

DMEPOS Update: Accreditation/Surety Bond Information; Update on CMS's Open Door Teleconferences on Competitive Bidding

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Accreditation/Surety Bond Information

Although the deadlines for accreditation and surety bond(s) have passed for most suppliers of durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS"), certain issues bear discussion to (1) ensure that the process was done correctly and (2) assist those who are currently in the accreditation or bonding process.¹ With regard to accreditation, we heard rumors that those who were exempt from accreditation needed to submit documentation to the National Supplier Clearinghouse ("NSC") about such exemption. However, if you are exempt from accreditation, e.g., physicians, physical therapists, etc., then you do not need to submit any documentation to the NSC about such exemption unless the NSC specifically requests such documentation, which typically occurs if there is some confusion/concern about how you are operating your business and whether you fit within the exemption.

All DMEPOS suppliers should have obtained and submitted a \$50,000 continuous bond for each of their NPIs by October 2, 2009. As such, because DMEPOS suppliers must have an NPI per location, if a DMEPOS supplier has 20 locations, that supplier should have submitted a bond for \$1,000,000 to the NSC. It is important to note that surety bonds must come from an "**Authorized Surety**," which is defined as a surety that has been issued a Certificate of Authority by the U.S. Department of the Treasury as an acceptable surety on Federal bonds and the certificate has neither expired nor been revoked.² A current listing of such Authorized Sureties can be found at <http://fms.treas.gov/c570/c570.html>.

Please contact us and/or see our previous *Client Alerts* for additional information on accreditation and surety bond requirements.

Competitive Bidding Program Update

We have been following the Centers for Medicare and Medicaid Services (“CMS”) and its Competitive Bidding Implementation Contractor (“CBIC”) Special Open Door Forum teleconferences regarding the DMEPOS Competitive Bidding Program.³ This *Client Alert* highlights the topics discussed during the third, fourth, fifth and sixth teleconferences. The October 14 and November 4, 2009 teleconferences will be open calls, allowing prospective bidders to ask questions and collectively benefit from the answers from CMS and CBIC. ***NOTE:*** For purposes of this summary, the comments made by CMS and the CBIC will be attributed to CBIC, who led the teleconferences. Further, a complete list of the Special Open Door Forum teleconferences and related presentations, transcripts and audio recordings are available on the CBIC website at <http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/docsCat/Open%20Door%20Forums%20Calendar?opendocument>.

- ***CONTRACT TERMS*** – CBIC advised participants that suppliers must be mindful of key Competitive Bidding program contract terms that will be enforced:
 - (1) suppliers must comply with Competitive Bidding program guidelines for the full contract period, which will be announced when the bidding period opens;⁴
 - (2) suppliers must furnish the same DMEPOS items to Medicare beneficiaries as they provide to their non-Medicare customers;⁵
 - (3) suppliers must furnish competitively bid DMEPOS items to any Medicare beneficiary who resides in or who visits a competitive bidding area (“CBA”), with the exception of skilled nursing facilities and nursing facilities that are awarded contracts as specialty suppliers (these providers may only provide bid items, specifically enteral nutrition in Round 1, to their own residents);⁶
 - (4) suppliers must furnish the DMEPOS items that are prescribed by the physicians or consult with physicians regarding suitable alternatives;⁷
 - (5) suppliers must submit quarterly reports on DMEPOS items that are furnished under its contract, including the number of items furnished and the manufacturer/model/model number of the items furnished;
 - (6) suppliers must maintain their enrollment, accreditation and licensure status; and
 - (7) suppliers are not guaranteed a minimum amount of business.
- ***STATE LICENSURE*** – In response to questions from suppliers, CBIC began the teleconference with a clarification of certain information regarding the state licensure directories available to suppliers on the CBIC website (<http://www.dmecompetitivebid.com>). Specifically, CBIC confirmed that these directories are intended to be references for in-state suppliers, and that out-of-state suppliers should contact the relevant state agencies identified in these directories regarding licensing requirements for out-of-state suppliers. CBIC stated that it will rely on state guidelines regarding licensure and that all suppliers are responsible for identifying and obtaining all required licenses. Further, CBIC confirmed that, during the bidding process, it will verify with the NSC that each supplier has all required licenses on file. CBIC advised participants that a licensure fact sheet has been published and is available now on the CBIC website.⁸

- GRANDFATHERED SUPPLIERS*** – CBIC also discussed the guidelines applicable to grandfathered suppliers. The Social Security Act requires a grandfathering process for rented durable medical equipment (“DME”) and oxygen and oxygen equipment furnished by non-contract suppliers prior to the time the Competitive Bidding program is in effect.⁹ Grandfathered suppliers may continue to provide beneficiaries with equipment for the remainder of the rental period or until the item is no longer medically necessary. CBIC confirmed that the grandfathering provisions are applicable to suppliers of DME and oxygen, but stated that these provisions are not applicable to suppliers of enteral nutrition items. For rented DME, grandfathered suppliers must accept the fee schedule amounts as payment for added competitively bid base items, and must accept the single payment amounts as payment for competitively bid accessories. Suppliers also must accept assignment on claims. New contract suppliers of DME may rent to beneficiaries for 13 months and must accept single payment amounts as payment. For rented oxygen and oxygen equipment, grandfathered suppliers will be paid the single payment amount and must accept assignment on all claims. New contract suppliers of oxygen and oxygen equipment also will be paid the single payment amount for at least 10 months of oxygen rental. CBIC also clarified that the grandfathering provisions are applicable to Medicare beneficiaries who are transitioning from Medicare Advantage plans.
- CHANGES OF OWNERSHIP*** – Although the sale or transfer of a competitive bidding contract is strictly prohibited, CMS will allow the transfer of competitive bidding contracts in the event of a supplier change of ownership (“CHOW”). CBIC advised that certain different rules apply depending on whether the supplier is a successor entity or a new entity.¹⁰ Successor entities that acquire the assets of an existing contract supplier must submit to CMS a signed novation agreement, stating that the successor entity will assume all obligations of the existing contract supplier. This novation must be submitted **at least 30 calendar days before** the anticipated effective date of the CHOW.¹¹ If a new entity will be formed as the result of a merger or acquisition, the existing contract supplier must submit to CMS its final draft of a novation agreement **within 30 calendar days before** the effective date of the CHOW.¹² Thereafter, the newly formed supplier entity must submit to CMS an executed novation agreement **within 30 calendar days after** the effective date of the CHOW.¹³
- EXPANSION PLANS*** – CBIC advised that when reporting expansion plans, suppliers should address various elements of these plans including staffing, finance, facilities, inventory control, distribution methods and subcontractors. CBIC also outlined the steps for calculating capacity and directed suppliers to worksheets on the CBIC website that will help suppliers perform these capacity calculations.
- BIDDING ETIQUETTE*** – Every bidding supplier must ensure that each of its locations has an active NSC number. Further, a bidding supplier cannot bid against itself, which, according to CBIC, means that a supplier cannot bid against a “commonly owned” or “commonly controlled” entity. Bids must be “bona fide,” meaning rational and feasible, supportable by documentation (e.g., a manufacturer’s invoice). If a non-bona fide bid, as determined by CBIC, is submitted, then that bid for the product category in that CBA is disqualified.

- *BIDDING DEADLINES* – Round 1 Rebid competitive bidding registration for user IDs and passwords began in mid-August and is open until November 4, 2009 at 9:00 PM EST. Once the bidding is closed, a supplier cannot change its bid. As such, it is important for suppliers to verify their bid amounts for every item in the product category, ensuring that each bid amount is less than or equal to the current fee schedule amount.
- *BID ELEMENTS* – There are three elements of a bid – Form A, Form B, and hardcopy documents. Form A must be submitted through the CMS DMEPOS Bidding System (“DBidS”) and requests general information about the supplier or network. Suppliers must submit a Form A in order to obtain a bidder number. Only one Form A must be submitted for all CBAs, product categories and locations. Form A must be completed and approved by the supplier’s Authorized Official or Back-Up Authorized Official before the supplier may proceed to completing Form B or submitting hardcopy documents. Form B also must be submitted on DBidS, and one Form B must be submitted for each product category/CBA combination. Bidder charts for each CBA are available on the CBIC website to help suppliers estimate capacity and determine appropriate bid amounts. The hardcopy documents must be mailed in one package and must indicate the bidder number, obtained by completing Form A, on each page of each document.
- *FINANCIAL DOCUMENTATION REQUIREMENTS* – CBIC reviewed the financial documentation requirements for submitting bids. Suppliers are required to submit 1 year of financial documents - specifically, the most recent year’s documentation prior to the date the bid is submitted. Suppliers must provide copies of “financial statements” including income statements, balance sheets, statements of cash flows and the revenue and expense portions of the supplier’s tax return. In response to participants’ questions, CBIC clarified that the supplier’s tax return should reflect the supplier’s fiscal calendar (the same time period for which the supplier normally prepares and submits its taxes). Additionally, CBIC advised that suppliers must submit a credit report, including the numerical credit score, that is less than ninety (90) days old.¹⁴ CBIC also advised participants on certain logistical requirements regarding the preparation and submission of financial documentation (e.g., including the assigned bidding number on all pages, preparation of financials using accrual basis or cash basis accounting). CBIC clarified that new suppliers that have operated for less than 1 year must provide an “appropriate combination” of actual and pro forma financial data for the 1 year period, but should not aggregate or combine the actual and the pro forma financial documents. In response to a participant’s question regarding the requirements for newly formed entities, CBIC advised that if the supplier is newly formed, the supplier may submit certain pieces of financial documentation, such as the credit report, on behalf of an individual, most likely the primary shareholder (according to CBIC).
- *COVERED DOCUMENT REVIEW* – CBIC discussed the newly designed covered document review process that is required by MIPPA. CBIC will review financial documents that it receives by the Covered Document Review Date (“CDRD”) to determine if any financial documents are missing. CBIC clarified that this review will

only focus on whether any required financial documentation is *missing*, and not on whether the individual documents submitted for this review are accurate or complete. CBIC advised participants that the CDRD will be the later of 30 days prior to the close of the bid submission period or 30 days after the start of the bidding period. Currently, the Round 1 Rebid 60-day bidding window is scheduled to open on **October 21, 2009**. Thus, the current target CDRD is **November 21, 2009**, but CBIC advised participants that it will confirm the actual CDRD when the bidding period opens next week. CBIC will notify bidders regarding any missing financial documents within 45 days after the CDRD, and bidders will have 10 business days from the date of this notice to submit the missing financial documents. CBIC clarified that it will only accept the missing documents from bidders, and will not accept changes to bid amounts or other changes to bids (e.g., submissions of revised financial documents).

- *PIVOTAL BID/SINGLE PAYMENT AMOUNT* – In determining the pivotal bid for each product category, CBIC will pick the lowest composite bid that includes a sufficient number of suppliers to meet beneficiary demand. Winning suppliers will be at or below the pivotal bid and meet eligibility, accreditation and financial requirements. CBIC will then take the qualified suppliers and determine the median bid amount, which will become the single payment amount.
- *SMALL SUPPLIER PARTICIPATION* – CBIC explained to participants how it will set its small supplier targets,¹⁵ as well as how small suppliers may submit bids as part of a network.¹⁶ CBIC explained that CMS has set a thirty percent (30%) target for small supplier participation in the Competitive Bidding program. CBIC confirmed that “small suppliers” were defined in the competitive bidding final rule as those that generate gross revenues of \$3.5 million or less in their annual receipts, including Medicare and non-Medicaid revenue.¹⁷ In response to participants’ questions, CBIC clarified that a small supplier may bid as both an individual supplier and as part of a network. CBIC advised that if the supplier wishes to submit individual and network bids within the same CBA, the bids must be submitted for different products. If the supplier wishes to submit individual and network bids within different CBAs, the bids may be submitted for the same product.
- *SUBCONTRACTORS* – CBIC also reviewed with participants some of the guidelines applicable to subcontractors participating in the Competitive Bidding program. Specifically, contractors are required to notify CMS of subcontracting arrangements within ten (10) business days of a competitive bidding contract award or of entering into a subcontracting agreement. Subcontractors must comply with Medicare Supplier Standards with regard to purchases of inventory, repair of rented equipment and delivery and instruction on the use of DMEPOS items. Subcontractors are also required to be accredited, as applicable, per the Medicare Improvements for Patients and Providers Act of 2008 (“MIPPA”) accreditation requirement, and must also be licensed as required under the applicable state rules.
- *TRAVELING BENEFICIARIES* – Regarding traveling beneficiaries, CBIC advised participants that payment for DMEPOS items is always based on the permanent residence

of the beneficiary, but that the type of supplier who may provide the beneficiary with the DMEPOS item depends on whether the DMEPOS item is a bid or non-bid item and where the beneficiary obtains the DMEPOS item. If the beneficiary's permanent residence is in a CBA and the beneficiary needs a DMEPOS item included in the Competitive Bidding program for the CBA where the beneficiary is visiting, the beneficiary must obtain the DMEPOS item from a contract supplier. However, if the beneficiary needs a non-bid DMEPOS item, the beneficiary may obtain the non-bid item from any Medicare-enrolled supplier. If the beneficiary's permanent residence is not in a CBA and the beneficiary needs a DMEPOS item included in the Competitive Bidding program for the CBA where the beneficiary is visiting, the beneficiary must obtain the DMEPOS item from a contract supplier. If the beneficiary needs a non-bid DMEPOS item, however, the beneficiary may obtain the item from any Medicare-enrolled supplier.

As stated above, the seventh and eighth teleconferences on October 14, 2009 and November 4, 2009 will be open calls, allowing prospective bidders to ask questions and collectively benefit from the answers of CMS and CBIC.

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Other EpsteinBeckerGreen *Client Alerts* that address DMEPOS issues are:

- *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);
- *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)
- *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* (June 2009)
- *DMEPOS Update: Round One Rebid to Begin in Late October 2009; Important Reminders; Program Begins Again in 2011; Study Criticizes Competitive Bidding Program; CMS Severely Limits Physician DME Consignment Closets* (August 2009)
- *DMEPOS Updates: (1) CMS Delays Implementation Date for New Consignment Closet Rules; (2) Information from CMS' Second Special Open Door Teleconference on Competitive Bidding* (September 2009).

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¹ All suppliers of durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”), with certain exceptions, should have been accredited by September 30, 2009 and should have obtained and submitted a surety bond for each of their NPIs by October 2, 2009. DME suppliers that only bill A/B Medicare Administrative Contractors for Part B drugs and biologicals do not need to be accredited. Also exempted from accreditation are physicians, audiologists, optometrists, prosthetists, opticians, occupational therapists and physical therapists. Certain DMEPOS suppliers are exempt from bonding requirement: (1) Government-owned suppliers, (2) State-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics if the business is solely-owned and operated by said personnel and is billing only for orthotics and prosthetics, and related supplies, (3) Physicians and non-physician practitioners if the DMEPOS items are furnished only to his or her patients as part of his or her professional service, and (4) Physical and occupational therapists if: (a) the business is solely-owned and operated by the therapist, and (b) if the DMEPOS items are furnished only to his or her patients as part of his or her professional service.

² 42 C.F.R. § 424.57(a)

³ The first two teleconferences took place on August 19, 2009 (registering to access the IACS bidding system) and September 2, 2009 (learning the rules for submitting bids).

⁴ See 42 C.F.R. § 414.422(b).

⁵ See *id.* § 414.422(c).

⁶ See *id.* § 414.422(e).

⁷ See *id.* § 414.420(d).

⁸ The state Licensure fact sheet referenced during the teleconference is currently available on the CBIC website at: [http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/Fact_Sheet_Licensure.pdf/\\$File/Fact_Sheet_Licensure.pdf](http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/files/Fact_Sheet_Licensure.pdf/$File/Fact_Sheet_Licensure.pdf).

⁹ The April 10, 2007 final rule for the Competitive Bidding program, 72 Fed. Reg. 17992, outlines the grandfathering provisions. In 2008, CMS published sub-regulatory guidance in the Medicare Claims Processing Internet-Only Manual to establish guidelines for non-contract suppliers to notify beneficiaries of the grandfathering

options. Centers for Medicare and Medicaid Services, Medicare Claims Processing Manual, Chapter 36. In a notice of proposed rulemaking dated July 13, 2009, CMS proposed to revise the definition of a “grandfathered item” and to include in the regulations a grandfathering notification process. 74 Fed. Reg. 33520.

¹⁰ Both successor entities and new entities must meet all requirements applicable to contract suppliers for the applicable Competitive Bidding program. 42 C.F.R. § 414.422(d)(2)(i). Existing contract suppliers must notify CMS if negotiating a CHOW **60 calendar days before** the anticipated date of the change. *Id.* § 414.422(d). Both successor entities and new entities must submit to CMS the documentation required by 42 C.F.R. § 414.414(b)-(d), if it has not been submitted previously by the existing contract supplier or the successor entity, or is no longer current. Duplicates of previously submitted information need not be submitted if that information is still current. This information must be provided to CMS **within 30 calendar days prior** to the anticipated effective date of the CHOW. *Id.* § 414.422(d)(2)(ii).

¹¹ *Id.* § 414.422(d)(2)(iii).

¹² *Id.* § 414.422(d)(2)(iv).

¹³ *Id.*

¹⁴ CMS confirmed that credit reports will only be accepted if prepared by: Dun & Bradstreet, Experian, Equifax, TransUnion or Standard & Poor’s.

¹⁵ CMS will meet its small supplier participation target using 3 steps: (1) CMS will set a target number by multiplying the total number of qualified suppliers whose composite bids are at or below the pivotal bid by 30 percent; (2) CMS will identify the number of qualified small suppliers who composite bids are at or below the pivotal bid; and (3) CMS will select additional qualified suppliers whose bids are above the pivotal bid until its small supplier target is reached. *See* 42 C.F.R. § 414.414(g)(1).

¹⁶ CMS advised participants that, to be part of a network, each “member” supplier must meet the definition of “small supplier” and must be unable to service the entire CBA independently, and must provide a certification statement on both of these points. Each “member” supplier must meet all of the bidding eligibility requirements, including accreditation, licensing, bonding (if applicable) and having an active NSC number. Each “member” supplier may only join 1 network per CBA per product category. Networks may not exceed 20 percent of the market share at the time of bidding, and must be limited to 20 members or less. The members of a network must form a legal entity, per CMS, such that an agreement is in place prior to submitting a network bid and so that this agreement may be submitted with the other required bidding documentation. Each “member” supplier’s financial documents must be submitted as part of one combined bid submission package. *See id.* § 414.418.

¹⁷ *Id.* § 414.402.

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