With its passage of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Congress mandated a fundamental change in the way Medicare reimburses suppliers of durable medical equipment (DME). Beginning in 2007, Medicare will pay for major items of DME according to the results of a competitive bidding process.

Congress laid out the central features and requirements of the competitive bidding program but left it to the Centers for Medicare and Medicaid Services (CMS; formerly the Health Care Financing Administration [HCFA]) to fill in most of the details. Quite possibly, CMS will implement a competitive bidding system closely resembling a competitive bidding demonstration program that it conducted in two communities between 1999 and 2002. DME suppliers and manufacturers planning for the advent of Medicare competitive bidding would do well to familiarize themselves with the way that demonstration program was designed and implemented.

This article first provides background to the dispute over appropriate methods for DME reimbursement that led Congress to abandon the existing fee schedule system in favor of a competitive bidding system. Then it describes key provisions of the prescription drug act related to DME reimbursement. The article concludes with a summary of the 1999–2002 competitive bidding demonstration program that will serve as the best indication of the likely future of Medicare reimbursement.

Suppliers of durable medical equipment must go toe-to-toe on price. Will manufacturers be just interested bystanders?

Jesse A. Witten and Renee M. Howard
for DME until CMS announces its actual plans.

The Reimbursement Policy Debate

Compared with the sums that the Medicare program pays for hospital, nursing home, and other types of care, DME expenditures are just a drop in the bucket—accounting for only about 2.5% of Medicare expenditures annually. Such is the size of the program, however, that Medicare spending on DME still totals about $7 billion per year. Moreover, Medicare payments account for approximately one-third of all health-care expenditures on this group of products.

The General Accounting Office (GAO), the Office of the Inspector General of the U.S. Department of Health and Human Services (OIG), the Medicare Payment Advisory Commission, and certain members of Congress have, for years, criticized the current Medicare reimbursement system for DME as being wasteful. They have also claimed that DME fee schedules lack a logical foundation. For the most part, DME fee schedules are tied to supplier charges from the base period 1986–1987. Those charges were simply supplier list prices and were not necessarily tied either to market prices or to actual costs. Critics of the current system further contend that DME fee schedules have become increasingly outdated as new products and new manufacturing technologies have been developed, and as a higher level of competition has reduced prices.

In addition, the critics complain about the use of HCFA Common Procedure Coding System (HCPCS) codes for DME billing, charging that the product categories are too broad. They object that products whose properties, use, performance, and price are not sufficiently similar are nonetheless grouped under the same HCPCS code. The use of excessively capacious HCPCS codes makes it impossible to determine precisely which items of DME were used and whether payment for numerous products listed under a particular code is reasonable. Also, it obscures the need for regrouping products that now exist within a given HCPCS code. The GAO has frequently cited the case of one HCPCS code that includes 200 different catheters. According to the GAO, these catheters range in price from $1 to $18, and Medicare pays approximately $11 for any of them.

In a much-publicized 2002 study, and in subsequent testimony to Congress, the OIG compared Medicare reimbursement for 16 types of DME with the prices paid by the Veterans Administration (VA) and the Federal Employee Health Benefits Program (FEHBP). The office found that Medicare pays considerably more overall, and that Medicare could save $958 million a year if it paid what the VA pays for those 16 types of products. The OIG testimony carried substantial weight with Congress and was even cited in the legislation.

This was the backdrop against which Congress legislated that Medicare abandon the existing fee schedule system in favor of a system based on competitive bidding.

Despite the projected cost savings for Medicare, however, many people have objected to competitive bidding in this area. They fear that small suppliers will be unable to compete on cost against larger regional or national companies, and that competitive bidding will effectively make it impossible for new suppliers to enter the market. They are also concerned that basing reimbursement on competitive bidding will cause product quality and customer service to suffer. For example, some durable equipment requires professional servicing for which Medicare provides no reimbursement. Cutting back on reimbursement through a competitive bidding process could force suppliers of these DME items to cut back on
their uncompensated provision of professional support services. Some critics have additionally questioned whether Medicare beneficiaries will have adequate access to DME or to suppliers of such equipment. Also, those opposed to competitive bidding have predicted that the cost of administration will be substantial and the government bureaucracy required complex.

As the prescription drug act attests, Congress ultimately sided with the proponents of competitive bidding. CMS is preparing plans for implementing this new system.

**Prescription Drug Act**
**DME Provisions**

Under the prescription drug act, reimbursement for most DME will be frozen until 2008, until CMS has rolled out much of its competitive bidding program. Reimbursement for certain major types of DME, however, will be reduced in 2005 to the median reimbursement amount paid by FEHBP. DME subject to the reimbursement reduction includes oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic supplies such as lancets and testing strips, and hospital beds and air mattresses in certain HCPCS codes (see sidebar, page 81).

The reimbursement freeze and reductions were intended as interim measures to control costs until CMS is prepared to implement a reimbursement methodology based on competitive bidding. According to the prescription drug act, competitive bidding will be rolled out in 2007 in 10 of the nation’s largest metropolitan statistical areas and in 2009 in an additional 80 of those heavily populated areas. Thereafter, competitive bidding will be applicable throughout the rest of the country.

**CMS’s Responsibilities.** CMS is responsible for identifying the products subject to competitive bidding. Congress has directed the agency to begin with DME of the highest cost and volume and offering the greatest potential for savings. In addition to selecting and grouping products for competitive bidding purposes, CMS will be responsible for establishing multiple so-called competitive acquisition areas throughout the United States. These are to be bounded geographic areas within which competitive bidding will take place. CMS may exempt rural areas—and even urban areas with low population density—from the system except in cases where a particular item has a significant national market through mail order.

Congress has also required that CMS adhere to the following guidelines in designing the competitive bidding program.

- CMS must establish both quality and financial standards that suppliers must meet to be eligible to bid.
- CMS must ensure that small suppliers be given a fair opportunity to be considered for participation.

**Manufacturer Input**

CMS is beginning to assemble an advisory and oversight committee, as mandated by Congress, to help it design and implement the competitive bidding program on which much future Medicare reimbursement will be based. The agency intends to appoint 12 to 15 committee members, who will be representatives of the consumer, physician, supplier, and manufacturer communities. Manufacturers anticipating that the new Medicare reimbursement regime will have a substantial impact on their business should plan to inform CMS and the advisory committee of their positions on product category groupings, geographic boundaries for competitive bidding, and other pertinent issues.

No formal mechanism for submitting comments to CMS or to the advisory committee being formed is yet defined or in place. It is expected that, over the coming year, CMS and its advisory committee will announce public meetings and other means by which manufacturers and other affected parties may provide their input.

**Suppliers and Contracts.** Only suppliers that have submitted a bid and been awarded a contract will be eligible to receive Medicare reimbursement. A supplier submitting a bid for a given item of DME must agree not only to supply the item but also to offer “services that are attendant to the furnishing of” it. Contracts established with winning bidders will be effective for three years; the product category will be put up for rebid every three years. CMS may stagger the issuance of contracts such that contracts in different geographic areas expire at different times.

**Medicare Patients.** Beneficiaries will continue to be responsible for a 20% copayment. Under the new system, the copayment amount will
equal 20% of the competitive bidding award amount for the given item, with Medicare paying 80% of that price.

**Exclusions.** The prescription drug act specifies certain items now treated as DME for exclusion from the DME competitive bidding program. Products affected by this provision are inhalation drugs; parenteral nutrients, equipment, and supplies; products categorized as Class III devices under FDA regulations; and items for which competitive bidding, in CMS’s judgment, may not result in cost savings for Medicare.

**Program Advisory Committee.** Congress has directed CMS to appoint a program advisory and oversight committee to assist in developing and operating the competitive bidding program. That committee, which is to include nongovernmental experts, has not yet been appointed (see sidebar, page 82).

**Restrictions on Litigation.** Many current DME suppliers will inevitably suffer economic loss due to competitive bidding. Many may be put out of business. Fearing that a competitive bidding program could lead to litigation against the government, Congress limited the ability of adversely affected parties to obtain relief in the courts. The prescription drug act provides that there shall be no judicial or administrative review of any CMS decisions regarding:

- Payment amounts.
- The awarding of contracts.
- Designation of competitive acquisition areas.
- Phase-in implementation.
- The selection of items and services for competitive acquisition or certain other issues related to bidding structure.
- The number of suppliers selected.

Adversely affected parties seeking judicial relief will have to focus their complaints on matters for which Congress has allowed judicial review.

**Extended Scope.** Some items and services that technically do not fall within the definition of durable medical equipment also will be included in the DME competitive bidding program. This category comprises certain medical supplies, home dialysis supplies, enteral nutrients, electromyogram devices, salivation devices, blood products, and transfusion medicine. Other provisions of the prescription drug act require CMS to develop additional competitive bidding programs, including, notably, one for outpatient prescription drugs. Also, the prescription drug act requires CMS to establish a demonstration project to test the suitability of competitive bidding for clinical laboratory services.

The Demonstration Projects

What form the competitive bidding program finally designed by CMS will take is difficult to predict with confidence. However, an earlier DME competitive bidding demonstration program may provide some clues.

The Balanced Budget Act of 1997 directed CMS (when it was still HCFA) to test competitive bidding as a method of pricing and paying for certain categories of DME. The agency carried out two demonstrations. One, lasting from 1999 until 2002, took place in Polk County, FL, an area with approximately 92,000 traditional Medicare fee-for-service beneficiaries and 40 major DME suppliers. The second demonstration, in 2001–2002, involved San Antonio, TX, a community with approximately 118,000 traditional Medicare fee-for-service beneficiaries and 48 major DME suppliers.

Congress ordered HCFA to

### Table I. A composite bid for each supplier is calculated from its bids on all the items in a product category, weighted by volume. In this example, item 1 represents 40% of the purchase volume, item 2 represents 30%, item 3 represents 20%, and item 4 represents 10%. The complete calculation appears as: (item 1 price × 0.4) + (item 2 price × 0.3) + (item 3 price × 0.2) + (item 4 price × 0.1) = composite bid.

<table>
<thead>
<tr>
<th>Bidder</th>
<th>Item 1 Bid ($)</th>
<th>Item 2 Bid ($)</th>
<th>Item 3 Bid ($)</th>
<th>Item 4 Bid ($)</th>
<th>Composite Bid ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>50.00</td>
<td>25.00</td>
<td>80.00</td>
<td>40.00</td>
<td>47.50</td>
</tr>
<tr>
<td>B</td>
<td>52.00</td>
<td>22.00</td>
<td>85.00</td>
<td>40.00</td>
<td>48.40</td>
</tr>
<tr>
<td>C</td>
<td>45.00</td>
<td>28.00</td>
<td>75.00</td>
<td>35.00</td>
<td>44.90</td>
</tr>
<tr>
<td>D</td>
<td>55.00</td>
<td>25.00</td>
<td>81.00</td>
<td>45.00</td>
<td>50.20</td>
</tr>
<tr>
<td>E</td>
<td>49.00</td>
<td>23.00</td>
<td>77.00</td>
<td>41.00</td>
<td>46.00</td>
</tr>
<tr>
<td>F</td>
<td>50.00</td>
<td>28.00</td>
<td>78.00</td>
<td>38.00</td>
<td>47.80</td>
</tr>
<tr>
<td>G</td>
<td>49.00</td>
<td>27.00</td>
<td>80.00</td>
<td>40.00</td>
<td>47.70</td>
</tr>
<tr>
<td>H</td>
<td>48.00</td>
<td>27.00</td>
<td>78.00</td>
<td>37.00</td>
<td>46.60</td>
</tr>
</tbody>
</table>

### Table II. Suppliers from Table I ranked by composite bid.

<table>
<thead>
<tr>
<th>Bidder</th>
<th>Composite Bid ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>44.90</td>
</tr>
<tr>
<td>E</td>
<td>46.00</td>
</tr>
<tr>
<td>H</td>
<td>46.60</td>
</tr>
<tr>
<td>A</td>
<td>47.50</td>
</tr>
<tr>
<td>G</td>
<td>47.70</td>
</tr>
<tr>
<td>F</td>
<td>47.80</td>
</tr>
<tr>
<td>B</td>
<td>48.40</td>
</tr>
<tr>
<td>D</td>
<td>50.20</td>
</tr>
</tbody>
</table>
include oxygen equipment and supplies in the demonstration. On its own initiative, HCFA brought other types of DME into the demonstration, either because past GAO studies suggested that Medicare could save money with them, or because they were standardized types of DME, or because they represented a large percentage of Medicare DME reimbursement. Also, HCFA wanted to include both rental and purchased DME. The demonstrations ultimately covered the following product categories.

- Oxygen equipment and supplies (both demonstrations).
- Hospital beds (both).
- Enteral nutrition (Polk County).
- Urological supplies (Polk County).
- Surgical dressings (Polk County).
- Wheelchairs and accessories (San Antonio).
- General orthotics (San Antonio).
- Nebulizer drugs (San Antonio).

HCFA solicited bids for each applicable product category at the two demonstration sites. Suppliers bid prices for the various items within any category; that is, a supplier that wanted to supply “wheelchairs and accessories” had to submit a bid for every product within that category. On the other hand, suppliers did not have to bid for every product category. They were free to bid only for those categories in which they wanted to be considered, say, wheelchairs and accessories, and to pass on categories, say, oxygen equipment and supplies, of no interest. Only suppliers participated in the program; manufacturers did not bid and were not involved in the bidding process.

HCFA selected the winning bidders for each product category. The selection process began with the highest composite bids (see Table II). Suppliers G, F, B, and D were losing bidders because their composite bids were only slightly above the cutoff bid—losing bidders—would not be able to bill Medicare for items in the category.

HCFA tried to identify natural breaks in the range of composite bids in setting cutoff bids. The agency also sought to select cutoff bids so as to ensure that there would be an adequate number of suppliers for each product category within the demonstration site. Nonetheless, in San Antonio in particular, some suppliers whose bids were only slightly above the cutoff bid objected to their exclusion when they abruptly lost Medicare business.

Returning to the hypothetical example illustrated in the tables, HCFA might have reviewed the composite bids and set the cutoff bid at $47.60 in order to qualify a desirable number of suppliers for the product category. That would have made suppliers C, E, H, and A winning bidders (see Table II). Suppliers G, F, B, and D would be losing bidders because their composite bids were higher than $47.60.

For the demonstration program, in order to set the amounts that Medicare would pay for each of the items within a product category, HCFA performed certain calculations. First, it derived an adjustment ratio for each winning bidder by dividing the cutoff bid by that bidder’s composite bid (see Table III). The eight hypothetical bidding suppliers used for the illustration in Table I would then be ranked according to their composite bids (see Table II).

In the demonstration, HCFA determined a cutoff bid for each product category that was based on the composite bids. Suppliers with composite bids below the cutoff bid for a particular product category were deemed winning bidders for that category. Suppliers with composite bids above the cutoff bid—the losing bidders—would not be able to bill Medicare for items in the category.

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The table below illustrates how HCFA determined the adjustment ratio used in determining the Medicare payment amount.

<table>
<thead>
<tr>
<th>Bidder</th>
<th>Cutoff Bid ($) + Composite Bid ($) = Adjustment Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>C</td>
<td>47.60 ÷ 44.90 = 1.06</td>
</tr>
<tr>
<td>E</td>
<td>47.60 ÷ 46.00 = 1.03</td>
</tr>
<tr>
<td>H</td>
<td>47.60 ÷ 46.60 = 1.02</td>
</tr>
<tr>
<td>A</td>
<td>47.60 ÷ 47.50 = 1.00</td>
</tr>
</tbody>
</table>

Table II. Calculation of the adjustment ratio used in determining the Medicare payment amount.

**GOVERNMENTAL & LEGAL AFFAIRS**

<table>
<thead>
<tr>
<th>Item</th>
<th>Calculation of Medicare Payment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>(45.00 × 1.06) + (49.00 × 1.03) + (48.00 × 1.02) + (50.00 × 1.00) ÷ 4 = $49.28</td>
</tr>
<tr>
<td>2</td>
<td>(28.00 × 1.06) + (23.00 × 1.03) + (27.00 × 1.02) + (25.00 × 1.00) ÷ 4 = $26.47</td>
</tr>
<tr>
<td>3</td>
<td>(75.00 × 1.06) + (77.00 × 1.03) + (78.00 × 1.02) + (80.00 × 1.00) ÷ 4 = $79.59</td>
</tr>
<tr>
<td>4</td>
<td>(35.00 × 1.06) + (41.00 × 1.03) + (37.00 × 1.02) + (40.00 × 1.00) ÷ 4 = $39.27</td>
</tr>
</tbody>
</table>

Table IV. The reimbursement price of each item in a product category is determined by averaging qualified suppliers’ bid prices as modified by the suppliers’ adjustment ratios.
amount. This approach ensured that each supplier would be paid more overall than it had bid for all the items in a product category, though the price for any single item could be set below what the supplier had bid.

Employing the data presented in the hypothetical example makes the calculation of the Medicare payment amount clear (see Table IV). The bids for each item in the product category, adjusted by the suppliers’ adjustment ratios, are averaged. Depicted algebraically, Medicare would pay for each item an amount equal to (supplier C’s bid × its adjustment ratio) + (supplier E’s bid × its adjustment ratio) + (supplier H’s bid × its adjustment ratio) + (supplier A’s bid × its adjustment ratio) ÷ 4.

CMS has viewed the design and implementation of the demonstration project as a success. So have supporters of competitive bidding. It is therefore quite possible that CMS will implement an approach to competitive bidding for Medicare reimbursement similar to that used in the demonstration project.

Conclusion

After a lengthy debate, Congress has mandated adoption of competitive bidding for Medicare reimbursement of DME. Suppliers and manufacturers that intend to continue serving Medicare beneficiaries will have to understand the regulatory changes and be prepared to operate under them. Although CMS will likely not unveil its plans for some time, suppliers and manufacturers can look to the concluded demonstration projects for insight into what may be in store for them.

Furthermore, some private payers also are reportedly exploring the feasibility of replacing DME fee schedules with a competitive acquisition approach. These insurers may look to the pattern set by Medicare and by the past demonstration projects as they consider whether and how to proceed.

References


Jesse A. Witten is a partner and Renee M. Howard is an associate with Jones Day (Washington, DC), an international law firm. They specialize in healthcare law, including regulatory matters. The views expressed herein are not necessarily those of Jones Day.