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CLIENT ALERT

DMEPOS Competitive Bidding Program: CMS Begins to Move Toward Nationwide Implementation and Seeks Public Comments Regarding Payment Methodology

by Amy Lerman

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The Centers for Medicare & Medicaid Services ("**CMS**") recently announced that the agency is seeking public comments as it moves toward nationwide implementation of the Medicare Durable Equipment, Prosthetics, Orthotics, and Supplies ("**DMEPOS**") Competitive Bidding Program (the "**Program**"). CMS published an Advance Notice of Proposed Rulemaking in the February 26, 2014, Federal Register.[1] The deadline to submit comments is **March 28, 2014**.

Background

The DMEPOS Competitive Bidding Program was established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.[2] The Program was created with the purpose of setting more accurate payment rates for DMEPOS items. Prior to implementing the Program, Medicare paid for these items using a fee schedule based on historic supplier charges dating back to the 1980s. Through the Program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain DMEPOS items to Medicare beneficiaries in competitive bidding areas ("**CBAs**").

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[1] 79 Fed. Reg. 10754 (Feb. 26, 2014).

[2] Historically, the Medicare program pays for most DMEPOS items furnished after January 1, 1989, pursuant to fee schedule methodologies that are set forth in Sections 1834 and 1842 of the Social Security Act as well as 42 C.F.R. Part 414, Subpart D of the Medicare regulations. Section 1847 of the Social Security Act establishes a Medicare DMEPOS Competitive Bidding Program. For more information regarding the evolution of the DMEPOS Competitive Bidding Program since its inception, please see Epstein Becker Green's other Client Alerts regarding the DMEPOS Competitive Bidding Program (http://www.ebglaw.com/clientalerts.aspx).

The first round of the Program began on July 1, 2008, but was quickly suspended due to implementation concerns.[3] Suppliers submitted new bids for the first round "rebid" and the single payment amounts ("**SPAs**") based on the winning suppliers' bids went into place in the first nine CBAs on January 1, 2011. The second round of the Program began in 91 additional CBAs, on July 1, 2013. Round 1 suppliers also have completed the process for recompeting to retain their first round contracts, with new payments for these contracts in place as of January 1, 2014.

To date, the Program has established new, lower payment amounts in the CBAs for certain DMEPOS items. These new payment amounts have replaced the traditional Medicare fee schedule amounts for these items. According to CMS, the Program has saved more than $400 million for Medicare beneficiaries and taxpayers in its first two years of operation and is projected to save an additional $17.2 billion for beneficiaries and $25.8 billion for the Medicare program over the next ten years.[4]

Currently, the Program is in effect for selected DMEPOS items in 100 CBAs across the country, as well as a nationwide mail order program for diabetic testing supplies. As required by the Affordable Care Act, by no later than **January 1, 2016**, Medicare must use information gained from the Program to adjust the Medicare fee schedule amounts for DMEPOS items in areas where the Program has not yet been implemented.

Looking Ahead: CMS Seeking Stakeholder Input

Making adjustments to the nationwide payment methodology for DMEPOS items presents a number of issues for CMS' consideration. To this end, and prior to publishing an actual proposal in a future rulemaking, CMS is soliciting public comments regarding the methodology it would use to comply with the statute when using competitive bidding pricing information to adjust payment amounts in non-competitive bidding areas based on DMEPOS Competitive Bidding Program information. CMS is also requesting comments regarding ideas for potentially simplifying the competitive bidding payment rules and enhancing beneficiary access to DMEPOS items through the Program for certain durable medical equipment ("**DME**") and enteral nutrients, supplies, and equipment ("**enteral nutrition equipment**").

Adjusting the Medicare fee schedule based on the DMEPOS Competitive Bidding Program presents a number of issues for consideration. As a first step, CMS is soliciting comments regarding several aspects of developing a new methodology that would adjust Medicare fee schedule amounts in non-competitive bidding areas based on data that is being gathered from the Program. CMS seeks input in several areas, including:

[3] Medicare Improvements for Patients and Providers Act of 2008, H.R. 6331, 110th Cong. § 154 (2008) (enacted).

[4] Centers for Medicare & Medicaid Services, Press Release, "CMS Seeks Input on Next Phase of Competitive Bidding Implementation" (Feb. 24, 2014), available at http://www.cms.hhs.gov.

- Do the costs of furnishing various DMEPOS items vary based on the geographic area in which they are furnished?

- Do the costs of furnishing various DMEPOS items vary based on the size of the market served, in terms of population and/or distance covered or other logistical or demographic reasons?

- Should an interim or different methodology be used to adjust payment amounts for items that have not yet been included in all competitive bidding programs (*e.g.,* items such as transcutaneous electrical nerve stimulation (TENS) devices that have been phased into only nine Round 1 CBAs thus far)?

CMS also seeks comments regarding whether it should consider simplifying the payment rules under competitive bidding programs for certain DME and enteral nutrition equipment. Currently, the Medicare program allows additional payments for the numerous supplies and accessories that are furnished for use with beneficiary-owned DME and enteral nutrition. A resulting effect is that claims processing systems need to count rental months, prevent duplicate payments for separately coded items, and track utilization of ongoing replacements of supplies and accessories. CMS is proposing to simplify the payment rules under competitive bidding programs for certain DME and enteral nutrition equipment by making a single monthly payment to a supplier for ***all*** related items needed each month. The monthly payments would continue as long as the covered items are medically necessary and the supplier is responsible for furnishing all items needed each month. CMS seeks input regarding several aspects of this proposal, including:

- Are lump sum purchases and capped rental payment rules for certain DME and enteral nutrition equipment still needed?

- Are there reasons why Medicare beneficiaries need to ***own*** (as opposed to rent) expensive DME or enteral nutrition equipment?

- Would there be any negative impacts associated with continuous bundled monthly payments for certain DME or enteral nutrition equipment?

An Opportunity to Comment: How Will Stakeholders React?

Since the inception of the Program, industry groups have criticized its design and impact on reimbursement rates for the affected DMEPOS items. While CMS has indicated that the Program is running smoothly and saving money for both beneficiaries and the Medicare program, industry and beneficiary advocates alike have said the Program lacks transparency, hurts patient access, decreases the quality of care that suppliers are able to provide to Medicare beneficiaries, and is driving many of the smaller DMEPOS suppliers out of business. The criticisms have come from all possible angles but, so far, have not impacted the rollout of the Program. Bipartisan efforts in Congress produced several bills aimed either at

changing the structure of the Program or halting the Program, all of which have languished on various subcommittees.[5] In 2011, nearly 250 economists, computer scientists, and engineers with expertise in the theory and practice of auctions discussed their perceptions of "numerous fatal flaws" in the Program, in an open letter to President Obama.[6] Not even the threat of litigation has changed the course of the Program.[7]

Now, as CMS looks toward Program expansion, all stakeholders have an opportunity to provide commentary that may ultimately shape the Program beyond 2016. Importantly, this also presents an opportunity, through the formal rulemaking process (an option that has not previously been possible), to encourage CMS to address the concerns that have already been raised. What can we expect to hear from DMEPOS suppliers? Here are some possible issues that may be raised through the comment process:

> ***Non-Binding Bids.*** One of the major complaints from the industry is that the DMEPOS Competitive Bidding Program allows non-binding bids, which means suppliers can submit bids without their bids being enforceable against them. These bids are used to calculate the prices for DMEPOS items but the bidders have no commitment to sign contracts for the amounts of their bids. The use of non-binding bids has been criticized by the DMEPOS industry in various respects. For example, bidding suppliers have an incentive to submit bids merely to win, with no real intention of accepting the contracts that may be awarded based on such bids. Instead, they gain the luxury of deciding whether or not it would be advantageous to enter into contracts based on those winning bids.[8] According to industry representatives, the use of non-binding bids in the DMEPOS Competitive Bidding Program created pricing schemes that have forced many suppliers to lay off workers, close their businesses, or no longer service Medicare beneficiaries. In addition, Medicare beneficiaries have reported instances where DMEPOS suppliers that contracted under the initial phase of the Program were undermining their own financial health and subsequently failing to provide the levels of service beneficiaries had received previously.
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> ***Median Pricing.*** Another concern is that the Program relies on median pricing to set winning bids. Specifically, for each DMEPOS item or service, the winning bids' price offers are ordered from lowest to highest and the median (middle) bid

[5] *E.g.*, H.R.3790, 111th Cong. (2009-2010); H.R.1041, 112th Cong. (2011-2012); H.R.6490, 112th Cong. (2011-2012); H.R.27, 113th Cong. (2013-2014); H.R.1717, 113th Cong. (2013-2014).
[6] See "Letter from 244 Concerned Auction Experts on Medicare Competitive Bidding Program" (June 17, 2011), available at http://www.cramton.umd.edu/papers2010-2014/further-comments-of-concerned-auction-experts-on-medicare-bidding.pdf (hereinafter, "Auction Experts Letter").
[7] *E.g.*, *Amer. Assoc. for Homecare et al. v. Sebelius*, No. 1:13-cv-00922 (June 19, 2013).
[8] For further discussion regarding the use of non-binding bids, see Paulette C. Morgan, *Medicare Durable Medical Equipment: The Competitive Bidding Program*, Congressional Research Service (June 26, 2013), at 21-25.

price offered by these suppliers for that item or service becomes the SPA.[9] This means that the SPA for any particular DMEPOS item or service included in the Program is set below the amounts that half the bidders said was the minimum they would accept. By contrast, pricing in a traditional bidding / auction context is generally set at the highest bid among all winning bidders necessary to fulfill the market. Taken together, according to the 2011 open letter sent to President Obama, "[t]he use of non-binding bids together with setting the price equal to the median of the winning bids provides a strong incentive for low-ball bids—submitting bids dramatically below actual cost. This leads to complete market failure in theory. . . ."[10]

Lack of Transparency. Regardless of which pricing methodology CMS ultimately chooses, suppliers are very anxious to see increased transparency regarding the winning bids. Greater transparency ideally would help suppliers understand how CMS determined the bid amounts and the median prices. Many suppliers also have pointed to a lack of transparency as the cause behind issues unrelated to cost-savings or even quality, such as improper vetting of the financial strength of some DMEPOS suppliers awarded contracts in CBAs located far from their geographic bases of operations. Transparency is also essential in order to assess the quality and access effects of the Program on Medicare beneficiaries.

Key Takeaways

While the Competitive Bidding Program directly applies only to the suppliers that serve the Medicare program, what CMS ultimately adopts as a result of these rulemaking efforts may have broader ramifications across other types of providers. Given the importance of pricing and cost within the context of the Medicare program, we suggest that interested parties, including Medicare beneficiaries, providers, manufacturers, payors, and other stakeholders, consider providing comments by **March 28, 2014**, on the above topics. Ultimately, there needs to be an appropriate balancing of the goals that CMS is trying to accomplish through the DMEPOS Competitive Bidding Program and the real concerns about competitive bidding that are impacting suppliers and the patients they serve.

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This Client Alert was authored by **Amy Lerman***. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.*

[9] U.S. Gov't Accountability Office, Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid (GAO-12-693) (May 2012), at 8.
[10] Auction Experts Letter, *supra* note 6.

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