

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**

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Please see our previous *Client Alerts* regarding the Medicare Competitive Bidding Program for durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”).ⁱ

The Centers for Medicare and Medicaid Services (“CMS”) announced on August 3, 2009 that the 60-day supplier bidding period will begin in late October for the Round One Rebid of the Medicare Competitive Bidding Program for DMEPOS.ⁱⁱ This is in-line with the “Fall 2009” timeframe that CMS had previously announced.ⁱⁱⁱ

CMS started a supplier awareness effort in May 2009 to prepare suppliers for the registration period that begins later this August 2009. Suppliers must register before they may submit bids when bidding starts in late October 2009.

CMS, through the CMS Competitive Bidding Implementation Contractor (“CBIC”), has also launched an extensive education and outreach effort to guide suppliers through the competitive bidding process in each of the nine (9) competitive bidding areas. Information and materials may be found at www.dmecompetitivebid.com and a special toll-free help line (1-877-577-5331) has been established to assist bidders with questions and concerns. CMS will do more outreach in the coming months with a series of bidders’ conferences focusing on program information, registration and bidding – details on those conferences will be announced on www.dmecompetitivebid.com.

REMINDERS – Suppliers interested in bidding should prepare now by ensuring their enrollment information is up-to-date with the National Supplier Clearinghouse (“NSC”) and that they obtain all required State licenses for the DMEPOS items in the States in which they wish to bid. All DMEPOS suppliers (not just those in competitive bidding areas) must obtain their accreditation by September 30, 2009 or Medicare billing privileges will be revoked on October 1, 2009. (NOTE: Accreditation can take up to six (6) months.) In addition, certain Medicare suppliers (again, not just those in competitive bidding areas) will need to obtain and submit a surety bond to the NSC by the October 2, 2009 deadline or risk having their Medicare billing privileges revoked.

All DMEPOS suppliers must obtain accreditation and ensure they meet the surety bond requirements.^{iv} Further, as explained above, DMEPOS suppliers in the competitive bidding areas should be gearing up for competitive bidding. Nevertheless, Medicare beneficiaries can continue to get their Medicare-covered equipment and supplies from any Medicare-approved supplier until the program begins again in 2011.

On August 10, 2009, Brian O’Roark, PhD, Assistant Professor of Economics at Robert Morris University released his study on the effects of competitive bidding, entitled, “The Impact of Competitive Bidding on the Market for DME – A One Year Update” (the “2009 Study”).^v The 2009 Study critiqued the theory behind CMS’ bidding program and focused on the new problems for Medicare’s DME program if competitive bidding goes forward – including limiting the number of suppliers in the market for DME, resulting in market concentration and higher, not lower, prices. The 2009 Study questioned whether the DME firms can survive being left out of the Medicare market, which could lead to a market where cheaper products replace the higher quality products currently being used by patients. The Study questioned whether the increased level of specialization of DME suppliers will help or hurt customer service and ultimately the costs of provision – e.g., with competitive bidding, the risk is that one supplier may no longer be able to take care of a patient’s needs for multiple products. Further, the economies of scale of larger DME companies that were predicted by CMS did not come to pass in Round 1. In fact, only a little over 9% of the current DME suppliers in the nine competitive bidding areas were awarded contracts. If the Round 1 Rebid operates similarly, the Study reports that it could mean disruptions in supply and less access to needed care.

American Association for Homecare (AAHomecare), which represents healthcare providers, equipment manufacturers, and other organizations in the homecare community, has the 2009 Study on its website and hosted a media conference call on August 10, 2009, to unveil the Study. In its Press Release, AAHomecare stated that the study “exposes severe flaws in the Medicare competitive bidding program . . . [and] found that [CMS] drastically misread the marketplace and that the current competitive bidding program reduces overall competition and hurts the quality of patient care.”^{vi}

CMS issued a surprising Transmittal revising the Medicare Program Integrity Manual in a way that will severely limit physician DMEPOS consignment closet arrangements.^{vii} This issuance was surprising because, last year, CMS issued a Proposed Rule that included a prohibition on shared space arrangements, but had specifically asked for comments on whether CMS should establish an exception to the space sharing prohibition for physicians and non-physician practitioners.^{viii} The Medicare Program Integrity manual revisions, which are effective September 8, 2009, will prohibit DMEPOS suppliers with consignment closets in physician offices from providing items and services to Medicare patients and billing for those items and services. The manual revision specifically states that “most consignment closet or stock and bill arrangements do not satisfy the DMEPOS supplier standards.” Effective September 8, 2009,

CMS states that such arrangements will only be possible when the DMEPOS supplier meets the following conditions:

1. The title to the DMEPOS shall be transferred to the enrolled physician, 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 the 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.
5. Two or more enrolled DMEPOS suppliers shall not be enrolled and/or located at the same practice location.^{ix}

CMS has assigned responsibility for compliance with these manual provisions to the DMEPOS supplier, physician and the non-physician practitioner.

In addition to lacking a notice and comment period, the revised Program Integrity Manual provisions are effective in less than one (1) month, which will require an unrealistically short turnaround time for new enrollee physicians and non-physician practitioners to obtain DMEPOS supplier numbers from the NSC. Further, physicians must be cognizant of 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 the billing for such services in the absence of an 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 an handful of items including canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors.^x Then layer on top of these rules the guidance from the U.S. Department of Health and Human Services' Office of Inspector General (OIG) regarding the Federal anti-kickback statute's impact on such arrangements,^{xi} and you will come to realize that physician DMEPOS consignment closet arrangements have been placed in a very small box indeed.

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ⁱ Our other EpsteinBeckerGreen 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); *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); and *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). These Client Alerts are available under "News and Publications" at www.ebglaw.com.

ⁱⁱ CMS, Press Release, *Supplier Bidding to Start in October for Medicare's Competitive Bidding Program for Certain Medical Equipment and Supplies: Medicare to Launch Aggressive Supplier Education Effort in Nine Competitive Bidding Areas* (August 3, 2009), available at http://www.cms.hhs.gov/apps/media/press_releases.asp.

ⁱⁱⁱ CMS, Press Release, *Medicare Begins Supplier Education for the Competitive Bidding Program for Certain Medical Equipment and Supplies: Supplier Bid Window to Open in Fall 2009* (May 29, 2009), available at http://www.cms.hhs.gov/apps/media/press_releases.asp.

^{iv} EpsteinBeckerGreen Client Alert, *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).

^v Study is available on American Association for Homecare's website at www.aahomecare.org (last visited August 11, 2009). This study was a follow-up to a February 11, 2008 study by Dr. O'Roark and Stephen Forman, PhD, JD, MPA, entitled "The Impact of Competitive Bidding on the Market for DME," that investigated the "potential" implications of the CMS efforts (the "2008 Study"). The 2008 Study concluded that while short-run savings might be realized, the result of competitive bidding would ultimately produce artificial shortages and access problems in the intermediate run (5 to 20 years), increase price and reduce social welfare, result in job losses and inefficiencies and, more likely than not, result in monopoly profits for the successful bidders that CMS would have little incentive or ability to regulate. The 2008 Study suggested that CMS should take steps to enhance competition in the market for DME, rather than adopt what it described as artificial limitations.

^{vi} AAHomecare, Press Release, *New Economic Study Exposes Faults in Controversial Medicare Competitive Bidding Program Scheduled to Start this Fall* (Aug. 10, 2009), available at www.aahomecare.org.

^{vii} CMS Transmittal # R297PI, *Compliance Standards for Consignment Closets and Stock and Bill Arrangements* (Aug. 7, 2009) (revising the Medicare Program Integrity Manual, ch. 10, Section 21.8), available at <http://www.cms.hhs.gov/transmittals>.

^{viii} See 73 Fed. Reg. 4503, 4508, 4513 (Jan. 25, 2008) (Proposed Rule).

^{ix} See *supra* note vii.

^x See 42 CFR § 411.355(b)(4).

^{xi} 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), 98-01 (Mar. 19, 1998).

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