New DMEPOS Competitive Bidding Program May Spell Trouble for Medicare

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On April 10, 2007, the Centers for Medicare and Medicaid Services ("CMS") published its final rule implementing the long-awaited competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") under Medicare Part B. In its final rule, issued nearly a full year after its proposed rule was released, CMS rejects several of the more drastic measures contemplated in the proposed rule, including, for instance, allowing a winning supplier to provide beneficiaries with rebates equaling the difference between the awarded single payment amount and the supplier’s submitted bid on an item. The agency also scrapped its original proposal that would have required winning suppliers to repair or replace all patient-owned durable medical equipment subject to the program, regardless of whether the supplier had ever supplied the item. Despite these and other refinements, which resulted in a more tempered approach, fundamental administrative and economic vulnerabilities promise to plague the competitive bidding program and could prove to be an overwhelming burden on both suppliers and the federal government.

The following article briefly highlights three key problems: (1) reimbursement rates that are based on already-reduced fee schedules and that may be below the bid amounts submitted by winning DMEPOS suppliers; (2) administrative burdens placed on suppliers attempting to participate in the program; and (3) hardships experienced by an already overwhelmed agency—and concludes with some observations about the future of competitive bidding for DMEPOS under Medicare Part B.

Multiple Reductions to Reimbursement Rates

Integral to the success of the DMEPOS competitive bidding program is that new Medicare payment levels will be, at least in the aggregate, lower than the current fee schedule payment rates. Bidding suppliers are required to submit bids for individual items capped at the current fee schedule rate for that item. In addition to this cap, the actual payment amounts for each item will be set at the...
median of winning bids for that item submitted by suppliers whose composite bids (i.e., the sum of a supplier’s weighted bids for all items in a product category) are equal to or lower than the pivotal bid for the category (i.e., the lowest winning composite bid that includes a sufficient number of suppliers to meet beneficiary demand). This is intended to assure a “single payment amount” (i.e., the payment amount for an item furnished under competitive bidding) that is lower than the current Medicare fee schedule amounts for DMEPOS items. The formula used to select a median to establish the single payment amount also means that some winning bidders will be required to accept payment levels below their bid amount for a particular item.

The Part B payment reductions through the competitive bidding program come at a time when a number of sectors of the DMEPOS industry have already undergone dramatic cuts in reimbursement levels, even after Congress included competitive bidding as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”). Between 2003 and 2007, there have been a number of cuts in Medicare reimbursement that render the savings intended by Congress to have a less meaningful impact. For example, products covered under the Medicare power mobility device (“PMD”) benefit, including power wheelchairs and power-operated vehicles, were completely overhauled following fraud and abuse schemes primarily centered in Harris County, Texas. Some of these changes included the development of 59 new HCPCS codes (from 5 to 64) and new national and local coverage policies representing the largest revisions to the PMD benefit since 1993. Establishing a fee schedule for PMDs was one of the last steps CMS undertook to complete its effort to restructure the Medicare policy of PMDs and resulted in severe reductions that have already forced some PMD manufacturers to discontinue supplying certain high-quality PMDs to Medicare beneficiaries.

In addition to power mobility, the home oxygen industry has also been made subject to a variety of recent pricing cuts. The Deficit Reduction Act of 2005 (“DRA”) established a 36-month limit on monthly payments for stationary and portable oxygen equipment furnished on or after January 1, 2006 after which the supplier transfers title for the stationary and/or portable oxygen equipment to the beneficiary. When CMS issued its final rule to implement the DRA’s changes, it also amended the payment scheme for oxygen equipment. This was in addition to the MMA’s reduced fee schedule amounts, which required a reduction in payments by the percentage difference between the amount of payment otherwise determined for 2002 and the median amount of payment under the Federal Employee Health Benefits Program (“FEHBP”), as determined by the OIG. According to an OIG report, in 2002, FEHBP median payments were approximately 12.4% less than Medicare payments for stationary home oxygen equipment and approximately 10.8% less than Medicare payments for portable home oxygen equipment. CMS has also noted that significant savings have been achieved through these substantial reductions.

The competitive bidding program’s reductions in reimbursement levels—on top of these already dramatically reduced payments—promise to discourage participation by suppliers and, in some instances, could threaten these suppliers’ very existence. Limiting supplier numbers will limit Medicare beneficiaries’ options for care.

In addition, some suppliers are concerned that these cuts in reimbursement could result in influx not only cheaper, but lower quality goods. As suppliers are forced to obtain lower-cost products to realize a profit from competitive bidding, the Medicare
program could force suppliers committed to furnishing only high-quality products to be priced out of the system. Despite the issuance of the DMEPOS quality standards in August of 2006, suppliers will only be able to offer most products that meet the most basic requirements. Those suppliers meeting the minimum standards will be most incentivized to participate in the competitive bidding program.

**Administrative Burdens on DMEPOS Suppliers**

Already observed in the initial phases of the competitive bidding program are a number of unanticipated administrative burdens on suppliers that may deter them and others from participating in the competitive bidding program. For example, CMS’s final rule requires suppliers to submit bids on all items contained in a product category, regardless of whether the supplier actually furnishes the item. This is a requirement even when some product categories consist of codes for which no items are available. CMS’s requirement that suppliers submit bids on all items in a product category also means that a supplier may be required to add a product to its business line or contract with another supplier to furnish the product. This may prove to be an easier task for smaller suppliers (defined as suppliers that generate gross revenue of $3.5 million or less in annual receipts), who can enter into supplier networks to provide products and services under a particular product category. Larger suppliers, on the other hand, are prohibited from participating in such networks and must instead subcontract with other entities. For both small and large suppliers, the requirement will result in cooperation among entities that might not ordinarily interact with one another and cause them to supply products that are not traditionally part of their businesses. Additionally, forging relationships and executing contracts, all before bids are due, amount to added burdens, uncertainties and expenses that shift suppliers’ resources towards administrative compliance, further confounding their financial ability to submit low bids.

In addition, placing competitor companies in a position to collaborate increases the potential for antitrust issues to arise. Senators Max Baucus (D-Montana), Chair and Chuck Grassley, (R-Iowa) Ranking Member of the U.S. Senate Finance Committee, in a recent letter to CMS, noted their concern that CMS has not yet responded to issues raised by the program that could result in practical and legal problems for suppliers, including unaddressed antitrust issues. These issues form, in part, a basis for the senators’ request to extend the bid submission deadline by another 90 days. Other letters from members of Congress have also emphasized CMS’s lack of responsiveness on the antitrust concerns as well as the fact that the competitive bidding process is burdensome for suppliers and requires significant additional time for compliance. Presumably in response to these Congressional requests, on July 27, 2007, CMS announced that it would extend the bidding deadline for suppliers to September 25, 2007 and would extend the start of the first round of competitive bidding for most product categories from April 1, 2008 to July 1, 2008.

**CMS’s Administrative Burden**

In addition to low payment levels and supplier burdens imposed by the competitive bidding program, there are also tremendous administrative burdens associated with the revamping of any program, especially when the program ultimately is rolled out nationwide. For the initial phase of bidding, Congress has mandated that CMS must implement the competitive bidding program in ten localized competitive bidding areas for a limited
array of product categories. As the highly technical program is initiated, CMS has already extended the bidding deadline three times in response to numerous reports of problems with the computerized bidding program—a symptom of complications that may be magnified when the program is applied across the United States. If the program proceeds under the Congressional timeline (i.e., a complete roll-out of the program after 2009), CMS will ultimately be responsible for administering the program in hundreds of competitive bidding areas for a multitude of product categories. Before its complete roll-out, CMS will be required to operate both the competitive bidding program and the traditional fee schedule program for those items of DMEPOS that are not subject to competitive bidding. The technical and administrative burdens will be compounded as unanticipated issues arise. Further, the Competitive Bidding Implementation Contractor must be trained to ensure that the program is administered properly. Arguably, costs should diminish over time as the agency gains more experience. But, it is unclear whether this will be the case, and it is equally unclear whether the short- and long-term costs and burdens of the program will prove worthwhile for the federal government.

Observations

For a payor program to adopt restrictive reimbursement policies designed to contain costs is nothing new. However, for Congress and CMS to mandate competitive bidding policies that are so severely restrictive and burdensome may prove to be an unfortunate projection as to the savings such a program would create. In creating the competitive bidding program for DMEPOS, Congress and CMS have created an additional layer of complexity to an already labyrinthine reimbursement regime that promises for some time to increase the federal government’s administrative burden. The movement towards the new competitive bidding paradigm is fraught with uncertainties, and although the goals of competitive bidding programs are well-conceived, the initial turmoil set into motion likely will continue for quite some time before benefits are observed.

Endnotes

1 Matthew E. Wetzel and Betty C. Pang, MD are associates in the Health Care and Life Sciences Practice Group of Latham & Watkins LLP.

2 Centers for Medicare & Medicaid Services, Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule, 72 Fed. Reg. 17992 (April 10, 2007).

3 Centers for Medicare & Medicaid Services, Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Proposed Rule, 71 Fed. Reg. 25654 (May 1, 2006).

4 See 71 Fed. Reg. at 25701 (proposed 42 C.F.R. § 414.416(c)).

5 See id. 25681, 25701 (proposed 42 C.F.R. § 414.422(c)).


8 Under the final rule, a “product category” means a “grouping of related items that are used to treat a similar medical condition.” 42 C.F.R. § 414.402.


10 Such fraud and abuse schemes in Harris County, Texas included physicians prescribing millions of dollars’ worth of PMDs to patients who did not need them, receiving or paying illegal kickbacks, conspiring with owners of a physical therapy clinic and billing for services that were not performed.


12 See Centers for Medicare & Medicaid Services, Home Health Prospective Payment System Rate Update for Calendar Year 2007

13 See id.


15 In the Regulatory Impact Analysis section of the proposed DMEPOS competitive bidding rule, CMS recognizes that prices have fallen for certain DMEPOS suppliers, specifically pointing out the 2005 reductions in oxygen supplies. See 71 Fed. Reg. at 25693.


17 See 42 C.F.R. § 414.412(d).

18 See 42 C.F.R. § 414.402.

19 See 42 C.F.R. § 414.418.

20 See id.

21 Letter from Max Baucus and Chuck Grassley, Senate Finance Committee, to Leslie V. Norwalk, Acting Administrator, Centers for Medicare and Medicaid Services (July 20, 2007); see also Centers for Medicare and Medicaid Services, Deadline Extensions for DMEPOS Competitive Bidding (July 27, 2007), available at http://www.cms.hhs.gov/CompetitiveAcqforDMEPOS.


23 See Letter from Baucus and Grassley, supra note 19.