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DMEPOS Update:

- CMS Prepares to Re-Launch Competitive Bidding Program;
- Next Steps for DMEPOS Suppliers Preparing to Submit Bids;
 - PAOC Meeting on Competitive Bidding Program

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This is the sixth in our series of *Client Alerts* regarding the Medicare Competitive Bidding Program for durable medical equipment, prosthetics, orthotics and supplies ("**DMEPOS**").¹

CMS Prepares to Re-Launch Competitive Bidding Program

On May 29, 2009, the Centers for Medicare & Medicaid Services ("**CMS**") announced the next steps in the Medicare Part B DMEPOS Competitive Bidding Program. These next steps will implement the Round 1 Rebid phase of the program, beginning with opening the bid window in the Fall of 2009.

¹ Our other *Client Alerts* are entitled: *Registration and Competitive Bidding Period for First Round of the DMEPOS Competitive Bidding Program Extended: Bids Due by July 20, 2007* (July 2007); *Important Updates for DMEPOS Suppliers* (January 2008); *CMS Announced Dates for the Second Round of DMEPOS Competitive Bidding and Single Payment Amounts and Contract Offers for the First Round of DMEPOS Competitive Bidding (April 2008); DMEPOS Update: Physicians and Certain Other Professionals Now Exempt from DMEPOS Accreditation Requirements and MIPPA Delays Competitive Bidding, Terminates Round 1 Contracts* (September 2008); and *DMEPOS Update: CMS Issues Then Delays Interim Final Rule On Competitive Bidding, Issues Final Rule Requiring Surety Bonds and Reverses on Exempting Pedorthists From Accreditation* (February 2009). These *Client Alerts* are available under "News and Publications" at <u>www.ebglaw.com</u>.

Round 1 of the DMEPOS Competitive Bidding Program was implemented on July 1, 2008, in ten (10) competitive bidding areas ("**CBAs**"), as mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("**MMA**"). As part of the Medicare Improvements for Patients and Providers Act of 2008 ("**MIPPA**"), Congress enacted a temporary delay of the DMEPOS Competitive Bidding Program and mandated certain changes to the program.

In brief, MIPPA required CMS to terminate contracts awarded in Round 1 and to conduct the competition for the Round 1 Rebid in 2009. Additionally, MIPPA establishes a financial document review process and a requirement for contract suppliers to report subcontractor relationships with other suppliers. MIPPA also excluded certain DMEPOS items and areas from the Competitive Bidding process and provided an exemption to the Program for hospitals that furnish certain types of DMEPOS items to their own patients. However, MIPPA did not fundamentally change the nature of the Competitive Bidding Program as established by MMA or the existing Competitive Bidding regulations that were finalized in 2007. Further information on these changes can be found in our September 2008 and February 2009 *Client Alerts*.

For now, Medicare beneficiaries may continue to use their current DMEPOS suppliers for those items and areas that are subject to the Competitive Bidding Program.

Next Steps for DMEPOS Suppliers Preparing to Submit Bids

CMS will begin shortly the implementation process with some pre-bidding supplier awareness and educational programs regarding the steps that DMEPOS suppliers must take now to be ready for program registration and bidding. These steps include the following:

 Obtaining Appropriate State Licenses. DMEPOS suppliers submitting bids in product categories in CBAs must meet all DMEPOS state licensure requirements and any other applicable state licensure requirements, if any, for that product category, for every state in that CBA. For example, a supplier submitting a bid for Cincinnati would, if successful, provide product to the Cincinnati-Middletown MSA, an area which services parts of Ohio, Kentucky and Indiana. As such, that supplier must be appropriately licensed in all three (3) states.

Prior to submitting bids for CBAs and product categories, suppliers must have copies of the applicable state licenses on file with the National Supplier Clearinghouse ("**NSC**"). As part of the bid evaluation process, CMS will verify with the NSC that the DMEPOS supplier has on file copies of all applicable required state licenses.

2. Updating Medicare Enrollment Files with the National Supplier Clearinghouse. DMEPOS supplier standards require all suppliers to notify the NSC of any changes to the information provided on the Medicare enrollment application, the CMS-855S form, within thirty (30) days of the change. Although this is a requirement for all DMEPOS suppliers, this is an especially important requirement for suppliers who will be involved in the Competitive Bidding Program because suppliers must ensure that their information is accurate to be able to participate in the Competitive Bidding Program. DMEPOS suppliers are encouraged to use the March 2009 version of the 855S to review and update their list of products and services (Section 2.D), the Authorized Official(s) information (Sections 6.A and 15) and the correspondence address (Section 2.A2). Information and instructions on how to submit changes of information may be found on the NSC website at http://www.palmettogba.com/nsc.

- 3. Getting Accredited. DMEPOS suppliers have been advised that they must be accredited by September 30, 2009 or will risk having their Medicare Part B billing privileges revoked on October 1, 2009. Suppliers must be accredited for a DMEPOS product category in order to submit a Competitive Bidding Program bid for that product category. CMS cannot contract with DMEPOS suppliers that are not accredited by a CMS-approved accreditation organization. Further information on the DMEPOS accreditation requirements can be found in our January 2008 Client Alert referenced above and on the CMS website at http://www.cms.hhs.gov/MedicareProviderSupEnroll/01_Overview.asp (which includes a list of the CMS-approved accreditation organizations).
- 4. Getting Bonded. DMEPOS suppliers must obtain and submit a surety bond by the October 2, 2009 deadline or risk having their Medicare Part B billing privileges revoked. Suppliers (with certain exceptions) must be bonded in order to bid in the DMEPOS Competitive Bidding Program. A list of sureties from which a bond can be secured may be found on the Department of the Treasury's website (http://www.fms.treas.gov/c570/c570 aa.html). Further information on the surety bond requirement can be found in our February 2009 Client Alert referenced above.

Bidder registration is expected to begin this summer before bidding opens in the Fall. CMS made certain process improvements to the Competitive Bidding Program in anticipation of the Round 1 Rebid process, including an upgraded online bid submission system, early bidder education and increased oversight of bidders that are new to product categories or CBAs to ensure that they meet CMS' requirements for participating in the Program.

PAOC Meeting on Competitive Bidding Program

On June 4, 2009, CMS convened a meeting of the DMEPOS Competitive Bidding Program Advisory and Oversight Committee ("PAOC"). At the PAOC meeting, CMS staff confirmed that this summer, it will reveal the actual dates of the new bidding process that will occur in the CBAs. Winners of those bids will be announced in the Summer of 2010.²

As explained in our February 2009 Client Alert, under the new bidding rules, bidders will have the opportunity to provide missing financial documentation to complete their bids, and the timeframe of that documentation has been changed from three (3) years to one (1) year. During the PAOC meeting CMS expressed that although they will evaluate only one year's worth of financial data, it will be a good snapshot of the DMEPOS supplier's financial capability, given the current economic climate.

A representative of Palmetto GBA, the competitive bidding implementation contractor ("CBIC") which administers the bidding process on behalf of CMS, told PAOC meeting attendees that the CBIC is creating fact sheets and webcasts on common problems arising under the Competitive Bidding Program. Common problems include Medicare beneficiaries who travel and will thus not always be located in their CBA when they need products, grandfathered suppliers who will continue to provide products to certain Medicare beneficiaries, and how a supplier may calculate the appropriate bid amount.³

² Mindy Yochelson, Medicare: Board Members Cite Challenges for CMS on Changes to DME Competitive *Bidding*, BNA's Health Care Daily Report (June 9, 2009) ("*BNA PAOC Article*"). ³ *Id.*

With regard to calculating appropriate bid amounts, the Palmetto/CBIC representative stated that the bid must be viewed as "bona fide" and be supported by documentation. Further, Joel Kaiser, Deputy Director of CMS' Division of DMEPOS Policy, stated that bids are screened to ensure that the bids are reasonable based on a statistical calculation that will identify bids are that much lower than is statistically realistic. This calculation will be made across all CBAs, so CMS has eliminated the possibility that a bid considered unrealistic in one CBA could be considered realistic in another CBA.⁴

Accreditation also was addressed during the PAOC meeting. Kim Brandt, Director of CMS' Program Integrity Group, stated that 51,000 suppliers have been accredited or are pending accreditation, but certain groups are lagging behind on accreditation, such as pharmacists.⁵ Kim Brandt also stated that CMS will be sending letters to suppliers in the NSC database that have not submitted surety bonds. Brandt estimated that 25,188 DMEPOS suppliers will exit the Medicare program due to the combined costs of the surety bond and accreditation requirements.⁶

CMS also explained the changes to the online registration (IACS) and bidding systems (DMEPOS Bidding System or DBids) to the PAOC meeting attendees. This summer, when registration begins, bidders will receive user identification numbers and passwords. Under the new bidding system, suppliers may cut and paste data that is requested on multiple bid forms, which should make the process less time-consuming. Questions regarding the online process will be directed to a dedicated help desk and go through a process that elevates problems to a second tier, which is intended to address complaints about the Round 1 process.⁷

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⁴ Id.

⁵ Id.

⁶ Id.

⁷ Id.

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