drugs) and supplies used in conjunction with DME; (2) enteral nutrients, equipment, and supplies; and (3) off-the-shelf orthotics. The MMA excluded from competitive acquisition inhalation drugs; parenteral nutrients, equipment, and supplies; and Class III devices. Moreover, the Secretary was permitted to exempt rural areas and areas with low population density in urban areas (unless there was a significant national market through mail order for particular items), and items and services unlikely to result in significant savings.

The statute directed the Secretary to establish competitive bidding areas (“CBAs”), which could differ for different items and services. Competitive acquisition was scheduled to be phased in geographically, applying to 10 of the largest metropolitan statistical areas (“MSAs”) in 2007, a total of 80 MSAs in 2009, and additional MSAs thereafter. The Secretary also could phase in competitive acquisition programs first among the highest cost and highest volume items and services or those that have the largest savings potential.

For each competitive acquisition area, the Secretary must solicit bids by suppliers to supply certain covered items. Only successful bidders could supply the covered items in the CBA, and they would be reimbursed based on the bid amount. The Secretary was required to ensure that small suppliers had the opportunity to be considered for participation under the program.

In order to be awarded a contract, bidding entities had to meet quality standards for suppliers, along with financial standards specified by the Secretary. Total amounts paid under the contracts were

expected to be less than would be paid otherwise, and beneficiary access to multiple suppliers would have to be maintained. The Secretary could limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand.

CMS published its final rule to implement the DMEPOS competitive bidding program on April 10, 2007.<sup>2</sup>

B. CMS Bidding Activities

CMS conducted the first round of DMEPOS competitive bidding last summer, and the deadline for bidding was September 25, 2007. The first round covered the following 10 MSAs: (1) Charlotte-Gastonia-Concord, NC-SC; (2) Cincinnati-Middletown, OH-KY-IN; (3) Cleveland-Elyria-Mentor, OH; (4) Dallas-Fort Worth-Arlington, TX; (5) Kansas City, MO-KS; (6) Miami-Fort Lauderdale-Miami Beach, FL; (7) Orlando-Kissimmee, FL; (8) Pittsburgh, PA; (9) Riverside-San Bernardino-Ontario, CA; and (10) San Juan-Caguas-Guaynabo, PR.

Ten categories of DMEPOS were included in phase one: (1) Oxygen Supplies and Equipment; (2) Standard Power Wheelchairs, Scooters, and Related Accessories; (3) Complex Rehabilitative Power Wheelchairs and Related Accessories; (4) Mail-Order Diabetic Supplies; (5) Enteral Nutrients, Equipment, and Supplies; (6) Continuous Positive Airway Pressure Devices, Respiratory Assist Devices, and Related Supplies and Accessories; (7) Hospital Beds and Related Accessories; (8) Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories; (9) Walkers and Related Accessories; and (10) Support Surfaces (Group 2 mattresses and overlays), although this category was subject to bidding only in Miami-Fort Lauderdale-Miami Beach, FL and San Juan-Caguas-Guaynabo, Puerto Rico.

Moreover, in January 2008, CMS announced the 70 MSAs (include the three largest MSAs - New York, Los Angeles, and Chicago) and eight product categories that it intended to include in the second round of competitive bidding. CMS planned to bid eight of the 10 product categories from round one in the second round: (1) Oxygen Supplies and Equipment; (2) Standard Power Wheelchairs, Scooters, and Related Accessories; (3) Complex Rehabilitative Power Wheelchairs and Related Accessories; (4) Enteral Nutrients, Equipment, and Supplies; (5) Continuous Positive Airway Pressure Devices, Respiratory Assist Devices, and Related Supplies and Accessories; (6) Hospital Beds and Related Accessories; (7) Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories; and (8) Walkers and Related Accessories. Note that although diabetes supplies were not

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<sup>2</sup> A Reed Smith client memo providing a detailed analysis of the final rule is available at <http://www.reedsmith.com/db/documents/hc0704.pdf>.

listed in this round of bidding, CMS officials indicated in a January 8, 2008 press conference that they were preparing to conduct nationwide competitive bidding for diabetes supplies in the future.<sup>3</sup>

On March 20, 2008, CMS announced the winning bid prices for the first round of competitive bidding, with reimbursement averaging 26 percent below Medicare fee schedule amounts. Moreover, on May 19, 2008, CMS released the names of the 325 suppliers that had signed contracts with Medicare to provide competitively bid DMEPOS items in the first round of competitive bidding, effective July 1, 2008. There were widespread concerns about the way the bidding process was handled, however, including confusing and contradictory guidance provided to suppliers during the bidding process, the questionable disqualification of numerous suppliers due to missing financial data, the awarding of contracts to suppliers without established businesses in the particular geographic region (since technically a supplier did not have to be located in the CBA to submit a bid), the adequacy of beneficiary and supplier education efforts, and the potential negative impact of the program on beneficiary access to DMEPOS. These concerns prompted Congress to intervene to delay implementation of the first round of the program and make a series of changes to improve the process in the future.

### **III. MIPPA DMEPOS COMPETITIVE BIDDING PROVISIONS**

#### **A. New Timetable for Competitive Bidding Program**

MIPPA terminates the contracts awarded under round one of the competitive bidding program, which had gone into effect July 1, 2008. Reimbursement to DMEPOS suppliers in the 10 CBAs reverts to the fee schedule amounts applicable prior to July 1, and all otherwise-eligible DMEPOS suppliers may furnish DMEPOS supplies in these areas regardless of whether they participated in the bidding process.

The Secretary is directed to rebid the first round in 2009, covering the same geographic areas and same products as previously selected, subject to the following modifications: (1) the Secretary must exclude Puerto Rico (resulting in the “new” first round covering nine rather than 10 MSAs); and (2) negative pressure wound therapy items and services are excluded from round one. Note that the legislation is not specific as to when in 2009 the competition must occur or when bid prices will actually go into effect.

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<sup>3</sup> For more details on round two, see the Reed Smith Client Memo posted at [http://www.reedsmith.com/\\_db/\\_documents/hc0801.pdf](http://www.reedsmith.com/_db/_documents/hc0801.pdf).

With regard to termination of winning round one contracts, MIPPA specifies that no Medicare payment will be made under those contracts on or after the date of the enactment (July 15, 2008). MIPPA provides that “to the extent that any damages may be applicable as a result of the termination of such contracts,” such damages will be paid from the Medicare trust fund. The law stipulates that this language should not be construed as providing an independent cause of action or right to administrative or judicial review with regard to the terminated contract. No guidance has yet been issued regarding how a supplier could petition for damages or the extent, if any, of financial relief. It is unclear at this time how viable it will be for suppliers to pursue relief under this provision or what CMS would consider to be reimbursement “damages.” CMS could be expected to argue that damages are not applicable because the standard contract included language noting that the contract was subject to changes in Medicare statute. This issue ultimately may be decided through litigation.

MIPPA delays round two bidding from 2009 to 2011, and clarifies the statutory language to specify that this competition shall take place in “an additional 70” areas, plus the nine MSAs in round one, rather than in 80 areas. The MSAs in the second round must be those that the Secretary announced earlier in 2008, although the Secretary may subdivide MSAs with populations of at least 8 million into separate CBAs.

MIPPA allows the Secretary to extend the program to additional areas after 2011, although national mail order bidding could take place after 2010. In implementing these future rounds, the Secretary must exempt from bidding (except for a national mail order program) the following areas: (1) rural areas; (2) MSAs not selected under rounds one or two with a population of less than 250,000; and (3) certain low population density areas within an MSA that is otherwise selected for bidding.

#### B. Reforms to the Competitive Bidding Program and Bidding Process

In light of widespread criticism regarding the way CMS and its contractor conducted the competitive bidding, including the methodology for establishing payments, the inclusion of complex medical equipment in bidding, the mechanics of bidding, the exclusion of numerous bidders for supposedly insufficient documentation, questions regarding the experience and qualifications of certain selected suppliers, and other aspects of the bidding program, MIPPA includes a series of provisions generally supported by industry designed to improve the bidding program.

##### 1. Supplier Feedback on Missing Financial Documentation

MIPPA establishes a process for CMS to notify a supplier regarding missing financial documentation if certain circumstances are met. Documents covered by this provision include financial, tax, or other such documents relating to supplier financial standards. The provision does not require notification regarding other documentation, such as the bid itself or accreditation documentation.

Under this provision, if a supplier submits a bid by the “covered document review date,” CMS must inform the supplier if a required financial document is missing within 45 days of the covered document review date (or within 90 days in subsequent rounds of bidding). The covered document review date is defined as the later of (1) 30 days before the bidding deadline; or (2) 30 days after the beginning of the bidding period. In such cases, CMS may not reject the bid on the basis of the missing documentation if all documents identified in the notice to the bidder are submitted within 10 business days after the notice date.

This provision applies only to the timely submission of covered documents, and does not apply to any determination as to the accuracy or completeness of the submitted documents or whether such documents meet applicable requirements. It also does not prevent the Secretary from rejecting a bid for other reasons (i.e., on the basis of the bid amount), nor does it permit a bidder to change bidding amounts or to make other changes in a bid submission.

## 2. Modification of Accreditation Requirements

By way of background, the MMA required the Secretary to establish and implement quality standards for Medicare DME suppliers, to be applied by recognized independent accreditation organizations. In August 2006, CMS released final supplier quality standards, and all suppliers eventually will be required to comply with these quality standards in order to furnish any Medicare Part B DMEPOS item or service and to receive and retain a supplier billing number.<sup>4</sup> CMS generally has been phasing in the accreditation requirement in conjunction with implementation of the competitive bidding program and as new suppliers enroll in Medicare. CMS has previously announced that *all* existing DMEPOS suppliers will need to submit proof of accreditation by a deemed accreditation organization by September 30, 2009.<sup>5</sup>

MIPPA makes it a statutory requirement that all DMEPOS suppliers be accredited as meeting the DMEPOS quality standards in order to furnish DMEPOS items and services on or after October 1, 2009. Moreover, MIPPA extends the accreditation requirement to subcontractors who enter into arrangements with contract suppliers to assist in the furnishing of items and services under a competitive bidding

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<sup>4</sup> The text of the standards is available at [http://www.cms.hhs.gov/DMEPOSCompetitiveBid/downloads/CMS\\_DMEPOS\\_Quality\\_Standards\\_081406.pdf](http://www.cms.hhs.gov/DMEPOSCompetitiveBid/downloads/CMS_DMEPOS_Quality_Standards_081406.pdf).

<sup>5</sup> For details, see [http://www.cms.hhs.gov/MedicareProviderSupEnroll/03\\_DeemedAccreditationOrganizations.aspx#TopOfPage](http://www.cms.hhs.gov/MedicareProviderSupEnroll/03_DeemedAccreditationOrganizations.aspx#TopOfPage).

contract; during the first round of competitive bidding, CMS had not required subcontractors to become accredited.<sup>6</sup>

MIPPA further amends the accreditation requirements as they apply to certain health care professionals (including orthotists and prosthetists as specified by the Secretary). Specifically, MIPPA provides that the accreditation requirements do not apply to such professionals unless the Secretary determines that the quality standards are designed specifically to be applied to such professionals. Likewise, the Secretary may exempt such professionals from the quality standards and accreditation requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to the professionals' furnishing of DMEPOS items and services.

In light of the delay in bidding, CMS has announced the cancellation of the special accreditation deadlines previously established for the second round of bidding.<sup>7</sup> All DMEPOS suppliers must nevertheless be accredited by September 30, 2009, whether or not they are furnishing services in a CBA.

### 3. Disclosure of Subcontracting Arrangements

MIPPA requires suppliers to disclose to the Secretary within 10 days of entering into a competitive bidding contract information regarding all subcontracting relationships the supplier has for furnishing items and services under the contract, including whether each subcontractor is accredited as applicable. Further, the supplier must notify the Secretary within 10 days of entering into any subsequent subcontracting arrangement.

### 4. Products Excluded from Competitive Bidding

MIPPA excludes from competitive bidding certain power wheelchairs and certain items furnished by physicians and hospitals. Specifically, MIPPA excludes from bidding:

- (1) Complex rehabilitative power wheelchairs classified as group 3 or higher, along with related accessories;

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<sup>6</sup> The first round bidding documents defined a subcontractor as “An entity, including an individual or individuals, that contracts with a supplier to supply a service either to the supplier or directly to the beneficiary, for which Medicare reimburses the supplier the cost of the service.”

<sup>7</sup> The announcement is posted at [http://www.cms.hhs.gov/DMEPOSCompetitiveBid/04\\_Announcements\\_and\\_Communications.asp#TopOfPage](http://www.cms.hhs.gov/DMEPOSCompetitiveBid/04_Announcements_and_Communications.asp#TopOfPage). Prior to enactment of MIPPA, CMS had notified suppliers that they must have been accredited or have applied for accreditation by July 21, 2008 to be eligible to submit a bid for the second round and obtain accreditation by January 14, 2009 to be awarded a contract.

- (2) Certain off-the-shelf orthotics if furnished by physicians or other practitioners to their own patients as part of their professional service, or if furnished by a hospital to the hospital's own patients during an admission or on the date of discharge.
- (3) DME and supplies furnished by a hospital to the hospital's own patients during an admission or on the date of discharge, under certain circumstances.

5. Special Rule for Mail-Order Competition for Diabetic Testing Strips

CMS included mail-order diabetes supplies in the first round of competitive bidding, and indicated earlier this year that the agency intends to conduct nationwide competitive bidding for diabetes supplies in the future.

MIPPA provides that after the first round of bidding, a bidder seeking to furnish diabetes supplies must demonstrate to the Secretary that its bid covers a wide range of popular brands of diabetes supplies. That is, the bid must include 50 percent (or more as the Secretary may specify) of the types of diabetic testing strip products available (on an aggregate basis and taking into account volume for the different products). The HHS Office of Inspector General ("OIG") is required to conduct a study by 2011 to identify the types of diabetic testing strip products by volume that could be used to determine whether this standard is met, and to update the report for subsequent rounds of bidding.

6. OIG Pricing Verification

The OIG is directed to conduct a post-award audit or survey to assess the process used by CMS to conduct competitive bidding and its method for determining pivotal bid amounts and single payment amounts in rounds one and two. The OIG may continue to verify such calculations for subsequent rounds of the program.

C. Changes to DMEPOS Fee Schedule Payments

MIPPA finances the delay in DMEPOS competitive bidding by reducing standard fee schedule payments by 9.5 percent nationwide for all items covered by round one bidding program (including related accessories if furnished with the competitively-bid item), beginning January 1, 2009. The law clarifies that the fee schedule reduction also applies to diabetic supplies, but only if furnished through mail order. Items that were not subject to competitive bidding will receive an inflation update for 2009 equal to the percentage increase in the consumer price index for all urban consumers ("CPI-U") for the 12-month period ending with June 2008.

For 2010 through 2013, fee schedules will be increased annually to reflect the CPI-U increase (although in areas where competitive bidding is implemented, contract pricing will apply).



In 2014, the fee schedule for items not furnished in a CBA will again be updated for inflation. Additionally, the payment amounts for those items included in round one and subject to the 9.5 percent cut in 2009 will be increased by 2 percent, unless the Secretary has otherwise adjusted the rate for the item (under the Secretary's authority to use payment information obtained through the competitive bidding program to adjust rates outside of a CBA), or if the item is being furnished in a CBA.

D. Other DMEPOS Bidding Provision

In addition to the provisions described above, MIPPA includes the following provisions modifying the DMEPOS competitive bidding program and related requirements:

- Adjustments to Rates Outside of CBAs – The MMA authorized CMS to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in a CBA. CMS has not yet established a methodology for exercising this authority. MIPPA requires the Secretary to promulgate rules to specify the methodology to be used to make any such payment adjustment. The methodology must take into account the costs of items and services in areas in which such provisions would be applied compared to payment rates for those items and services in CBAs.
- Competitive Acquisition Ombudsman – MIPPA requires the Secretary to establish a competitive acquisition ombudsman to respond to complaints and inquiries made by suppliers and individuals regarding the competitive acquisition program.
- Negative Pressure Wound Therapy Codes – MIPPA directs the Secretary to evaluate the existing Health Care Common Procedure Coding System (“HCPCS”) codes for negative pressure wound therapy to ensure accurate reporting and billing for such items and services.
- Report Deadlines and Scope – MIPPA modifies the deadline and scope of a mandated Government Accountability Office (“GAO”) report on the competitive bidding program, including requiring the GAO to examine, among other things: beneficiary access to DMEPOS resulting from awarding contracts to bidders without a physical presence in a CBA and who had no previous experience providing their contracted product category; beneficiary satisfaction; costs to suppliers participating in the program; the impact on small business suppliers; the impact on utilization of different items and services paid within the same HCPCS code; CMS administrative costs associated with the program; and the impact of the program on the provision of diabetic testing supplies. MIPPA also delays related mandated reports by the Program Advisory and Oversight Committee, the HHS Secretary, and the OIG.
- Implementation Funding – MIPPA provides \$20 million in funding for the DMEPOS bidding provisions in fiscal year (“FY”) 2008, and \$25 million in each of FYs 2009 through 2012.

#### **IV. CMS AND OIG IMPLEMENTATION GUIDANCE**

The retroactive cancellation of round one DMEPOS bidding contracts and changes in supplier eligibility and pricing policy effective July 1, 2008 has prompted CMS to issue a number of brief updates to suppliers on MIPPA implementation issues.<sup>8</sup> CMS has confirmed that items that had been included in the first round of the competitive bidding program can be furnished by any enrolled DMEPOS supplier in accordance with existing Medicare rules. Medicare payment for these items will be made under the standard fee schedule, rather than at contract prices.

With regard to claims processing, CMS will begin processing all incoming claims under standard fee-for-service rules by July 28, 2008, and any claims that were held will be processed no later than August 4, 2008. To the extent possible, CMS will automatically reprocess claims that were paid under the bidding program and those claims whose denial was based solely on competitive bidding program rules. Nevertheless, there may be instances in which suppliers in CBAs will need to alert their contractor to claims that should be adjusted.

Moreover, the delay of competitive bidding retroactively increased beneficiary copayment amounts for DMEPOS items furnished for the brief period while the competitive bidding program was in effect. As a result, beneficiaries who already paid or were billed for cost-sharing amounts based on lower contract prices temporarily in effect since July 1, 2008, are liable for additional cost-sharing amounts based on the higher fee schedule amounts. The OIG issued a policy statement<sup>9</sup> on July 24, 2008 assuring suppliers and providers affected by retroactive increases in payment rates under MIPPA (including DMEPOS suppliers in the initial CBAs) that they will not be subject to OIG administrative sanctions<sup>10</sup> if they waive retroactive beneficiary cost-sharing amounts attributable to those increased payment rates (subject to certain conditions). Note, however, that suppliers are not required to waive retroactive beneficiary liability, and they may instead choose to bill the beneficiary for the additional copayment obligation.

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<sup>8</sup> See <http://www.cms.hhs.gov/center/dme.asp>. Moreover, a brief notice informing Medicare beneficiaries of the delay in the bidding program is posted at <http://www.medicare.gov/spotlights.asp#dmepos>.

<sup>9</sup> See [http://oig.hhs.gov/fraud/docs/alertsandbulletins/2008/MIPPA\\_Policy\\_Statement.PDF](http://oig.hhs.gov/fraud/docs/alertsandbulletins/2008/MIPPA_Policy_Statement.PDF).

<sup>10</sup> Ordinarily, routine waivers of Medicare cost-sharing amounts could implicate the anti-kickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibiting inducements to beneficiaries.

## V. CONCLUSION

The MIPPA provisions delaying and reforming the DMEPOS competitive bidding program cap off a long and often frustrating period for suppliers in the initial competitive bidding areas. It can be hoped that CMS has learned from the numerous problems in the first round and will improve the mechanics of the bidding process, enhance the clarity of guidance offered to suppliers, and take other steps to prevent implementation of the program from adversely impacting beneficiary access to quality DMEPOS items in the bid areas.

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Please contact our Senior Health Policy Analyst Debra A. McCurdy (703/641-4283, [dmccurdy@reedsmith.com](mailto:dmccurdy@reedsmith.com)), Carol Loepere (202/414-9216, [cloepere@reedsmith.com](mailto:cloepere@reedsmith.com)), Elizabeth Carder-Thompson (202/414-9213, [ecarder@reedsmith.com](mailto:ecarder@reedsmith.com)), Robert J. Hill (202/414-9402, [rhill@reedsmith.com](mailto:rhill@reedsmith.com)), Kathleen McGuan (202/414-9278, [kmcguan@reedsmith.com](mailto:kmcguan@reedsmith.com)) or any other member of the Reed Smith health care group with whom you work if you would like additional information or if you have any questions.

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