

**DMEPOS UPDATES:****(1) CMS Delays Implementation Date for  
New Consignment Closet Rules****(2) Information from CMS's Second Special Open  
Door Teleconference on Competitive Bidding**

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**Delayed Implementation of Change Request 6528 Affecting Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS")**

As described in our August 2009 *Client Alert*, the Centers for Medicare and Medicaid Services ("CMS") issued Change Request ("CR") 6528 revising the Medicare Program Integrity Manual in a way that will severely limit physician and non-physician practitioner DMEPOS consignment closet and stock and bill arrangements. These changes will impact a vast number of arrangements between DMEPOS suppliers and physicians and non-physician practitioners and was to become effective September 8, 2009. However, on September 1, 2009, CMS delayed the implementation of CR 6528 until **March 1, 2010**.<sup>1</sup> All other information in this CR remains the same as was published in Transmittal 297.

While CMS's use of the terms "consignment closet" and "stock and bill" arrangements is somewhat confusing, it is important that both DMEPOS suppliers that stock DMEPOS items in physician or non-physician practitioners offices and those physicians and non-physician practitioners that bill under the Medicare program should closely review CR 6528 to determine whether it impacts their arrangement. Non-physician practitioners impacted by this rule include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse midwives, clinical social workers, clinical psychologists, registered dietitians and nutrition professionals.

Specifically, effective March 1, 2010, CMS will only allow Medicare-enrolled DMEPOS suppliers to maintain inventory at a practice location owned by a physician or a non-physician practitioner for the purpose of DMEPOS distribution when the DMEPOS supplier meets the following conditions:

1. The title to the DMEPOS shall be transferred to the enrolled physicians, non-physician practitioner practice at the time the DMEPOS is furnished to the beneficiary;
2. The physician or non-physician practitioner shall bill for the DMEPOS supplies and services using their own enrolled DMEPOS billing number;
3. All services provided to a Medicare beneficiary concerning fitting or use of a DMEPOS shall be performed by individuals being paid by the physician or non-physician practitioner's practice, and not by any other DMEPOS supplier; and
4. The beneficiary shall be advised that if he or she has a problem or question regarding the DMEPOS, then the beneficiary should contact the physician or non-physician practitioner, and not the DMEPOS supplier who placed the DMEPOS at the physician or non-physician practitioner's practice.

In addition to these new enrollment rules, all the parties affected by these new consignment closet/stock and bill rules must consider the fraud and abuse guidance from the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") and CMS regarding these arrangements. The OIG issued a *Special Fraud Alert* in 2000 and has posted four (4) Advisory Opinions that provide insight into the OIG's position regarding how the Federal anti-kickback statute and Federal civil monetary penalty law affect these arrangements.<sup>2</sup> The physicians and DMEPOS suppliers must also take into consideration the Federal physician self-referral law (commonly referred to as the "Stark Law"), which prohibits physicians from furnishing DMEPOS items from their practice to Medicare patients and billing for such services in the absence of a Stark Law exception. The usual Stark Law exception is the in-office ancillary services exception, which limits the type of durable medical equipment items that can be supplied by physicians in their offices to canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors.<sup>3</sup>

There are ways to structure these arrangements that continue to be compliant under the various laws, but we recommend that you discuss your arrangements with us or someone else who is familiar with the various laws and applicable guidance.

### **CMS Hosts Second Open Door Forum on DMEPOS Competitive Bidding**

On September 2, 2009, CMS hosted the second, in a series of, Special Open Door Forum teleconferences sponsored by CMS and its Competitive Bidding Implementation

Contractor ("CBIC") to educate suppliers about the Round 1 Rebid of the Competitive Bidding process.<sup>4</sup>

Highlights from the teleconference included:

- All suppliers intending to submit a bid application to participate in the DMEPOS Competitive Bidding Program must first register in Individuals Authorized Access to the CMS Computer Services ("IACS") to obtain a user ID and password to access the online bidding system. Participants were reminded that the registration process for obtaining user IDs and passwords is open, and were encouraged to register early to avoid delays in accessing the online bidding system when bidding opens. Authorized Officials are strongly encouraged to register no later than **September 14, 2009**. Backup Authorized Officials are strongly encouraged to register no later than **October 9, 2009**. IACS registration closes at 9:00 PM EST on **November 4, 2009**.
- Although the Round 1 CBAs have remained the same for the Round 1 Rebid, participants were alerted to the name change for one of the Florida CBAs. The CBA previously known as "Miami-Fort Lauderdale-Miami Beach, FL" is now known as "Miami-Fort Lauderdale-Pompano Beach, FL". However, participants were advised that the geographic area for this CBA has not changed.

The Round 1 Rebid CBAs include the following –

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

See CMS, Metropolitan Statistical Areas, Competitive Bidding Areas, and Zip Codes, *available at* [http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01a\\_MSAs\\_and\\_CBAs.asp](http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01a_MSAs_and_CBAs.asp) (last viewed Sept. 4, 2009).

- Participants were advised that, although CMS has received requests to exclude additional product categories, the Medicare Improvements for Patients and Providers Act ("MIPAA") requires that the list of product categories for the Round 1 Rebid remain the same as the list of product categories for Round 1, except for the two exclusions mandated by MIPAA: (1) the exclusion of Negative Pressure Wound Therapy from Round 1; and (2) the exclusion of Group 3 Complex Rehabilitative Wheelchairs from the Competitive Bidding program.
- Participants were advised that a "bona fide" bid must be equal to or less than the Medicare fee schedule amount and must be realistic. If CMS requires further

proof that a bid submitted is “bona fide,” bidders will be asked to provide documentation, such as a manufacturing invoice.

- Several participants, particularly suppliers of mail order diabetic supplies, asked about licensure requirements.<sup>5</sup> Participants were directed to the National Supplier Clearinghouse (“NSC”) for specific information regarding state licensing standards and requirements.
- Participants were advised that suppliers may bid in a CBA even if they do not have an existing location in the CBA, as long as the supplier can comply with all of the Competitive Bidding Program requirements and supplier standards, including licensure. This can often be accomplished by engaging subcontractors.
- Participants were reminded about the rules for subcontractors and, specifically, the types of tasks for which suppliers may not subcontract (e.g., intake and assessment, coordination of care with physicians, submission of claims on behalf of beneficiaries, ownership and responsibility for equipment furnished to beneficiaries, ensuring product safety and other functions required to be performed by the primary contracting supplier). Further, participants were advised that CMS will be issuing additional guidance regarding subcontractors.
- Several participants asked for further clarification regarding the submission of bids for oxygen supplies and equipment. Participants were advised that suppliers must submit bids for the oxygen category as monthly rental bid amounts, rather than based on the purchase price of a new item (the standard for submitting bids in all of the other Round 1 Rebid product categories). CMS explained that the idea behind the bidding process for oxygen equipment is that suppliers of this equipment are paid to rent the equipment to a beneficiary for a certain period of time, after which point the ownership of the equipment transfers from the supplier to the beneficiary. It advised participants to submit bids for capped rental equipment based on the premise that, by the end of the capped rental period, CMS will have paid the supplier 105 percent of the purchase price for the equipment. CMS further explained that, using the median winning bid, it will calculate the monthly rental amount for the capped rental equipment.

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

- *Registration and 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 Podiatrists 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)

These *Client Alerts* are available under "News and Publications" at <http://www.ebglaw.com>.

<sup>1</sup> See CMS Manual Transmittal 300, Change Request 6528, *Compliance Standards for Consignment Closets and Stock and Bill Arrangements* (Sept. 1, 2009); See also CMS Manual Transmittal 297, Change Request 6528, *Compliance Standards for Consignment Closets and Stock and Bill Arrangements* (Aug. 7, 2009) (revising the Medicare Program Integrity Manual ch. 10, section 21.8). Both of these transmittals are available at <http://cms.hhs.gov/transmittals>.

<sup>2</sup> See OIG, Special Fraud Alert, *Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer* (Feb. 2000), available at <http://www.oig.hhs.gov>; OIG Advisory Opinions 8-20 (Nov. 19, 2008), 06-02 (Mar. 21, 2006), 02-4 (Apr. 19, 2002), 98-1 (Mar. 19, 1998).

<sup>3</sup> See 42 CFR 411.355(b)(4).

<sup>4</sup> A complete list of the Special Open Door Forum teleconferences is available on the CBIC website at <http://www.dmecompetitivebid.com/Palmetto/Cbic.nsf/docsCat/Open%20Door%20Forums%20Calendar?opendocument>. The first teleconference took place on August 19, 2009 and focused on how to register to access the bidding system (IACS). Future teleconferences will focus on what suppliers need to know before submitting bids, financial documentation and small supplier considerations, how bids are evaluated and the bid submission process.

<sup>5</sup> One participant pointed out that many suppliers of mail order diabetic supplies operate nationwide but are not licensed in every state, despite the fact that some states will not grant licenses to suppliers that do not have physical presence in the state. Participants were advised that suppliers need to comply with each state's requirements and that suppliers' bids will be disqualified if found to be non-compliant.

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