ReedSmith

The Medicare Competitive Bidding Program
for Durable Medical Equipment, Prosthetics, Orthotics, & Supplies

Prepared for:
Health Care Clients

May 18, 2007

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ReedSmith

TO: HEALTH CARE CLIENTS

DATE: May 18, 2007

RE: The Medicare Competitive Bidding Program for Durable Medical Equipment, Prosthetics, Orthotics, & Supplies

I. INTRODUCTION

The Centers for Medicare & Medicaid Services ("CMS") has formally launched the Medicare durable medical equipment ("DME"), prosthetics, orthotics, and supplies ("DMEPOS") competitive bidding program through publication of its final rule ("Final Rule") and opening of the 60-day bidding period.[1] The bidding deadline is July 13, 2007, although potential bidders must register to bid by June 30, 2007.

Under the Final Rule, suppliers will be required to be successful bidders and meet certain program standards in order to supply selected DMEPOS items to Medicare beneficiaries in 10 competitive bidding areas ("CBAs") beginning April 1, 2008. Winning suppliers will be reimbursed based on the median of the winning suppliers' bids for each of the selected items in the CBA (rather than the Medicare fee schedule or supplier bid amount). It is important to note that, subject to very limited exceptions, suppliers that do not bid, or are not successful bidders, will not be able to bill Medicare for competitively-bid items in the CBAs.

Competitive bidding is being phased in geographically, and initially will take place in the following metropolitan statistical areas ("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-

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1 72 Fed. Reg. 17,992 (April 10, 2007). The text of the rule is available at http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/pdf/07-1701.pdf. Note that many important features of the program are being announced and implemented outside of the formal regulatory process, such as through internet postings on the CMS web site (http://www.cms.hhs.gov/center/dme.asp) and at the competitive bidding implementation contractor cite, http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home. We recommend that interested parties check these sites frequently.

Kissimmee, FL; (8) Pittsburgh, PA; (9) Riverside-San Bernardino-Ontario, CA; and (10) San Juan-Caguas-Guaynabo, PR. The program will be expanded to additional areas beginning in 2009.

Competitive bidding also is being phased in by DMEPOS product category. The program will apply initially to the following 10 categories of DMEPOS: (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 will be subject to bidding only in Miami-Fort Lauderdale-Miami Beach, FL and San Juan-Caguas-Guaynabo, Puerto Rico. Suppliers can bid on one or more "product categories," but must bid on all specified codes within the category.

Other key features of the Final Rule include the following:

- Quality Standards -- Suppliers must be accredited as meeting supplier quality standards before the contract can be awarded (CMS subsequently set an accreditation deadline of August 31, 2007 for bidders in the first bidding cycle). A supplier's accreditation must at least be pending before a bid can be submitted.

- Common Ownership -- Commonly-owned or -controlled suppliers must submit a single bid to furnish a product category in a CBA, and each commonly-owned or controlled supplier that is located in the CBA must be included in the bid.

- SNFs/NFs -- The competitive bidding rules generally apply to DMEPOS provided to Medicare beneficiaries in a skilled nursing facility ("SNF") or nursing facility ("NF"), although CMS is adopting special provisions to allow a SNF or NF with a Part B supplier number to bid to serve its own residents exclusively (without having to meet the general requirement of serving the entire CBA). This provision applies only when the SNF or NF is the direct supplier; separate Part B supplier companies affiliated with a nursing home organization will be required to submit bids under the standard competitive bidding rules and will not be allowed to serve only nursing home residents. Moreover, if a SNF or NF is not a successful bidder, the facility will be required to use a winning bidder to furnish covered Part B items to its residents.

- Physicians -- CMS is allowing physicians and certain other practitioners, along with physical therapists and occupational therapists in private practice, to furnish certain items exclusively to their patients at the single bid price without going through the bid process.

- Small Suppliers -- The Final Rule implements a number of provisions to ensure small supplier participation and access to the competitive bidding market. CMS will set a target number for small supplier participation equaling 30 percent of the number of winning suppliers. If necessary, CMS may offer contracts to small suppliers that submitted bids higher than but close to the winning bids in order to reach that goal. CMS

also will allow small suppliers to form networks if they cannot service the entire CBA independently.

- Other Key Provisions -- CMS generally will select at least five winning bidders for each product category in a CBA, up from two in the May 1, 2006 proposed rule ("Proposed Rule")[2]. CMS is not adopting a controversial proposal to allow suppliers to offer rebates to beneficiaries if their bid price were below the single payment amount. CMS also is not adopting at this time a process to use competitive bidding pricing in non-bid areas, or reforms to the "gap fill" price methodology for all DMEPOS items.

- Bidding Timeline – CMS opened the bidding period on May 15, 2007. The bidding deadline is July 13, 2007, although there is a June 30 deadline to register with the competitive bidding implementation contractor ("CBIC") in preparation for bidding.[3] CMS intends to announce winning bidders in December 2007. Bid prices go into effect April 1, 2008. The mail order diabetes supplies contracts will run until December 31, 2009, while the contract period for the other first round product categories ends March 31, 2011.

The following is an overview of the major features of the Final Rule, focusing on key changes from the Proposed Rule. We would be pleased to provide you with additional information on any aspect of the program.

II. STATUTORY & REGULATORY BACKGROUND

A. Legislative History

The Balanced Budget Act of 1997 ("BBA") authorized the Secretary of the Department of Health and Human Services ("Secretary") to implement up to five Part B competitive bidding demonstration projects. CMS used this authority to establish three DMEPOS competitive bidding projects, two in Polk County, Florida, and one in the San Antonio, Texas area. Under these projects, only suppliers that met the demonstration's quality standards and submitted competitive bids could serve Medicare beneficiaries using selected products in the demonstration areas – usually at rates significantly below the Medicare fee schedule amounts.

Building on the BBA provision, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") added a new requirement for the Secretary to implement

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2 71 Fed. Reg. 25,654. A Reed Smith client memo analyzing the Proposed Rule is available on our web site at http://www.reedsmith.com/_db/_documents/hc0605.pdf.

3 Registration and application information is available at http://www.dmecompetitivebid.com.

competitive acquisition programs for DMEPOS beginning in 2007. Products to be included could include: (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 ("OTS") orthotics. The MMA excludes from competitive acquisition inhalation drugs; parenteral nutrients, equipment, and supplies; and Class III devices.[4] Moreover, the Secretary is authorized to exempt rural areas and areas with low population density in urban areas (unless there is a significant national market through mail order for particular items), and items and services unlikely to result in significant savings.

The Secretary is directed by statute to establish competitive acquisition areas, which may differ for different items and services. Competitive acquisition will be phased in, applying to 10 of the largest MSAs in 2007, 80 MSAs in 2009, and additional MSAs thereafter. The Secretary may 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 may supply the covered items in the acquisition area, and they will be reimbursed for such items at the bid amount. The Secretary must ensure that small suppliers have the opportunity to be considered for participation under the program. In determining the categories for bids, the Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

In order to be awarded a contract, bidding entities must meet new quality standards for suppliers, along with financial standards specified by the Secretary. Total amounts paid under the contracts are expected to be less than would be paid otherwise, and beneficiary access to multiple suppliers must be maintained. The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand. Any contract awarded must be open for competitive bidding at least every three years.

The Secretary is authorized to allow physicians to prescribe a particular brand or mode of delivery of an item or service if the use of the particular item or service would avoid an adverse medical outcome. This may not affect the amount of payment otherwise applicable.

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4 Note that the preamble to the Proposed Rule states that surgical dressings are "not eligible for competitive bidding"; CMS does not elaborate on the grounds for this exclusion.

B. Regulatory and other Related Developments

CMS published its Proposed Rule to implement the DMEPOS competitive bidding program on May 1, 2006. In order to facilitate implementation, CMS finalized certain provisions of the Proposed Rule relating to supplier accreditation organizations on August 18, 2006.[5] Also in August 2006, CMS released final supplier quality standards.[6] All suppliers eventually will be required to comply with the supplier standards in order to furnish any Medicare Part B DMEPOS item or service and to receive and retain a supplier billing number, although CMS is phasing in implementation of this requirement in conjunction with the competitive bidding program.

In October 2006, CMS announced that Palmetto GBA has been named the CBIC for the DMEPOS competitive bidding program. As the contractor for this project, Palmetto will be responsible for preparing the request for bids, performing bid evaluations, selecting qualified suppliers, and setting payments for all competitive bidding areas. In addition, Palmetto will be responsible for overseeing an education program for beneficiaries, suppliers, and referral agents. Palmetto also will assist CMS and its other contractors in monitoring program effectiveness, access, and quality.

On April 10, 2007, CMS published the Final Rule implementing the remaining regulatory provisions of the DMEPOS competitive bidding program. Note, however, that important details regarding contracting and bidding, along with a variety of educational materials, are being released by the CBIC.[7]

III. FINAL COMPETITIVE BIDDING RULE

A. Competitive Bidding Areas

1. MSA Selection

The Final Rule codifies the MMA's timeframe to phase in the competitive bidding program geographically as follows:

- 10 of the largest MSAs in 2007;

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5 71 Fed. Reg. 48,354.

6 See http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/04_New_Quality_Standards.asp#TopOfPage.

7 See http://www.dmecompetitivebid.com.

- 80 of the largest MSAs in 2009, and
- Additional areas after 2009.

The preamble to the Final Rule ("Preamble") provides additional details on CMS's phase-in plans. First, while the initial bidding will take place in 2007, bid pricing and associated rules do not go into effect until April 1, 2008 – a change from the Proposed Rule's implementation date of October 1, 2007. In CY 2008, CMS intends to conduct competitive bidding in 70 of the largest MSAs, with the prices effective April 1, 2009. The next round of bidding will take place in 10 additional MSAs and will occur in CY 2009, with bid prices going into effect on January 1, 2010. An additional round of bidding will occur in CY 2010 and will include 10 more MSAs, and prices will be effective January 1, 2011.

CMS used a complex methodology to determine the specific MSAs to include for 2007, based generally on (1) the total population of an MSA; (2) the Medicare allowed charges for DMEPOS items per fee-for-service beneficiary in an MSA; (3) the total number of DMEPOS suppliers per fee-for-service beneficiary who received DMEPOS items in an MSA; and (4) an MSA's geographic location. For 2007, CMS decided to exclude New York, Los Angeles, and Chicago (the three largest MSAs based on total population) "because of the logistics associated with the start-up of this new and complex program." CMS plans to implement competitive bidding in these three cities in CY 2009, however. In the Final Rule, CMS also codified its authority to exclude from an MSA rural areas and areas with low population density.

For 2007, competitive bidding will take place in 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

10. San Juan-Caguas-Guaynabo, PR

Note that CMS has exercised its authority to select the boundaries for the CBAs that are not identical to that of the MSAs. Moreover, the exact boundaries of the CBAs are different for mail order diabetes suppliers and retail suppliers. Maps and zip code level information regarding each CBA is available at http://www.dmecompetitivebid.com/cbic/cbic.nsf/(Pages)/Competitive+Bid+Areas.

2. Mail Order Competitive Bidding

In the Proposed Rule, CMS considered allowing mail order suppliers to submit bids to furnish items during the 2007 and 2009 competitive bidding phases for beneficiaries who elect to use a mail order supplier. Moreover, CMS proposed implementing nationwide or regional competitive bidding for mail order suppliers effective January 1, 2010, and it suggested mandating mail order replacement of all supplies such as blood glucose test strips and lancets.

In the Final Rule, CMS defines a mail order contract supplier as a contract supplier that furnishes items through the mail to beneficiaries who maintain a permanent residence in a CBA. CMS also added a definition of "nationwide mail order contract supplier" (a mail order contract supplier that furnishes items in a nationwide CBA), and a definition of regional mail order contract supplier (a mail order contract supplier that furnishes items in a regional CBA). The Final Rule authorizes CMS to designate nationwide or regional mail order bidding after CY 2009.

Although CMS is not proposing establishing a nationwide or regional mail order bidding program in the first round of bidding in 2007, it is including mail order bidding at the local CBA level for the delivery of certain diabetic supplies only (e.g., test strips and lancets used with blood glucose monitors, but not the monitors themselves). CMS notes in a fact sheet that approximately 60 percent of diabetic supplies are currently delivered to Medicare beneficiaries through mail-order arrangements. If a beneficiary in a CBA *chooses* to obtain diabetic supplies through mail-order, they must use a mail order contract supplier. Mail order contract suppliers will be required to furnish the same brands of test strips they furnish to non-Medicare patients, and their payment will be based on the single payment amount established for each code (discussed below). Because competitive bidding applies only to mail order diabetes supplies in the first round, the general requirement to obtain items from a contract supplier does not apply to retail diabetes supplies. In other words, a beneficiary still has the option to obtain diabetic

supplies from any enrolled retail Medicare supplier, and payment to the supplier will be based on the current fee schedule payment methodology.[8]

B. Items Included in Competitive Bidding/Use of Product Categories

As provided under the MMA, the following items are subject to competitive bidding: (1) DME (including DME used with infusion and drugs, other than inhalation drugs) and supplies used in conjunction with DME, but excluding class III devices[9]; (2) enteral nutrients, equipment, and supplies; and (3) OTS orthotics.[10] The statute authorizes CMS to phase in first those products with the greatest potential for savings. In determining an item's potential savings, CMS will consider the following factors: annual Medicare DMEPOS allowed charges; annual growth in expenditures; number of suppliers; savings in the DMEPOS demonstrations; and reports and studies.

To facilitate bidding, CMS is establishing "product categories," defined as a grouping of related items that are used to treat a similar medical condition. Policy groups established by the DME Medicare Administrative Contractors ("DME MACs") for coverage purposes will serve as the starting point for establishing competitive bidding product categories, but CMS may choose to refine the groups for bidding purposes. The list of product categories and the specific items included in each product category in each bid cycle will be identified by program instructions or by other means.

For 2007, CMS has announced that the following product categories will be subject to competitive bidding:

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8 For more information on mail order diabetic testing supplies, see http://www.dmecompetitivebid.com/cbic/cbic.nsf/123c46a12e4607f9852572330015b04f/fa6f8fb9f312ef5e852572df004a5307?OpenDocument.

9 The Preamble discusses CMS's interpretation of the coverage status of a number of specific items of DMEPOS. For instance, CMS states that diabetic shoes and inserts, prosthetics for the foot, splints and casts, prosthetic devices that aid vision, and surgical dressings are not covered by the competitive bidding statute and thus are not eligible for competitive bidding.

10 Off-the-shelf orthotics are those that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary. The Final Rule defines "minimal self-adjustment" as "an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist or an individual who has specialized training."

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 Supplies

8. Negative Pressure Wound Therapy Pumps and Related Supplies and Accessories

9. Walkers and Related Accessories

10. Support Surfaces (group 2 mattresses and overlays[11]) -- Miami and San Juan Only

Suppliers can bid on one or more product categories, but they must bid on all specified HCPCS codes within the category.[12] Furthermore, while suppliers will not be required to supply every brand of product in each code, the Final Rule includes a nondiscrimination provision requiring contract suppliers to make the same items available to beneficiaries under the Medicare DMEPOS competitive bidding program that they make available to other customers. The supplier's bid will list the specific brands that the supplier will furnish for each HCPCS code, and CMS will post on the internet the list of brands that each contract supplier furnishes.[13]

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11 CMS initially included Group 3 support surfaces (E1094) in bidding, but subsequently announced that only Group 2 items will be included in the first round.

12 A complete listing of codes subject to the initial round of competitive bidding is available at http://www.dmecompetitivebid.com/cbic/cbic.nsf/(subpages)/CBICSuppliersProduct+Categories. In the Final Rule, CMS clarifies that while it will always identify an item by its HCPCS code, it may combine several codes and/or modifiers to form one competitively bid item or specify a particular method by which the item is furnished.

13 The CBIC has clarified that a supplier is not "locked into" furnishing only those products listed on the application for the duration of the contract period. The CBIC will update the list quarterly, and suppliers must report what products they actually are furnishing. See http://www.dmecompetitivebid.com/cbic/cbic.nsf/123c46a12e4607f9852572330015b04f/1160359185690d77852572c6006f13dc?OpenDocument.

C. Requirement to Obtain Competitively Bid Items from a Contract Supplier

Under the Final Rule, Medicare beneficiaries who maintain their permanent residence in a CBA must obtain competitively-bid items from a contract supplier for that area, subject to the following exceptions.

1. Exception for Physicians, Treating Practitioners, Physical Therapists, and Occupational Therapists

Under the Final Rule, physicians (including podiatric physicians) and treating practitioners (e.g., physician assistants, clinical nurse specialists, nurse practitioners) have the option to furnish certain types of competitively bid items to their own patients without submitting a bid if the following conditions are met:

- The items that may be furnished under this provision are limited to crutches, canes, walkers, folding manual wheelchairs, blood glucose monitors, and infusion pumps that are DME;
- The items must be furnished by the physician or treating practitioner to his or her own patients as part of his or her professional service; and
- The items must be billed using a billing number assigned to the 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.

Likewise, CMS is giving physical therapists in private practice and occupational therapists in private practice the option to furnish OTS orthotics to their own patients as part of their professional service without participating in bidding if certain conditions are satisfied. Items furnished and billed by a physician, treating practitioner, physical therapist, or occupational therapist under this provision will be paid at the single payment amount for the CBA (rather than the fee schedule).

CMS notes that a physician, treating practitioner, physical therapist, or occupational therapist who wishes to furnish *other* competitively-bid DMEPOS items in a CBA (and can otherwise legally do so) would have to submit a bid and be awarded a contract. CMS also points out that the competitive bidding rules do not impact the applicability of the physician self-referral provisions in section 1877 of the Social Security Act (the "Act"), commonly known as the Stark Law. In other words, a contract supplier cannot furnish an item as a result of a referral prohibited under the Stark Law.

2. Other Exceptions

The Final Rule also provides that Medicare beneficiaries who maintain their permanent residence in a CBA may obtain competitively-bid items from a noncontract supplier in the following circumstances:

- Grandfathered Items -- A beneficiary who was renting certain DME or oxygen and oxygen equipment prior to the start of the competitive bidding program may elect to continue to obtain the item from a noncontract supplier in accordance with the grandfathering provisions described below.

- Beneficiary Travel -- A beneficiary who is outside of the CBA where he or she maintains a permanent residence may obtain an item from a supplier with a valid Medicare supplier number if he or she is either in another CBA that does not include the item in its program or is in an area that is not a CBA. On the other hand, if the beneficiary is in another CBA where the item is included in competitive bidding, the beneficiary must obtain the item from a contract supplier. In either case, payment to the supplier will be based on the single payment amount for the item in the CBA area where the beneficiary maintains a permanent residence, and the claims jurisdiction will be based on the beneficiary's permanent residence.

- Medicare Secondary Payer Situations -- Under the Final Rule, Medicare may make a secondary payment for an item furnished by a noncontract supplier that the beneficiary is required to use under his or her primary insurance policy.

- Special Rules for Physicians - A physician, treating practitioners, and physical and occupational therapists can furnish certain specified competitively-bid items without being a contract supplier under certain circumstances. Those rules are discussed below.

Unless one of these exceptions applies, Medicare will not pay for the item if furnished by a noncontract supplier. Likewise, if a noncontract supplier located in a CBA furnishes an item included in the competitive bidding program for that area in violation of program rules, the beneficiary will have no financial liability to the noncontract supplier unless the beneficiary has signed an advanced beneficiary notice ("ABN") accepting liability for all costs.[14]

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14 A fact sheet regarding the use of ABNs by noncontract suppliers is available at http://www.dmecompetitivebid.com/cbic/cbic.nsf/123c46a12e4607f9852572330015b04f/3bcf46bf45ad172e852572c80054981c?OpenDocument.

D. Basic Bidding Rules

1. Requirements to Submit Bids for DMEPOS

As noted, in order for a supplier to receive payment for competitively-bid items in a CBA, the supplier generally must have submitted a bid to furnish those particular items and been awarded a contract by CMS, with certain very limited exceptions.

2. Supplier Eligibility

Under the Final Rule, CMS will not award a contract to any entity unless it is accredited as meeting applicable quality standards. CMS may allow a grace period for suppliers that have not yet been accredited at the time they submit their bid. CMS states in the Preamble that the grace period would apply only if the supplier has submitted an application to a CMS-approved accreditation organization and is waiting for the accreditation process to be completed, but the supplier must obtain its accreditation before it is awarded a contract. CMS subsequently specified that for the first round of bidding, suppliers must be accredited by August 31, 2007.[15]

Suppliers also must meet other basic eligibility rules, including being enrolled as a Medicare supplier, having all necessary state and local licenses, and meeting all applicable financial standards specified by the Secretary. Bidders also must disclose information regarding prior or current legal actions, sanctions, and revocations from the Medicare program, program-related convictions, exclusions, or debarments against the company or against any members of the board of directors, chief corporate officers, high-level employees, affiliated companies, or subcontractor by any federal, state, or local agency. CMS will not award a contract to any supplier that does not meet these eligibility requirements.

3. Ability to Serve Entire CBA

a. General Requirement

The Final Rule generally requires a contract supplier to agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier (although as discussed below, CMS will permit SNFs and NFs to bid to furnish DMEPOS exclusively to their own residents). If a beneficiary is unable to come to the supplier's storefront, CMS expects the contract supplier to deliver the item to the beneficiary and, if

15 See http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS/01_overview.asp.

necessary, set up the item in the beneficiary's residence and train the beneficiary how to use the item. As discussed below, CMS will allow small suppliers to form networks in order to serve the full geographic area included in a CBA.

b. Special Rule for Skilled Nursing Facilities & Nursing Facilities

Under the Final Rule, SNFs and NFs with their own Medicare Part B supplier numbers will be required to compete if they seek to bill Medicare for competitively bid DMEPOS items[16] furnished to their own residents; otherwise, SNFs and NFs must contract with a winning supplier. CMS has adopted a special rule, however, that will allow SNFs and NFs to bid to serve only their residents, without having to meet a general requirement of being able to serve the entire CBA.[17] Facilities that elect to submit bids for furnishing items only to their own residents may not furnish these items to any other beneficiary in the region. In addition, SNFs and NFs will be required to be accredited as a DMEPOS supplier in order to furnish items under the DMEPOS competitive bidding program, even if they are only furnishing items to their own residents. If a SNF or NF is not a winning bidder, they will need to make arrangements with a contract supplier to furnish competitively-bid items to their residents.

Significantly, Part B supply companies that are owned or affiliated with nursing home organizations – but organized as separate companies –will be required to submit bids under the standard competitive bidding rules; that is, they will not be allowed to serve only nursing home residents and must instead agree to provide items to any beneficiary in the region.

As a practical matter, this provision could present hurdles to common arrangements between nursing homes and affiliated Part B supply companies, since the Part B supplier could no longer choose to serve only the nursing home population (i.e., they also would be required to serve home care patients), and they could no longer limit the number of nursing homes they chose to serve. Nursing facilities with such arrangements will need to consider becoming an accredited DMEPOS supplier

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16 While Part B coverage is not available for most DME furnished in a SNF setting because a SNF is not considered a patient's "home," a limited number of items including enteral nutrients and supplies, urologicals, and surgical dressings may be furnished under Part B in the nursing home setting in stays that are not covered under Part A.

17 CMS does not permit hospital-based suppliers to bid to furnish DMEPOS only to their own patients, since CMS believes that they function more like other commercial suppliers.

(which presents a logistical issue given the short bidding window) or explore options for contracting with a winning Part B supplier.

4. Common Ownership – Single Bid

CMS agreed with commenters that allowing commonly-owned suppliers (or a supplier that has a controlling interest in another supplier) to submit different bids for the same product category in the same CBA would "undermine the integrity of the bidding process." Thus CMS is requiring bidders to disclose whether they have an "ownership" or "controlling interest" in one or more other suppliers, or if one or more other suppliers has an ownership or controlling interest in it. CMS considers two or more suppliers to be commonly-owned if one or more of them has an ownership interest totaling at least 5 percent in the other(s). The term "ownership interest" is defined as "the possession of equity in the capital, the stock, or the profits of another supplier." A "controlling interest" exists if one or more of owners of a supplier is an officer, director, or partner in another supplier.

Under the Final Rule, commonly-owned or -controlled suppliers with multiple locations in the same CBA must submit a single bid on behalf of all the locations, and must indicate the combined capacity for all those locations. The bid also must include any locations outside the CBA that would be furnishing items in the CBA if a contract is awarded. If CMS awards a contract based on the single bid submitted by the commonly-owned or -controlled suppliers, all of these related suppliers would become contract suppliers. CMS will reject multiple bids submitted by commonly-owned or -controlled suppliers for the same product category in the same CBA.**18**

Note that the Final Rule does not specifically discuss situations in which multiple suppliers do not have an ownership interest in each other, but do share a common parent entity that is not acting directly as a supplier.

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18 CMS will request information in the bid applications regarding a supplier's key personnel to, among other things, determine common ownership "to ensure that companies are not bidding against themselves to furnish the same product categories in the same CBA by submitting different bids for commonly owned separate locations."

5. Bidding as a Network

CMS is adopting its proposal to allow suppliers to form networks for bidding purposes, with certain modifications. Under this provision, a legal entity, such as a joint venture, limited partnership, or contractor/subcontractor relationship, would be formed to act as the applicant and submit the bid. Each member of the network must be eligible to participate and meet any accreditation and quality standards. CMS also finalized the requirement that the network member's market share cannot exceed 20 percent of the Medicare market within the CBA.[19]

In a new provision, CMS is limiting network members to small suppliers (i.e., gross annual revenue of $3.5 million or less). To address concerns that networks may be anticompetitive if they have excessively large number of members, the Final Rule also limits the size of the network to 20 suppliers. Moreover, the Final Rule now requires each network member to sign a statement certifying that the supplier joined the network because it is unable to furnish all of the items in the product category for which the network is submitting a bid to beneficiaries throughout the entire CBA geographic area. According to CMS, this provision is necessary to ensure that "each network member joined the network for a legitimate, legal purpose." CMS will now require each member of the network to furnish all of the items within the product categories for which the network is awarded a contract. CMS also is modifying the claims submission process for networks; each network member will be required to submit its own Medicare claims and receive payment for those claims, rather than designate a primary supplier to submit claims and receive payment on behalf of all network member suppliers. Finally, CMS will allow small suppliers to join more than one network, but a small supplier cannot join more than one network that submits a bid to furnish items in the same product category in the same CBA (nor can the supplier submit an individual bid and a network bid for the same product category in the same CBA).

E. Evaluation of Bids

1. Market Capacity

CMS has finalized its proposal to select the number of contract suppliers necessary to meet the projected demand for DMEPOS items in the CBA. To determine expected demand, CMS will review Medicare claims data to determine the number of units of each item furnished during the past two years,

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19 Once a network receives a contract, there is no limit on what percentage of the demand in the CBA that the network can furnish.

and then estimate the number of new beneficiaries that have entered the market during the last two years. CMS also will consider seasonal changes and other trends in beneficiary demand for products.

To gauge the necessary number of suppliers to meet expected beneficiary demand, CMS will examine suppliers' current capabilities and the number of units the supplier is willing and capable of supplying at the bid price in the CBA. CMS will require evidence of financial resources to support market expansion, such as letters from investors or lending agents. CMS will compare expected capacity and Medicare volume to determine how many suppliers it would need in an area. CMS cites consultations with industry representatives that suggest that "most DMEPOS suppliers would be able to easily increase their total capacity to furnish items by up to 20 percent and the increase could be even larger for products like diabetes supplies that require relatively little labor."

In the Final Rule, CMS states that it may make two types of adjustments to a supplier's projected capacity. First, if a supplier estimates that it can furnish more than 20 percent of the expected beneficiary demand for the product category in the CBA, CMS will lower that supplier's capacity estimate to 20 percent to ensure that at least five suppliers are selected to furnish a product category in a CBA.[20] If there are not at least five qualified suppliers in a CBA, CMS will award contracts to at least two qualified suppliers. Second, CMS might further adjust a supplier's capacity estimates if CMS concludes that the supplier's financial and business expansion documentation does not support the projected capacity. In such cases, CMS will lower the supplier's projected capacity to its historical capacity. Note that any adjustments CMS might make to a supplier's projected capacity would not impact the supplier's ability to actually furnish items if it is awarded a contract. Moreover, the projected capacity submitted by a supplier would not become a binding term of the contract because contract suppliers will be required to furnish the items in their contract to all beneficiaries who maintain a permanent residence in the CBA, or who visit the CBA, and who request the items from them (unless an exception applies).

2. Bid Amounts/Composite Bids

A supplier's bid for a product category must specify its bid price for furnishing each item (i.e., HCPCS code) within the product category for the duration of the contract period, which can be up to

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20 Note that CMS would not make such a capacity adjustment in the case of regional or national mail order suppliers.

three years.[21] The submitted bid must include all costs related to the furnishing of each item, such as delivery, set-up, and training. CMS did not adopt its proposal to apply an annual inflation update for multi-year contracts; as a result, suppliers must consider the possible effects of inflation or price increases when they formulate their bids.

CMS will use composite bids to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category, which will allow CMS to determine which suppliers could offer the lowest aggregate costs. CMS will weight individual items within the product categories based on national beneficiary utilization data; the weights will be provided to suppliers prior to bidding.[22] To compute a composite bid, CMS will multiply a supplier's bid for each item in the product category by the item's weight and sum the numbers across items.

3. Determining the Pivotal Bid/Small Supplier Target

Under the Final Rule, CMS will array the composite bids for a product category from lowest to highest. CMS will establish as the "pivotal bid" the lowest composite bid for a product category that includes a sufficient number of suppliers to meet beneficiary demand for items in the product category. All bidders who are eligible for selection (that is, that have satisfied CMS eligibility, quality, accreditation, and financial requirements) and whose composite bid for the product category is less than or equal to the pivotal bid would be selected as winning bidders.[23]

In a new provision, however, the Final Rule allows a small supplier[24] to be selected as a winning bidder even if its composite bid is above the pivotal bid if necessary to ensure sufficient small supplier participation. Specifically, CMS will set a target number for small supplier participation equaling 30 percent of the number of winning suppliers. If CMS determines after the initial evaluation of bids that

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21 For the first round of competitive bidding, CMS has announced that the contract period for mail order diabetic supplies is April 1, 2008 – December 31, 2009, and the contract period for all other first round product categories is April 1, 2008 – March 31, 2011.

22 Product weights for the first round of bidding are available on the CBIC website.

23 CMS sets forth a special process to select additional contract suppliers if necessary to meet beneficiary demand or if a supplier's contract is suspended or terminated.

24 A small supplier is defined as a supplier that generates gross revenue of $3.5 million or less in annual receipts.

there are not enough small suppliers with winning bids to meet the target goal of 30 percent in each product category, then CMS will give small suppliers that submitted bids higher than but close to the pivotal bid the option of accepting a contract to furnish the product category at the single payment amounts. CMS will start with the supplier closest to the pivotal bid amount, and continue until it reaches the target number of small suppliers or there are no additional small suppliers that submitted a bid for the product category.

4. Assurance of Savings and Multiple Contractors

CMS will not accept any bid for an item that is higher than the payment amount that otherwise would apply if the item were not included in the competitive bidding program (i.e., the fee schedule amount for the item).

In an important change from the Proposed Rule, the Final Rule provides that CMS generally will select a least **five** bidders for each product category in a CBA, up from two in the Proposed Rule.[25] If there are not at least five qualified suppliers, CMS will award contracts to at least two qualified suppliers.

F. Determining Single Payment Amounts for Individuals Items

Once CMS has selected contract suppliers for a product category based on the composite bid and the pivotal bid, CMS will establish single payment amounts for each individual item (by HCPCS code) in the product category. The single payment amount will equal the median of the bid prices for the item submitted by winning suppliers for the product category (that is, those suppliers whose composite bids for the product category are equal to or below the pivotal bid for that product category). If there is an even number of bids, the single payment amount for the item is equal to the average of the two middle bids. Thus, under this single payment amount policy, a winning supplier will not necessarily be reimbursed the actual amount for each code that the supplier submitted in its bid. Instead, approximately half of winning suppliers will be reimbursed less than they bid for a particular item, and the other half will be paid more.

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25 As previously noted, the commitment to select five suppliers for each product category in a CBA does not apply to regional or national mail order bidding.

CMS states that only bids from eligible, qualified, and financially sound suppliers will be used to determine the single payment amounts and select contract suppliers. Moreover, in light of potential incentives for suppliers to submit unreasonably low bids in order to ensure selection as a contract supplier, CMS has acknowledged the need for "a process to identify and eliminate irrational, infeasible bids." To that end, CMS will evaluate bids to ensure that they are *bona fide*, and CMS may request that a supplier submit additional financial information, such as manufacturer invoices, so the agency can verify the supplier can provide the product to the beneficiary for the bid amount. If CMS concludes that a bid is not *bona fide*, CMS will eliminate the bid from consideration.

G. Special Payment Rules

1. Payments to Contract Suppliers

The payment basis for items furnished under competitive bidding is 80 percent of the single payment amount for the CBA in which the beneficiary maintains a permanent residence, and the beneficiary is responsible for the 20 percent copayment. Payment for items furnished under competitive bidding is made on an assignment-related basis.

CMS generally will follow current Medicare rules regarding whether a rental or purchase payment would be made for a competitively bid item and whether other requirements would apply to the furnishing of that item, with certain exceptions.

- Inexpensive or Other Routinely Purchased DME Items. The beneficiary must be given a choice of either renting or purchasing such items. CMS will calculate a single rental payment amount based on 10 percent of the payment for new items.

- Rental Items Requiring Frequent and Substantial Servicing. CMS will require bids to be submitted for the monthly rental of items in this payment category, with the exception of continuous passive motion exercise devices, for which bids must be submitted on a daily rental basis.

- Oxygen and Oxygen Equipment. CMS will calculate single payment amounts based on separate bids submitted and accepted for the furnishing on a monthly basis of each of the oxygen and oxygen equipment payment classes.[26] Rental payments are limited to 36 months. However, CMS added a new provision that will provide additional payments to contract suppliers that must begin furnishing oxygen equipment when a beneficiary switches from his or her previous noncontract supplier. Specifically, a contract supplier that must begin furnishing oxygen equipment after the rental period has already begun to

26 CMS set forth new payment classes for oxygen and oxygen equipment for items furnished after 2006. See 71 Fed. Reg. 65,884.

a beneficiary who is no longer renting the item from his or her previous supplier (because the previous supplier elected not to become a grandfathered supplier or the beneficiary elected to change suppliers) will receive at least 10 rental payments for furnishing the equipment (assuming the item continues to be medically necessary).[27] This rule does not apply when a beneficiary switches from a *contract* supplier to another contract supplier to receive his or her oxygen equipment.

- Capped Rental Items. CMS will calculate a single payment amount based on bids for the purchase of new items in this category. For items furnished on a rental basis, the single payment amount for months 1 through 3 will be based on 10 percent of the single payment amount for purchase of the item, and for months 4 through 13 it will be based on 7.5 percent of the single payment amount (after which title transfers to the beneficiary). The lump sum purchase option for power wheelchairs is retained. Also note that CMS is adding a new provision to ensure that a contract supplier can recover its costs for rented capped rental items when a beneficiary switches from a noncontract supplier to a contract supplier. Specifically, a contract supplier that must begin furnishing a capped rental item during the rental period to a beneficiary who is no longer renting the item from his or her previous supplier will receive 13 monthly rental payments for the item, regardless of how many monthly rental payments Medicare previously made to the prior supplier (assuming the item remains medically necessary). At the end of this new 13 month rental period, the contract supplier will transfer title to the beneficiary. This rule does not apply when a beneficiary who is renting a capped rental item from a *contract* supplier elects to obtain the same item from another contract supplier.

- Enteral Nutrition Equipment and Supplies. Enteral nutrition equipment can be paid on a purchase or rental basis. Under the Final Rule, Medicare payments for rented enteral equipment may be made for 15 month, with a payment reduction for enteral equipment rental payments after the third month. Specifically, based on accepted bids for new equipment, CMS will calculate a single payment amount for rented items for months 1 through 3 based on 10 percent of the single payment amount for new items, with the rental payment reduced to 7.5 percent for rented items for months 4 through 15. For purchased enteral nutrition equipment, the single payment amount for new enteral nutrition equipment would be based on the bids submitted and accepted for new enteral nutrition equipment. CMS will calculate single payment amount for the purchase of enteral nutrients and enteral nutrition supplies based on the bids submitted for new equipment.

- Maintenance and Servicing of Enteral Nutrition Equipment. The Final Rule requires the contract supplier to which rental payment is made in month 15 for the furnishing of enteral nutrition equipment must continue to furnish, maintain, and service the equipment for as long as the equipment is medically necessary. CMS will make payments for the

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27 For example, if a contract supplier begins furnishing oxygen equipment to a beneficiary in months 2 through 26, CMS would make payment for the remaining number of rental months in the 36-month rental period. If a contract supplier begins furnishing oxygen equipment to a beneficiary in month 27 or later, CMS would make 10 rental payments (assuming the equipment remains medically necessary). CMS asserts that 10 months is sufficient to cover the contract supplier's cost to furnish the equipment, irrespective of the modality that is used to administer the oxygen.

maintenance and service of enteral nutrition equipment beginning 6 months after 15 months of rental payments are made. These payments will equal 5 percent of the single payment amounts for the purchase of new enteral nutrition equipment. This provision applies only to enteral equipment; separate maintenance and servicing payments are not made for rented DME.

- Supplies Used in Conjunction with DME. CMS will calculate single payment amounts for the purchase of supplies used in conjunction with DME based on the bids submitted and accepted for these items.

- Orthotics. CMS will calculate single payment amounts for OTS orthotics on a purchase basis.

- Used Equipment – Bids will be submitted based on the furnishing of new equipment. Payment for used DME and enteral nutrition equipment will equal 75 percent of the single payment amounts calculated for new purchased equipment.

- Repair and Replacement of Beneficiary-Owned Items – In response to comments, CMS has decided not to adopt its proposal to require repair or replacement of patient-owned items subject to competitive bidding to be furnished by a contract supplier, since contract suppliers may not have the training and expertise needed to repair every make and model of equipment. Instead, Medicare will pay for maintenance and servicing of competitively bid items, including replacement parts that may be needed, that are performed by any supplier with a valid Medicare billing number. Payment generally will be made for parts and labor consistent with the current fee-for-service methodology. Historically, Medicare payment for repair and replacement under this methodology has been very limited. CMS notes, however, that if the *part needed to repair the item* is itself a competitively bid item for the CBA in which the beneficiary maintains a permanent residence, CMS will pay the supplier the single payment amount for the part. On the other hand, beneficiaries will be required to obtain a *replacement* of an entire item from a contract supplier, with payment made at the single payment amount. CMS also will make general maintenance and servicing payments to suppliers that service oxygen equipment (other than liquid and gaseous equipment), and an additional payment to a supplier that picks up and stores or disposes of beneficiary-owned oxygen tanks or cylinders that are no longer medically necessary.

2. Payments to Grandfathered Noncontract Suppliers

The Final Rule implements the statutory requirement to allow a "grandfathering" process for rented DME and oxygen and oxygen equipment when these items are included under a competitive bidding program.**28** The process will apply to suppliers that began furnishing the items to beneficiaries who maintain a permanent residence in a CBA prior to the implementation of the competitive bidding program. Beneficiaries will have a choice of whether to continue renting the item from the

28 Similar provisions would apply for the continuation of rental agreements for suppliers that lose their contract status in a subsequent competitive bidding program in the same CBA.

grandfathered supplier or a contract supplier (unless the grandfathered supplier is not willing to continue furnishing the item). Suppliers who agree to be grandfathered suppliers for a specific item must agree to be a grandfathered supplier for all beneficiaries who request to continue to receive the item from the supplier.

For items requiring frequent and substantial servicing as well as oxygen and oxygen equipment, the grandfathered supplier may continue to furnish these items to beneficiaries in accordance with existing rental agreements or supply arrangements, except the grandfathered supplier will be paid the single competitive bidding payment amounts. For capped rental items and inexpensive or routinely purchased items furnished on a rental basis, the grandfathered supplier may continue furnishing the items in accordance with existing rental agreements and continue to be paid under the applicable fee schedule.

Under the Final Rule, accessories and supplies used in conjunction with and necessary for the effective use of an item furnished under the grandfathering process also may be furnished by the same grandfathered supplier. Payment will be based on the single payment amount for the item.

H. Physician Authorization/Clinical Efficiency and Value

CMS is not requiring a contract supplier to provide every brand of product or mode of delivery included within a HCPCS code, and indeed, the agency expects suppliers to choose to offer only certain brands within a code. Under the Final Rule, a physician or treating practitioner[29] is authorized to prescribe in writing a particular brand of an item or mode of delivery of an item if he or she determines that it would "avoid an adverse medical outcome for the beneficiary." In such cases, the physician or treating practitioner must document in the beneficiary's medical record the reason why the particular brand or mode of delivery is necessary to avoid an adverse medical outcome.

If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must follow a process established under the Final Rule. Specifically, the supplier must: (1) furnish the particular brand or mode of delivery as prescribed; (2) consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery and

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29 CMS defines treating practitioner to include physician assistants, nurse practitioners, and clinical nurse specialists.

obtain a revised written prescription; or (3) assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner. In any case, Medicare will not make an additional payment to a contract supplier that furnishes a particular brand as directed by a prescription, and since payment under competitive bidding is on an assignment-related basis, the beneficiary cannot be charged extra for the item. Contract suppliers are prohibited from billing for an item different from the particular brand of item or mode of delivery specified in the written prescription. CMS does not include in the Final Rule the requirement that a supplier make a "reasonable effort" to furnish the brand, as provided in the Proposed Rule.

CMS believes it will "rarely be necessary" for a physician or treating practitioner to prescribe a particular brand or mode of delivery to avoid an adverse medical outcome, since HCPCS codes "are carefully written to include items that perform the same therapeutic function."

I. Revisions to HCPCS Codes during a Bidding Cycle

CMS is adopting the following rules regarding changes in HCPCS codes for competitively-bid items that occur during a bidding cycle:

(a) If a single HCPCS code for an item is divided into two or more HCPCS codes for the components of that item, the sum of single payment amounts for the new HCPCS codes equals the single payment amount for the original item. Contract suppliers must furnish the components of the item and submit claims using the new HCPCS codes.

(b) If a single HCPCS code is divided into two or more separate HCPCS codes, the single payment amount for each of the new separate HCPCS codes is equal to the single payment amount applied to the single HCPCS code. Contract suppliers must furnish the items and submit claims using the new separate HCPCS codes.

(c) If the HCPCS codes for components of an item are merged into a single HCPCS code for the item, the single payment amount for the new HCPCS code is equal to the total of the separate single payment amounts for the components.

(d) If multiple HCPCS codes for similar items are merged into a single HCPCS code, the items to which the new HCPCS codes apply may be furnished by any supplier that has a valid Medicare billing number, and payment for these items will be made under the Medicare fee schedule. This is a change from the Proposed Rule, under which suppliers would have been paid based on the average payment for the formerly separate codes.

In each case, suppliers must furnish the item and submit claims using the new HCPCS code.

J. Other Provisions Related to Competitive Bidding

The Final Rule addresses many other aspects of the competitive bidding program, including the following:

- Use of Subcontractors -- CMS anticipates that some contract suppliers will enter into arrangements with subcontractors. In the response to the request for bids, bidders must submit any plans for subcontracting, but CMS will not evaluate subcontractors to determine if they meet the accreditation, quality, financial, and eligibility standards. However, a contract supplier may not subcontract with any supplier that has been excluded from the Medicare program, any state health program or any other government executive branch procurement or nonprocurement activity. Moreover, the contract supplier will be responsible for fulfilling all of the terms of its contract, even if it uses one or more subcontractors.

- No Administrative or Judicial Review -- As specified under the MMA, the Final Rule provides that there will be no administrative or judicial review related to: establishment of competitive bidding payment amounts; awarding of contracts; designation of CBAs; the phased-in implementation schedule; selection of items; or the bidding structure and number of contract suppliers selected. A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by the rule.

- No Rebates to Beneficiaries -- In the Proposed Rule, CMS suggested allowing contract suppliers that submit bids for an individual item below the single payment amount to provide the beneficiary with a rebate equal to the difference between the supplier's actual bid and the single payment amount. CMS has decided not to adopt this proposal in the Final Rule, however, based on fraud and abuse concerns and the potential for rebates to provide incentives for beneficiaries to obtain unnecessary items.

- Change of Ownership -- A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change. CMS may award a contract to an entity that merges with, or acquires, a contract supplier if certain conditions are met, including that the successor entity meets all applicable competitive bidding requirements, submits specified documentation to CMS, and submits to CMS at least 30 days before the date of the change of ownership a signed novation agreement stating that it will assume all obligations under the contract.

- Breach of Contract -- Any deviation from contract requirements (including failure to comply with governmental agency or licensing organization requirements), constitutes a breach of contract. In such event, CMS may, among other things, require the contract supplier to submit a corrective action plan; suspend or terminate the contract supplier's contract; preclude the contract supplier from participating in the competitive bidding program; or revoke the entity's supplier number.

- Education and Outreach -- CMS will conduct a wide range of supplier and beneficiary education initiatives related to the competitive bidding program.

- Monitoring and Complaint Services -- CMS will direct the CBIC to develop and implement a complaint monitoring system for competitively bid items and services. The

system will be outlined in more detail through subregulatory guidance. CMS also will monitor Medicare claims data to ensure that competitive bidding does not negatively impact beneficiary access to medically necessary items.

K. Proposed Provisions Not Included in the Final Rule

Effective January 1, 2009, the MMA authorizes CMS to use payment information determined under competitive bidding to adjust fee schedule payments for items that are not in a CBA. While CMS expressed its intent to use this authority in the Proposed Rule, the agency did not set forth a detailed methodology for such a process. CMS agreed with commenters that it should not codify this provision until a more detailed plan is developed. CMS plans to conduct subsequent rulemaking prior to implementing this provision.

Likewise, the Proposed Rule included significant reforms of CMS's long-standing "gap fill" pricing policy that would affect DMEPOS fee schedule amounts in areas not subject to competitive bidding. CMS also proposed (1) establishment of a new fee schedule for home dialysis supplies and equipment that continue to be paid on a reasonable charge basis; (2) codification that the eyeglass coverage exclusion under Medicare Part B encompasses all devices that use lenses to aid vision or provide magnification of images for impaired vision; (3) codification of Medicare payment policy for therapeutic shoes, inserts, and shoe modifications; and (4) fee schedule updates for class III DME. CMS has not addressed these provisions in the Final Rule; instead, they will be finalized in a future rulemaking.

IV. CONCLUSION

Competitive bidding is expected to have a significant impact on Medicare DMEPOS pricing in the CBAs in which it is instituted. CMS expects the program to result in annual savings of $1 billion or more when fully implemented beginning in 2010. The new program also could result in changes in the distribution of DMEPOS, with consolidation of suppliers within individual CBAs.

The Final Rule reflects a number of improvements compared to the Proposed Rule (e.g., delayed implementation until April 2008, a minimum of five suppliers in each region, and special considerations for small suppliers and physicians). However, the Final Rule does not ultimately change the nature of the competitive bidding program, which requires suppliers to compete on the basis of price or risk losing their access to the Medicare market. It also maintains the financial incentive for bidders to supply the least expensive products within a code, which disadvantages manufacturers and suppliers of more advanced medical equipment (although CMS expects the nondiscrimination clause to preserve access to a wider range of products). The Final Rule also could result in more complicated supply arrangements

for nursing homes, which will be required to be winning bidders to provide DMEPOS to their residents or contract with a winning bidder.

The opening of the 60-day bidding window marks the beginning of an intense period of activity for suppliers considering bidding. There are a number of steps potential bidders should be taking, including the following:

- Suppliers that are not yet accredited should begin that process as soon as possible, since applications must be pending when a bid is submitted and accreditation must be completed by August 31, 2007 for a supplier to be eligible to participate in the first round of bidding.
- Suppliers need to register at the CBIC web site by June 30, 2007 if they intend to bid.[30]
- Small suppliers should determine whether they can cover all geographic areas for relevant product categories in a CBA or whether they would be eligible to join a network, since a new legal entity must be formed and a unified bid will need to be prepared.
- Suppliers should review the specific codes that must be supplied in the various product categories and determine which models/brands they will supply for each code, their planned pricing, and their expected capacity to furnish the items. Suppliers also should assess the impact of various bid pricing scenarios on their business, since the price is not likely to be the ultimate single payment amount.
- Suppliers can begin to amass the financial and other information will need to submit their bids.[31] The CBIC has posted a "getting started" checklist for bidding suppliers at http://www.dmecompetitivebid.com/cbic/CBIC.nsf/Attachments/1BA90A2F45A0E9EA852572660049932D/$FILE/CheckList.pdf.
- When ready to bid, application information is posted at http://www.dmecompetitivebid.com/cbic/cbic.nsf/(Pages)/Bid%20Application%20&%20Instructions.

In addition, suppliers should submit timely Medicare reenrollment applications and ensure compliance with the supplier standards to avoid deactivation of their supplier numbers by the National Supplier Clearinghouse. Likewise, manufacturers should be preparing for changes in the marketplace in the CBAs. Among other things, manufacturers can reach out to major suppliers in key geographic areas to ensure they are included in the suppliers' bid sheets.

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30 See http://www.dmecompetitivebid.com/cbic/cbic.nsf/(pages)/home.

31 See http://www.dmecompetitivebid.com/cbic/cbic.nsf/(subpages)/CBICSuppliersBid%20Application%20Tool%20Kit.

We would be pleased to provide you with additional information on any aspect of the program, or assist you in your analysis regarding participation in the program.

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Please contact our Senior Health Policy Analyst Debra A. McCurdy (202/414-9388, dmccurdy@reedsmith.com), Carol Loepere (202/414-9216, cloepere@reedsmith.com), Elizabeth Carder-Thompson (202/414-9213, ecarder@reedsmith.com), Robert J. Hill (202/414-9402, rhill@reedsmith.com), or any other Reed Smith attorney with whom you work if you would like additional information or if you have any questions.

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