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September 2004

MEDICARE

Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies

GAO-04-765

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GAO
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Highlights

Highlights of GAO-04-765, a report to congressional committees.

MEDICARE

Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies

Why GAO Did This Study

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires the Centers for Medicare & Medicaid Services (CMS) to conduct large-scale competitive bidding for durable medical equipment, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies provided to beneficiaries. The Balanced Budget Act of 1997 mandated that GAO study an earlier Medicare competitive bidding demonstration. To address this mandate, GAO assessed this past experience in relation to four issues that CMS might consider as it implements large-scale competitive bidding: (1) items for competitive bidding, (2) how to streamline implementation, (3) ways to collect information on specific items provided to beneficiaries, and (4) steps to ensure quality items and services.

What GAO Recommends

GAO is making several recommendations to CMS concerning competitive bidding, including recommendations on ways to increase potential savings, streamline implementation, help ensure that Medicare is paying appropriately for items, and promote beneficiary satisfaction. CMS agreed with most of our recommendations and indicated that it would give serious consideration to this report throughout development and implementation of national competitive bidding.

www.gao.gov/cgi-bin/getrpt?GAO-04-765.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Leslie G. Aronovitz at (312) 220-7600.

What GAO Found

CMS's experience in the Medicare competitive bidding demonstration may prove instructive as the agency implements provisions in MMA to conduct large-scale competitive bidding for durable medical equipment, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies. The experience gained during the demonstration provides insight as the agency considers four implementation issues:

- **Items for competitive bidding.** Items for competitive bidding could include those selected for the demonstration and others that account for high levels of Medicare spending. For example, nondemonstration items that CMS could choose for competitive bidding include power wheelchairs and lancets and test strips used by diabetics. In 2002, these three items accounted for about $1.7 billion in charges for the Medicare program and its beneficiaries.

- **How to streamline implementation.** Because of the large scale of future competitive bidding, it will be prudent for CMS to consider ways to streamline implementation. Two ways to streamline are developing a standardized competitive bidding approach that can be replicated in multiple geographic locations and using mail-order delivery for selected items, with uniform fees established through a nationwide competition.

- **Ways to collect information on specific items provided to beneficiaries.** Gathering specific information on competitively bid items provided to beneficiaries could help ensure that suppliers do not substitute lower-priced items to reduce their costs. Currently, CMS is not able, or does not routinely, collect specific information on the items that suppliers provide to beneficiaries.

- **Steps to ensure quality items and services for beneficiaries.** Routine monitoring could help ensure that beneficiaries continue to have access to suppliers that deliver quality items and services. The agency, when implementing significant Medicare changes in the past that affected payment methods, has lacked information on how the changes affected beneficiary access. As competitive bidding expands, small problems could be potentially magnified. Using quality measures to choose multiple suppliers and having suppliers meet more detailed standards than are currently required can also help ensure quality for beneficiaries.

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Abbreviations

AWP	average wholesale price
BBA	Balanced Budget Act of 1997
CMS	Centers for Medicare & Medicaid Services
DME	durable medical equipment
HCFA	Health Care Financing Administration
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MSA	metropolitan statistical area
OIG	Office of Inspector General
SADMERC	statistical analysis durable medical equipment regional carrier

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United States Government Accountability Office
Washington, D.C. 20548

September 7, 2004

The Honorable Charles E. Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

The Honorable Joe Barton
Chairman
The Honorable John D. Dingell
Ranking Minority Member
Committee on Energy and Commerce
House of Representatives

The Honorable William M. Thomas
Chairman
The Honorable Charles B. Rangel
Ranking Minority Member
Committee on Ways and Means
House of Representatives

In 2002, the Medicare program and its beneficiaries paid almost $9.7 billion for durable medical equipment (DME), prosthetics, orthotics, and supplies.[1] For most of these items, Medicare payment rates are not based on current market prices, but are primarily based on historical charges from the mid-1980s, adjusted for inflation in some years.[2] The Centers for

[1] Medicare guidance defines DME as equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. DME includes items such as wheelchairs, hospital beds, and walkers. Medicare defines prosthetic devices (other than dental) as devices that are needed to replace body parts or functions. Prosthetic devices include artificial limbs and eyes, enteral nutrition, ostomy bags, and cardiac pacemakers. Medicare defines orthotic devices to include leg, arm, back, and neck braces that provide rigid or semirigid support to weak or deformed body parts or restrict or eliminate motion in a diseased or injured part of the body. Medicare-reimbursed supplies are items that are used in conjunction with DME and are consumed during the use of the equipment, such as drugs used for inhalation therapy, or need to be replaced frequently (usually daily), such as surgical dressings.

[2] Prior to 1998, these payment rates were adjusted each year using formulas tied to the Consumer Price Index. Since 1998, payment rates have been updated in some years, but not others.

Medicare & Medicaid Services (CMS)—formerly called the Health Care Financing Administration (HCFA)[3]—lacked mechanisms to readily adjust payment rates to reflect marketplace changes. As a result, disparities arose between Medicare payment rates and market prices. As we and the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) have reported, the Medicare program and its beneficiaries have been paying too much for some items of DME, prosthetics, orthotics, and supplies—sometimes three or four times the amount paid by others.[4] In addition to increasing program costs, inflated payment rates increase beneficiaries' costs because beneficiaries are responsible for 20 percent of the Medicare rate as coinsurance.

The Balanced Budget Act of 1997 (BBA)[5] required CMS to test competitive bidding as a new way for Medicare to set fees for part B[6] items and services specified by CMS.[7,8] Competitive bidding provides incentives for suppliers to lower their prices for items and services to retain their ability to serve Medicare beneficiaries and potentially increase their market share. Using its authority under BBA, CMS conducted a competitive bidding demonstration to set Medicare part B payment rates for selected DME, prosthetics, orthotics, and supply items. The demonstration and CMS's authority to conduct competitive bidding ended on December 31, 2002. In December 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) required CMS to conduct competitive

[3] HCFA's name was changed to CMS as of July 1, 2001. We use the name CMS throughout this report.

[4] Janet Rehnquist, Inspector General, Department of Health and Human Services, *Medicare Reimbursement for Medical Equipment and Supplies*, testimony before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, and Education, 107th Cong., 2nd sess., Washington, D.C., June 12, 2002; GAO, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001); and GAO, *Medicare: Home Oxygen Program Warrants Continued HCFA Attention*, GAO/HEHS-98-17 (Washington, D.C.: Nov. 7, 1997).

[5] Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392 (1997).

[6] Medicare part B helps pay for certain physician, outpatient hospital, laboratory, and other services.

[7] While the statute required HHS to test competitive bidding, CMS administers the Medicare program and was responsible for testing competitive bidding.

[8] Physician services were not included in the authority to conduct competitive bidding.

bidding for DME, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies on a large scale.[9]

BBA also mandated that GAO study the effectiveness of the Medicare competitive bidding demonstration.[10] To address this mandate, as discussed with the committees of jurisdiction, we assessed four issues that CMS might consider as it implements MMA provisions for competitive bidding, given its prior demonstration experience. The four issues are (1) items to be chosen for competitive bidding, (2) how to streamline implementation, (3) ways to collect information on specific items provided to beneficiaries, and (4) steps to ensure quality items and services to beneficiaries.

In preparing this report, we reviewed documents related to the competitive bidding demonstration for DME, prosthetics, orthotics, and supplies provided under Medicare part B. These included evaluations of the demonstration.[11] Two evaluation reports on the demonstration have been published,[12] and a final report is pending. We also conducted interviews with officials from CMS, the contractor that administered the demonstration, and its evaluators. We analyzed claims data on Medicare

[9] Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224. While the statute requires HHS to conduct the competitive bidding program, CMS administers the Medicare program and is responsible for implementing the program and establishing quality standards for suppliers of DME, prosthetics, orthotics, and supplies.

[10] BBA, § 4319(c), 111 Stat. 394.

[11] BBA required that HHS evaluate the competitive bidding demonstration for its impact on Medicare program payments, beneficiary access to care, quality, and diversity of product selection. BBA, § 4319(a), 111 Stat. 393. In 1998, CMS contracted with the University of Wisconsin-Madison to conduct an independent evaluation of the demonstration. The evaluation team consisted of researchers from the University of Wisconsin-Madison, the Research Triangle Institute, and Northwestern University.

[12] University of Wisconsin-Madison, Center for Health Systems Research and Analysis; Research Triangle Institute, Center for Economics Research; and Northwestern University, Institute for Health Services Research and Policy Studies, *Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS*: *First-Year Annual Evaluation Report* (Baltimore, Md.: Centers for Medicare & Medicaid Services, September 2000, Revised January 2001), and University of Wisconsin-Madison, Center for Health Systems Research and Analysis; Research Triangle Institute—Health, Social, and Economics Research; and Northwestern University, Institute for Health Services Research and Policy Studies, *Evaluation of Medicare's Competitive Bidding Demonstration for DMEPOS: Second-Year Annual Evaluation Report* (Baltimore, Md.: Centers for Medicare & Medicaid Services, April 2002).

spending for DME, prosthetics, orthotics, and supply items. To determine that these data were accurate, timely, and complete, we interviewed the CMS contractor that provided the data and reviewed CMS's internal control procedures. Where appropriate, we tested data manually against published sources for consistency. We determined that these data were sufficiently reliable for addressing the issues in this report. We solicited feedback on item selection and quality assurance steps from medical directors at the four DME regional carriers.[13] We also interviewed representatives from advocacy groups and industry. Appendix I includes a more detailed discussion of our scope and methodology. Our work was conducted from February 2003 through August 2004 in accordance with generally accepted government auditing standards.

Results in Brief

As CMS moves forward with its new competitive bidding effort, the experience it gained during the demonstration can provide insights as the agency considers four implementation issues. First, items to be chosen for competitive bidding could include those in the demonstration and others that account for high levels of Medicare spending. By selecting items with high overall Medicare spending for the competitive bidding demonstration, the agency achieved estimated gross savings of $8.5 million for the Medicare program and its beneficiaries. Second, because of the large scale of future competitive bidding, it will be prudent to consider ways to streamline implementation. Such streamlining approaches could include developing a standardized competitive bidding approach for multiple locations that builds on practical experience from the demonstration and using mail-order delivery for selected items included in a nationwide competition. Third, identifying approaches to collect better information on the specific items provided to beneficiaries would help ensure that Medicare is paying appropriately for items. Fourth, once implementation of competitive bidding begins on a large scale, routine monitoring could help ensure that beneficiaries' access to quality items and services is not compromised. To assist CMS in future efforts to conduct competitive bidding for DME, off-the-shelf orthotics, supplies, and enteral nutrients and related equipment and supplies, we are making recommendations on

[13] Medicare pays contractors to administer its fee-for-service claims. The contractors responsible for processing most part B claims are called carriers. In October 1993, CMS began processing all Medicare part B claims for DME, orthotics, prosthetics, and supplies through DME regional carriers. Each of the four DME regional carriers serves a separate region of the country.

selecting products, using mail-order delivery as a mechanism to implement a national competitive bidding strategy, obtaining more detailed information on products provided to beneficiaries, and monitoring beneficiary satisfaction. CMS agreed with most of our recommendations and stated that it would give serious consideration to this report throughout the development and implementation of national competitive bidding.

Background

Medicare is a federal program that helps pay for a variety of health care services and items on behalf of about 41 million elderly and disabled beneficiaries. Medicare part B covers DME for the beneficiary's use in the home, prosthetics, orthotics, and supplies if they are medically necessary and prescribed by a physician. Part B also covers certain outpatient prescription drugs that are used with DME or that are not usually self-administered by the patient. Some of these drugs are classified as supplies.

Medicare Payment for DME, Prosthetics, Orthotics, and Supplies

In submitting claims for Medicare payment, suppliers use codes in the Healthcare Common Procedure Coding System (HCPCS) to identify DME, prosthetics, orthotics, and supplies that they are providing to beneficiaries. These codes are used for health insurance billing purposes to identify health care services, equipment, and supplies used in beneficiaries' diagnoses and treatments. Individual HCPCS codes used by suppliers can cover a broad range of items that serve the same general purpose, but vary in price, characteristics, and quality. The HCPCS National Panel, a group composed of CMS and other insurers, maintains the HCPCS codes.

Medicare uses a variety of methodologies, which are specified in law, for determining what it will pay for specific types of DME, prosthetics, orthotics, and supplies. Medicare has established a fee schedule for DME and supplies, which lists the fees paid for these items in each state. Prosthetics and orthotics are paid according to 10 regional fee schedules. Prior to the passage of MMA, outpatient prescription drugs covered by Medicare part B were paid on a fee schedule based on 95 percent of the manufacturers' average wholesale price (AWP), a price determined by

manufacturers themselves.[14] Except for these outpatient prescription drugs, the amounts paid under the fee schedules are generally based on the amounts charged by suppliers in 1986 and 1987 (or the amount set by Medicare if the item was subsequently added to the fee schedule). Suppliers are reimbursed according to the supplier's actual charge or the Medicare fee schedule amount, whichever is lower.

Over the years, we have reported that Medicare fees for certain medical equipment, supplies, and outpatient drugs were excessive compared with retail and other prices. For example, in 2000, we reported that retail price data collected by the four DME regional carriers showed that Medicare payments were much higher than the median surveyed retail prices for five commonly used medical products.[15] While Medicare paid 5 percent less than AWP for covered prescription drugs, in 2001 we reported that prices widely available to physicians averaged from 13 percent to 34 percent less than AWP for a sample of physician-administered drugs.[16] For two inhalation drugs[17] covered by Medicare—albuterol and ipratropium bromide—prices widely available to pharmacy suppliers in 2001 reflected average discounts of 85 percent and 78 percent from AWP, respectively.[18]

Medicare Competitive Bidding

In 1997, BBA required CMS to establish up to five demonstration projects to be operated over 3-year periods that used competitive bidding to set fees for Medicare part B items and services. BBA required that at least one demonstration project include oxygen and oxygen equipment; all

[14] MMA changed Medicare's methodology for determining reimbursement for outpatient drugs covered under part B. Most part B drugs furnished on or after January 1, 2004, are reimbursed at 85 percent of the drugs' AWPs determined as of April 1, 2003. Beginning in 2005, Medicare part B drugs—with certain exceptions, such as some vaccines—will be paid using either a competitive acquisition program or an average sales price methodology.

[15] These products were lancets, eyeglass frames, a type of urinary catheter, and two types of catheter insertion trays. See GAO, *Medicare Payments: Use of Revised "Inherent Reasonableness" Process Generally Appropriate*, GAO/HEHS-00-79 (Washington, D.C.: July 5, 2000).

[16] In 1999, drugs provided in physician office settings accounted for over 75 percent of the almost $4 billion spent by Medicare for covered prescription drugs.

[17] Inhalation drugs are used as therapy for respiratory ailments, such as asthma or emphysema, and are delivered through a piece of equipment called a nebulizer.

[18] GAO-01-1118.

demonstration areas be metropolitan statistical areas (MSA) or parts of MSAs;[19] and criteria for selecting demonstration areas include availability and accessibility of services and probability of savings.[20]

CMS contracted with one of the four DME regional carriers—Palmetto Government Benefits Administrators (Palmetto)—to implement the competitive bidding demonstration for DME, prosthetics, orthotics, and supplies.[21] The demonstration was implemented in two locations—Polk County, Florida, and the San Antonio, Texas, area.[22] Two cycles of bidding took place in Polk County, with competitively set fees effective from October 1, 1999, to September 30, 2001, and from October 1, 2001, to September 30, 2002. There was one cycle of bidding in San Antonio, and competitively set fees were effective from February 1, 2001, to December 31, 2002. Bidding and implementation processes were similar at both locations.

CMS set up competitive bidding for groups of related DME, prosthetics, orthotics, and supplies and held a separate competition for each group. Items included in the demonstration were identified by HCPCS codes. Suppliers were required to bid on each HCPCS code included in the product group in which they were competing. Table 1 shows the eight product groups in CMS's competitive bidding demonstration at the two locations.

[19] The Office of Management and Budget defines an MSA as a county or group of counties containing a core of at least 50,000 people, together with adjacent areas having a high degree of economic and social integration with that core.

[20] BBA, § 4319(a), 111 Stat. 392.

[21] In this role, Palmetto was responsible for helping to plan the demonstration; educating beneficiaries, suppliers, and other stakeholders about the demonstration; soliciting and evaluating bids; processing claims; and responding to inquiries and complaints about the demonstration. CMS maintained oversight responsibility for the demonstration, reviewed all documents and Palmetto decisions, and made final design and policy decisions.

[22] The first demonstration location, Polk County, Florida, is an MSA that includes the cities of Lakeland and Winter Haven. The second demonstration location included three of the four counties (Bexar, Comal, and Guadalupe) in the San Antonio, Texas, MSA.

Table 1: Product Groups Included in the Demonstration's Two Locations

Product groups	Polk County	San Antonio location
Enteral nutrients, equipment, and supplies	•	
Hospital beds and accessories	•	•
Nebulizer inhalation drugs		•
Manual wheelchairs and accessories		•
Noncustomized general orthotics		•
Oxygen contents, equipment, and supplies	•	•
Surgical dressings	•	
Urological supplies	•	

Source: GAO analysis of CMS data.

The competitive bidding process was used to determine the suppliers included in the demonstration and the rates they would be paid. From among the bidders, the agency and Palmetto selected multiple demonstration suppliers to provide items in each group of related products. These suppliers were not guaranteed that they would increase their business or serve a specific number of Medicare beneficiaries. Instead, the demonstration suppliers had to compete for beneficiaries' business. With few exceptions, only demonstration suppliers were reimbursed by Medicare for competitively bid items provided to beneficiaries permanently residing in the demonstration area.[23] However, beneficiaries already receiving certain items were allowed to continue to use their existing nondemonstration suppliers.[24] All demonstration suppliers were reimbursed for each competitively bid item provided to

[23] Medicare payments for DME, prosthetics, orthotics, and supply items obtained in a demonstration location during the demonstration by a visiting beneficiary who had a permanent address elsewhere were based on the fee schedule in effect for the beneficiary's permanent address.

[24] Transition policies allowed beneficiaries to continue receiving oxygen equipment and supplies and nebulizer drugs from their original suppliers, regardless of whether the suppliers were included in the demonstration. However, the supplier had to accept the new demonstration fee schedules. Transition policies also allowed beneficiaries to maintain preexisting rental agreements or purchase contracts with their suppliers of enteral nutrition equipment, hospital beds and accessories, and manual wheelchairs and accessories. These suppliers were paid under the normal statewide Medicare fee schedule for the duration of the rental period.

beneficiaries at the demonstration fee schedule amounts.[25] The new fee schedules were based on the winning suppliers' bids for items included in the demonstration. Any Medicare supplier that served demonstration locations could provide items not included in the demonstration to beneficiaries.

About 1 year after CMS's demonstration authority ended, MMA required the agency to conduct competitive bidding for DME, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies. Competition is to be implemented in 10 of the largest MSAs in 2007, 80 of the largest MSAs in 2009, and additional areas thereafter. Items excluded from this authority are inhalation drugs; parenteral nutrients, equipment, and supplies; Class III devices;[26] and customized orthotics that require expertise to fit individual beneficiaries. CMS may phase in implementation of competitive bidding first for the highest cost and highest volume items or those items with the greatest savings potential. The law requires that a Program Advisory and Oversight Committee be established to provide recommendations to CMS on its implementation of competitive bidding.

MMA also gives CMS significant new authority to use competitive bidding results as a basis for determining reasonable payment rates throughout the country in 2009. CMS has the authority to apply the information obtained from competitive bidding to adjust payments in parts of the country outside of the competitive areas for DME, supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies. Thus, CMS will be able to more easily adjust its payment rates nationally to reflect market prices within the largest MSAs by using information gleaned through competitive bidding.

[25] The demonstration did not include beneficiaries enrolled in Medicare's managed care component. Provision of DME, prosthetics, orthotics, and supplies to these beneficiaries is included in the managed care plans' services and not billed separately to Medicare.

[26] The Food and Drug Administration uses a three-part classification system for devices, based on the device's level of risk and the extent of control necessary to ensure the safety and effectiveness of the device. Class III, or high-risk devices, usually sustain or support life, are of substantial importance in preventing impairment of human health, or present potential unreasonable risk of illness or injury.

CMS's Experience Can Guide Agency Efforts to Implement Competitive Bidding

While MMA sets specific requirements for competitive bidding, it also leaves certain implementation issues to CMS. As CMS implements competitive bidding, its payment- setting experience in the demonstration will prove useful as the agency considers items for competitive bidding and approaches to streamline implementation, collect information on specific items provided to beneficiaries, and ensure that beneficiaries' access to quality items and services is not compromised.

Many High-Cost Items Could Be Included in Large-Scale Competitive Bidding

Selecting items with high levels of Medicare spending may prove fruitful in generating significant savings in the first years of large-scale competitive bidding efforts. The demonstration provided CMS with experience in item selection, and MMA provides direction and guidance for future efforts. By including items that accounted for a large share of Medicare spending, the demonstration generated estimated gross savings that were substantially more than its implementation costs. In addition to the items included in the demonstration, others are worth considering for selection in future competitive bidding.

For the competitive bidding demonstration, Palmetto and CMS chose items from six of the eight product groups that accounted for almost 78 percent of Medicare allowed charges in calendar year 2002, as table 2 shows.[27] The demonstration also included items from two other product groups with lower levels of Medicare spending—urological supplies and surgical dressings. According to a CMS official, CMS did not include glucose monitors and supplies in competitive bidding because beneficiaries must frequently use brand-name supplies with their monitors. Ensuring that specific brands of glucose test strips were included would have complicated the first test of competitive bidding in the demonstration. However, the CMS official noted that CMS could consider including glucose supplies in future competitive bidding. Similarly, lower and upper limb prosthetics were not included because these items are generally custom made or fitted to beneficiaries and, for simplicity, the demonstration focused on noncustomized items.

[27] In 2003, Medicare placed related items into 62 product groups. For example, the wheelchair product group included manual and power wheelchairs and accessories, such as adjustable-height armrests and antitipping devices. Within these product groups, items are identified by HCPCS codes. A product group may consist of one HCPCS code or up to several hundred HCPCS codes.

Table 2: Product Groups Representing the Highest Medicare Spending in 2002 for DME, Prosthetics, Orthotics, and Supplies

Product group	Total Medicare allowed charges (dollars in millions)	Total Medicare allowed charges (percentage)	Some items from product group included in the demonstration
Oxygen contents, equipment, and supplies	$2,219	22.9	Yes
Wheelchairs and accessories	1,411	14.6	Yes
Nebulizer and related drugs	1,175	12.1	Yes
Glucose monitors and supplies	895	9.2	No
Enteral nutrients, equipment, and supplies	636	6.6	Yes
Lower and upper limb prosthetics	463	4.8	No
Hospital beds and accessories	359	3.7	Yes
Lower and upper limb orthotics	350	3.6	Yes
Total	**$7,508**	**77.5**	

Source: GAO analysis of CMS and statistical analysis durable medical equipment regional carrier (SADMERC) data.

Notes: Total allowed charges and percentages are rounded. Total allowed charges for each product group shown is the sum of allowed charges for the items included in that group. The allowed charge for each item is the payment for each item billed multiplied by the volume of the item billed on behalf of beneficiaries. The data used for this analysis were supplied by the SADMERC, a contractor that provides data analysis support to CMS. The data analyzed represented claims with service dates from January 1, 2002, through December 31, 2002, and were received by the SADMERC through December 31, 2003.

Our analysis of national Medicare spending for DME, prosthetics, orthotics, and supplies found that items included in the demonstration accounted for about half of all Medicare allowed charges in 2002. This was less than the total billing for all items in the product group because not all the individual items identified by HCPCS codes within product groups were included in the demonstration. For example, CMS excluded power wheelchairs from the competition.

Estimated savings for competitively bid items in the demonstration would total about 20 percent of the fee schedule amounts, according to the

demonstration evaluators. This equaled an estimated gross savings of $8.5 million in allowed charges, which include Medicare payments and beneficiary cost-sharing amounts.[28] The estimated cost of the demonstration was about $4.8 million—about 40 percent lower than the estimated $8.5 million reduction in allowed charges associated with the demonstration. The demonstration's $4.8 million cost included $1.2 million for planning and development from September 1, 1995, through July 1, 1998, and $3.6 million for demonstration operating expenses through December 2002.

For future efforts, MMA states that initial competitive bidding may include items with the highest Medicare cost and volume or items determined by the agency to have the largest savings potential. Working within these parameters for competitive bidding, CMS could select some items included in the demonstration as well as items with high Medicare spending that were not included in the demonstration. For example, nondemonstration items that CMS could choose include power wheelchairs and lancets and test strips used by diabetics. These three items accounted for about $1.7 billion, or about 17 percent, of Medicare allowed charges for DME, prosthetics, orthotics, and supplies in 2002.[29] A CMS official and DME regional carrier medical directors told us that these items could be considered for inclusion in future competitive bidding.

Two medical directors also suggested that continuous positive airway pressure devices[30] and accessories, with $137 million in allowed charges—or 1.4 percent of Medicare allowed charges for DME, prosthetics, orthotics, and supplies in 2002—could be considered for inclusion in future competitive bidding. CMS officials suggested that these devices and accessories could be included in early implementation of competitive bidding. Furthermore, if CMS is able to lower operating costs through efficiencies and streamlining, CMS could consider selecting additional products for competitive bidding with comparatively low levels of program spending for competitive bidding, such as commodes, canes, and crutches.

[28] The demonstration's evaluators estimated that gross savings were $4.0 million in Polk County and $4.5 million in the San Antonio location.

[29] Spending for power wheelchairs was about $857 million, for diabetic test strips about $752 million, and for lancets about $79 million in 2002.

[30] Individuals who have obstructive sleep apnea use continuous positive airway pressure devices while sleeping to provide constant levels of air pressure from a flow generator via a nose mask.

Larger-Scale Competitive Bidding May Benefit from Streamlined Implementation

While the demonstration laid the groundwork for future competition, given the expanded scale of future competitive bidding, CMS will have to focus on a second issue—ways to streamline implementation. The demonstration took place in just two MSAs and affected less than 1 percent of fee-for-service beneficiaries. In contrast, by 2009, MMA requires CMS to implement competitive bidding in 80 of the largest MSAs in the country. Our analysis showed that about half of Medicare's fee-for-service beneficiaries live in the 80 largest MSAs.[31] In order to expand competitive bidding, CMS could potentially use two streamlining approaches—developing standardized steps that are easily replicated in different locations and using mail-order delivery for selected items for which fees are determined through nationwide competitive bidding.

In conducting the demonstration, CMS and Palmetto gained practical experience in planning how competitive bidding could be conducted, communicating with beneficiaries and suppliers, choosing demonstration items, developing software to process demonstration claims, establishing policies, and soliciting and evaluating supplier bids. In expanding the scope of competitive bidding, CMS will be able to leverage its experience to develop a standardized or "cookie-cutter" approach that can be applied in multiple locations. This would include a standard set of competitively bid items, procedures and policies, and informational materials for suppliers and beneficiaries. Through standardization, the costs of implementation in individual MSAs would likely be reduced relative to program savings. In the demonstration, adding a second location allowed CMS and Palmetto to spread much of the implementation costs across two locations, rather than one.[32] The incremental costs of adding the San Antonio location, once the demonstration had been planned and begun in Polk County, were relatively low. For the San Antonio location, the estimated annual implementation

[31] Population estimates for the 80 largest MSAs are from Census 2000 and include the District of Columbia and Puerto Rico.

[32] In economic theory, this is called having "economies of scale," where producing more services or products can be accomplished at lower costs per unit because the overall costs are spread over a larger number of units. However, at some point, according to the economies of scale theory, the relative savings in implementation costs from expanding competitive bidding to more locations would likely decrease as fixed costs for additional locations stabilize. In addition, as CMS expands competitive bidding by MSA, at some point the agency might reach the maximum number of MSAs that it can administer without increasing fixed implementation costs.

costs ranged from $100,000 in a nonbidding year to $310,000 when bidding occurred, according to the second evaluation report.

Another potential streamlining approach would be to provide items by mail-order delivery—a convenience for beneficiaries—with uniform fees determined through nationwide competitive bidding. Because MMA authorizes CMS to designate the geographic areas for competition for different items, designating the entire country as the competitive area for selected items is a possibility. In addition, MMA states that areas within MSAs that have low population density should not be excluded from competition if a significant national market exists through mail-order for a particular item or service. In contrast to conducting competitive bidding on a piecemeal basis in multiple geographic areas, a consolidated nationwide approach would allow CMS to more quickly implement competitive bidding on a large scale. This approach would enable companies that provide, or demonstrate the ability to provide, nationwide mail-order service to compete for Medicare beneficiaries' business.

Items that lend themselves to mail delivery are light, easy to ship, and used by beneficiaries on an ongoing basis. Precedents exist for mail-order delivery of items that have been subject to competitive bidding. Demonstration suppliers provided surgical dressings, urological supplies, and inhalation drugs to beneficiaries by mail. In San Antonio, 30 percent of beneficiaries reported receiving their inhalation drugs through the mail, according to a demonstration evaluator, and Medicare paid an estimated 25 percent less than the fee schedule for Texas for these drugs.[33] Glucose test strips and lancets are two items currently mailed to Medicare beneficiaries' homes that could be included in a future nationwide competition. In 2002, these items accounted for $831 million, or about 8.6 percent, of Medicare allowed charges for DME, prosthetics, orthotics, and supplies. Because glucose test strips generally must be used with the glucose monitors made by the same manufacturer, CMS would need to ensure that the most commonly used types of test strips were included.

[33] MMA excludes inhalation drugs from competitive bidding. Other specific provisions of MMA set payments for these drugs.

Better Information on Specific Items Provided to Beneficiaries Could Ensure More Appropriate Payment

Finding ways to collect better information on the specific items provided to beneficiaries is the third issue for CMS to consider as it implements competitive bidding on a larger scale. Industry and advocacy groups have raised concerns that competitive bidding may encourage some suppliers to reduce their costs by substituting lower-quality or lower-priced items. However, CMS lacks the capability to identify specific items provided to beneficiaries because suppliers' claims use HCPCS codes, which can cover items that differ considerably in characteristics and price. Therefore, during the demonstration, CMS would not have been able to determine if suppliers tended to provide less costly items to beneficiaries. Furthermore, as CMS proceeds with competitive bidding, it will be difficult for the agency to appropriately monitor the type or price of specific items for which it is paying.

A single HCPCS code can cover a broad range of items serving the same general purpose but with differing characteristics and prices. For example, in April 2004, the HHS OIG reported that prices available to consumers on supplier Web sites it surveyed for different models of power wheelchairs represented by a single HCPCS code ranged from $1,600 to almost $17,000.[34] The 2003 Medicare fee schedule amount for all of the power wheelchairs under this code was a median of $5,297. Because Medicare pays the same amount for all of the items billed under the same HCPCS code, suppliers have an incentive to provide beneficiaries with the least costly item designated by that code. Since the Medicare program does not routinely collect specific information on items within a code for which it is paying, it is unable to determine if suppliers are providing lower-priced items or higher-priced items to beneficiaries. Using information from related work to determine the specific power wheelchairs provided to beneficiaries, the HHS OIG found that beneficiaries tend to receive lower-priced wheelchairs.[35] The OIG recommended that CMS create a new

[34] The HHS OIG studied purchase prices available to consumers and suppliers for power wheelchairs that Medicare reimburses when billed as HCPCS code K0011, which is the code suppliers most commonly use to bill Medicare for power wheelchairs. See U.S. Department of Health and Human Services, Office of Inspector General, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEI-03-03-00460 (Washington, D.C.: April 2004).

[35] The HHS OIG reported that the median price to consumers was $3,888 for a random sample of power wheelchair claims paid in 2001, with prices ranging from a low of $2,000 to a high of $5,995. Out of 247 prices the OIG reviewed for power wheelchairs actually provided to Medicare beneficiaries, there were four instances where the cost available to retail consumers on Internet Web sites was greater than Medicare's reimbursement amount.

coding system for the most commonly provided power wheelchairs to account for the variety in models and prices. CMS is currently working to develop a new set of codes to better describe the power wheelchairs currently on the market and plans to develop payment ceilings for each of the new codes.

Under competitive bidding, suppliers might have even greater incentive to substitute less costly products listed under a code. For example, one of the demonstration suppliers explained that while a specific curved-tip catheter was superior for patients with scar tissue or obstructions, competitive bidding would encourage suppliers to substitute other, less-expensive catheters that can be paid under the same code. Thus, even if competitive bidding reduces fees paid, when suppliers substitute less costly items for more costly items, Medicare can pay too much for the actual items provided to beneficiaries. CMS officials pointed out that this is also true under the current fee schedule.

CMS might better monitor the items being provided to beneficiaries if it subdivided certain HCPCS codes or collected identifying information. Subdividing HCPCS codes for items with significant variations in characteristics and price into smaller groupings is a way to narrow the differences among the items provided under a single code. The four DME regional carriers or the advisory committee established under MMA might be able to assist CMS in identifying those individual codes for items with the most significant variations in characteristics and price. Once these codes had been identified, CMS would be in a position to decide whether to request the panel that makes decisions on HCPCS codes for DME, orthotics, and supplies to consider whether to divide the codes into better-defined item groupings. Another way to get better information on the range of items provided under a code is to collect specific, identifying information (such as manufacturer, make, and model information) on selected, high-cost competitively bid items provided to beneficiaries. The DME regional carriers require suppliers to provide such information when it is requested for detailed reviews of claims for power wheelchairs. If CMS requested these data from suppliers for selected items provided under a HCPCS code for a statistically representative sample of claims, it would be able to analyze trends in the actual items provided to beneficiaries in competitive bidding areas or monitor the provision of items under the same code in competitive and noncompetitive areas.

Ensuring Quality and Service for Beneficiaries Is Critical

Because of concerns that competitive bidding may prompt suppliers to cut their costs by providing lower-quality items and curtailing services, a fourth issue for CMS to consider is ensuring that quality items and services are provided to beneficiaries. Quality assurance steps could include monitoring beneficiary satisfaction, as well as setting standards for suppliers, providing beneficiaries with a choice of suppliers, and selecting winning bidders based on quality in addition to amounts bid. During the demonstration, the agency and Palmetto gained practical experience in implementing quality assurance steps. This experience could prove instructive as CMS moves forward with competitive bidding efforts.

As competitive bidding proceeds, routine monitoring of beneficiaries' complaints, concerns, and satisfaction can be used as a tool to help ensure that beneficiaries continue to have access to quality items. During the demonstration, the agency and Palmetto used full-time, on-site ombudsmen to respond to complaints, concerns, and questions from beneficiaries, suppliers, and others. In addition, to gauge beneficiary satisfaction, the evaluators of the demonstration fielded two beneficiary surveys by mail—one for oxygen users and another for users of other products included in the demonstration.[36] These surveys contained measures of beneficiaries' assessments of their overall satisfaction, access to equipment, and quality of training and service provided by suppliers. Evaluators reported that their survey data indicated that beneficiaries generally remained satisfied with both the products provided and with their suppliers.

As competitive bidding expands and affects larger numbers of beneficiaries, small problems could be potentially magnified. Therefore, continued monitoring of beneficiary satisfaction will be critical to identifying problems with suppliers or with items provided to beneficiaries. When such problems are identified in a timely manner, CMS may develop steps to address them. In the past, when implementing significant Medicare changes, such as new payment methods for skilled nursing

[36] For comparison purposes, evaluators sent beneficiary surveys to beneficiaries in the two demonstration locations and to two groups of Medicare beneficiaries from areas similar to Polk County and the San Antonio location. Evaluators selected comparison sites outside of the demonstration areas to identify changes in the demonstration locations that were due to the demonstration and changes that may have resulted from general trends. Brevard County, Florida, was chosen as the comparison site for Polk County, and the Austin-San Marcos MSA, Texas, was the comparison site for the San Antonio location. Evaluators surveyed beneficiaries both before and after demonstration prices took effect in these locations.

facilities and home health services, the agency has lacked timely and accurate information about how the changes affected beneficiary access.

Nevertheless, it may not be practical in a larger competitive bidding effort to replicate the monitoring steps used in the demonstration. Developing less staff-intensive approaches to monitoring would reduce implementation costs. For example, a Palmetto official told us that while having an on-site ombudsman function may prove useful in the initial stages of competitive bidding, using a centralized ombudsman available through a toll-free number staffed by a contractor could provide some of the same benefits at a lower cost.

In addition, certain monitoring enhancements could prove useful. For example, CMS did not use a formal mechanism for ombudsmen to summarize or report information on complaints from beneficiaries or suppliers, according to the demonstration ombudsmen. Collecting and analyzing complaint information may provide a credible gauge of problems related to beneficiary access to quality products.

Continued use of satisfaction surveys could help track beneficiaries' satisfaction with items and services over time. However, advocacy group representatives have cautioned that beneficiaries may not have the technical knowledge to accurately assess the quality of the items or services being provided. Supplemental information might be obtained through standardized surveys of individuals who refer beneficiaries to suppliers, physicians, and supplier representatives, who may be better equipped to assess the technical quality of products and services.

Two MMA requirements—the selection of multiple suppliers to serve beneficiaries and the establishment of supplier standards—help ensure that beneficiaries are satisfied with suppliers and the items they provide. The selection of multiple suppliers to serve beneficiaries was part of the competitive bidding process used during the demonstration. The establishment of supplier standards is broader than the competitive bidding program in that it applies to all suppliers, regardless of whether they choose to participate in competitive bidding.

MMA requires that CMS select multiple suppliers that meet quality and financial standards to maintain choice in a competitive acquisition area. According to a CMS official, choosing to include multiple suppliers in the demonstration for each product group allowed beneficiaries to switch suppliers if dissatisfied with the quality of the services or items provided.

CMS officials stated that selecting multiple suppliers encouraged suppliers to compete on the basis of quality and service to gain beneficiaries' business. After completing the bid evaluation process, CMS generally selected about 50 percent of the suppliers that bid in each group, with an average of 12 suppliers selected across the product groups.[37]

MMA also requires that CMS establish and implement quality standards for all suppliers of DME, prosthetics, orthotics, and supplies.[38] These standards must be at least as stringent as the 21 general standards that all suppliers of DME, prosthetics, orthotics, and supplies are required to comply with in order to obtain and retain their Medicare billing privileges.[39] (See app. II.) For the demonstration, suppliers were also required to meet standards developed by Palmetto that were more stringent and explicit than the current 21 general standards.[40] For example, the demonstration standards required that only qualified staff deliver, set up, and pick up equipment and supplies and established time frames for suppliers to pick up equipment after a beneficiary had requested its removal. Palmetto monitored suppliers' adherence to the standards through initial and annual site visits.

Applying quality measures as criteria to select winning suppliers is another demonstration assurance step that can be used in future efforts. During the demonstration bid evaluation process, Palmetto solicited references from financial institutions and from at least five individuals who had referred beneficiaries to each bidding supplier. In reviewing referrals, Palmetto looked for evidence of quality and service. This included evidence of

[37] The number of suppliers selected ranged from 3 suppliers of surgical dressings in Polk County to 32 suppliers of oxygen equipment and supplies in San Antonio.

[38] These quality standards are to be applied by one or more designated, independent accreditation organizations selected within 1 year of implementing the quality standards. MMA, § 302(a), 117 Stat. 2223.

[39] Some of these 21 general standards promote quality services, while others exist to ensure that the supplier is a legitimate business. For example, the standards require that a supplier maintain a physical facility on an appropriate site and have a primary business telephone number listed under the name of the business. 42 C.F.R. § 424.57(c)(7), (9) (2003).

[40] Demonstration suppliers also were required to participate in the Medicare program; have active Medicare supplier numbers, which a supplier must have to submit claims and receive payment for items and services furnished under Medicare; and comply with all state and federal licensure and regulatory requirements, Medicare and Medicaid statutes and regulations, and Medicare billing guidelines.

financial stability and good credit standing, a record of providing products that met beneficiaries' needs, compliance with Medicare's rules and regulations, acceptable business practices, ethical behavior, and maintenance of accurate records. The bid evaluation process also included inspections of bidding suppliers' facilities that focused on indicators of quality and service. These on-site inspections were more comprehensive than those normally performed for Medicare suppliers of DME, prosthetics, orthotics, and supplies. For example, inspectors were tasked with determining if the supplier had access to the full range of products for which it had bid, documentation of infection control procedures, instructions on using equipment, and patient files with required information. In some cases, a demonstration supplier's selection was conditional on the supplier making specified improvements. For example, according to a CMS official, some suppliers were told to clarify instructions for beneficiaries, properly store oxygen equipment, or improve procedures for following up with patients after initial service was provided. CMS and Palmetto officials told us that comprehensive inspections were useful in ensuring the selection of quality suppliers.

Conclusions

CMS can use its experience from the demonstration to make informed decisions as it implements large-scale competitive bidding within the framework established by MMA. The demonstration showed that competitive bidding has the potential to garner significant savings for both the Medicare program and its beneficiaries, especially on items with high levels of Medicare spending. While the potential exists for significant savings, moving from small-scale to large-scale competitive bidding calls for streamlining implementation. Developing a cookie-cutter approach to competitive bidding—for example, using the same policies and processes in multiple locations—could help CMS roll out its implementation in over 80 locations more easily, while employing mail-order to deliver items with prices set through nationwide competitive bidding could allow CMS to more quickly implement competitive bidding on a large scale. To ensure that competitive bidding savings are not achieved by the suppliers' substitution of lower-cost items, CMS can consider ways to collect better information on the specific items that suppliers are providing to beneficiaries. Finally, careful monitoring of beneficiaries' experiences will be essential to ensure that problems are quickly identified. This will allow CMS to adjust its implementation and quality assurance steps as it manages competition on a greater scale.

Recommendations for Executive Action

To increase potential savings from competitive bidding, streamline implementation, help ensure that Medicare is paying appropriately for items, and promote beneficiary satisfaction, we recommend that the Administrator of CMS take the following seven actions:

- consider conducting competitive bidding for demonstration items and items that represent high Medicare spending that were not included in the competitive bidding demonstration;
- develop a standardized approach for competitive bidding for use at multiple locations;
- consider using mail delivery for items that can be provided directly to beneficiaries in the home, as a way to implement a national competitive bidding strategy;
- evaluate individual HCPCS codes to determine if codes need to be subdivided because the range in characteristics and price of items included under the individual codes is too broad;
- periodically obtain specific identifying information on selected high-cost items to monitor the characteristics of items subject to competitive bidding that are provided to beneficiaries, such as manufacturer, make, and model number;
- monitor beneficiary satisfaction with items and services provided; and
- seek input from individuals with technical knowledge about the items and services suppliers provide to beneficiaries.

Agency Comments and Our Evaluation

In its written comments on a draft of this report, CMS agreed with most of the recommendations and agreed to give serious consideration to the report throughout the development and implementation of national competitive bidding. CMS agreed to consider conducting competitive bidding for demonstration items and items that represent high Medicare spending that were not included in the demonstration. CMS indicated that the agency was working to develop a list of items for the first bidding cycle in 2007. CMS also agreed to develop a standardized approach for competitive bidding that could be used in multiple locations and indicated the agency's intention to outline such an approach through regulation.

CMS stated it would explore the feasibility of our recommendation to consider using mail-order delivery for items that could be provided directly to beneficiaries in the home, as a way to implement a national competitive bidding strategy. Based on CMS's comments, we clarified the discussion in the report to indicate businesses that currently provide, or have the potential to provide, national mail-order delivery would be appropriate to include as bidders in nationwide competition. CMS also agreed with our recommendations to periodically obtain specific identifying information on selected high-cost items and to monitor beneficiary satisfaction with the items and services provided and indicated that it would be establishing a process to do so. CMS agreed with our recommendation to seek input from individuals with technical knowledge about the items and services suppliers provide to beneficiaries. The agency noted that pursuant to MMA, CMS would be convening a panel of experts, the Program Advisory and Oversight Committee, to assist with implementation of competitive bidding.

CMS disagreed with one of our draft recommendations—to evaluate individual HCPCS codes to determine if they needed to be subdivided because the range in price of items included under the codes was too broad. The agency stated that subdividing codes according to price would lead to Medicare setting codes for particular brand names in circumstances where a manufacturer has established higher prices for products that do not have meaningful clinical differences or higher quality. In response to the agency's comment, we modified our discussion of HCPCS codes and revised our recommendation to state that CMS, in reevaluating individual HCPCS codes, should consider both the characteristics and prices of items.

We have reprinted CMS's letter in appendix III. CMS also provided us with technical comments, which we have incorporated as appropriate.

We are sending copies of this report to the Administrator of CMS, appropriate congressional committees, and other interested parties. We will also make copies available to others upon request. This report is also available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please call me at (312) 220-7600 or Sheila K. Avruch at (202) 512-7277. Other key

contributors to this report are Sandra D. Gove, Lisa S. Rogers, and Kevin Milne.

Leslie G. Aronovitz
Director, Health Care—Program
Administration and Integrity Issues

Scope and Methodology

To assess issues that the Centers for Medicare & Medicaid Services (CMS) might consider as it implements the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provisions concerning competitive bidding, we reviewed the relevant provisions of MMA. We also reviewed the first and second evaluation reports on the Medicare competitive bidding demonstration and discussed methodology and findings with the evaluators. We interviewed officials from CMS and Palmetto Government Benefits Administrators (Palmetto) about experience gained during the demonstration.

For the product selection issue, we analyzed calendar year 2002 Medicare durable medical equipment (DME), prosthetics, orthotics, and supply claims data obtained from the statistical analysis durable medical equipment regional carrier (SADMERC). Through this analysis, we identified the product groups and items that represented the largest Medicare allowed charges and the allowed charges for items included in the demonstration. We also used these data to identify items that accounted for higher Medicare spending but were excluded from the demonstration. We determined that the data obtained from the SADMERC were sufficiently reliable for addressing the issues in this report. These data were extracted from a CMS file that includes all Medicare claims payment data. CMS has a number of computerized edits to help ensure that Medicare payment data are accurately recorded, and the SADMERC has internal controls to ensure that data extracted from the CMS file are timely and complete. Where appropriate, we tested data manually against published sources for consistency. To identify items that could be included in future competitive bidding, we interviewed CMS and Palmetto officials and the medical directors at the four DME regional carriers.

For the issue of streamlining implementation, we obtained information on the cost of the demonstration from the second evaluation report. To estimate the number of fee-for-service beneficiaries who will be affected by future competitive bidding, we adjusted the Census 2000 population estimates for individuals age 65 and over to account for the number of beneficiaries enrolled in Medicare's managed care program by using data obtained from the Medicare Managed Care Market Penetration State/County Data Files. We assessed the reliability of the Census 2000 data by reviewing relevant documentation and working with an official from the U.S. Census Bureau. We assessed the reliability of the Medicare Managed Care Market Penetration State/County Data Files by reviewing relevant documentation. We determined these data sources to be sufficiently reliable for the purposes of our report. We also obtained information from

CMS on the demonstration items that beneficiaries obtained by mail and conducted research to identify items delivered directly to customers' homes by private sector organizations. We also solicited input from the medical directors at the four DME regional carriers concerning items that could be delivered by mail-order and included in a nationwide competition.

For the issue concerning information on specific items provided to beneficiaries, we reviewed prior GAO reports and testimonies. In addition, we interviewed the following representatives of industry and advocacy groups: Abbott Laboratories; the Advanced Medical Technology Association; the American Association for Homecare; the American Occupational Therapy Association; the American Orthotic and Prosthetic Association; the Consortium for Citizens with Disabilities; the Diabetic Product Suppliers Coalition; LifeScan, Inc.; Johnson & Johnson Company; Kinetic Concepts, Inc.; Tyco Healthcare Group; the National Alliance for Infusion Therapy; Roche Diagnostics; and the United Ostomy Association.

For the issue relating to ensuring quality items and services for beneficiaries, we discussed quality assurance steps and approaches for monitoring beneficiary satisfaction used during the demonstration with CMS and Palmetto officials and the demonstration's evaluators. We also interviewed the two demonstration ombudsmen to discuss beneficiaries' concerns and experiences in obtaining items during the demonstration. We discussed issues related to competitive bidding and beneficiaries' access to quality products and services with suppliers of DME, including three suppliers that participated in the demonstration; the industry and advocacy groups listed above; and the DME regional carrier medical directors. In addition, we compared quality standards for demonstration suppliers with the 21 supplier standards that apply to all Medicare suppliers of DME, prosthetics, orthotics, and supplies.

Medicare's 21 Standards for Medicare Suppliers of DME, Prosthetics, Orthotics, and Supplies

Suppliers of DME, prosthetics, orthotics, and supplies must meet 21 standards in order to obtain and retain their Medicare billing privileges. An abbreviated version of these standards, which became effective December 11, 2000, is presented in table 3. MMA requires CMS to develop new standards that must be at least as stringent as current standards for all Medicare suppliers of DME, prosthetics, orthotics, and supplies. Supplier compliance will be determined by one or more designated independent accreditation organizations.

Table 3: Standards for Medicare Suppliers of DME, Prosthetics, Orthotics, and Supplies

Standard number	Standard description
1	A supplier must be in compliance with all applicable federal and state licensure and regulatory requirements.
2	A supplier must provide complete and accurate information on the application for suppliers of DME, prosthetics, orthotics, and supplies. Any changes to this information must be reported to CMS within 30 days of the change.
3	An authorized individual (one whose signature is binding) must sign the application for billing privileges.
4	A supplier must fill orders from its own inventory, or must contract with other companies for the purchase of items necessary to fill the order. A supplier may not contract with any entity that is currently excluded from the Medicare program, from any state health care programs, or from any other federal procurement or nonprocurement program or activity.
5	A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased DME and of the purchase option for capped rental DME.
6	A supplier must honor all warranties under applicable state law and repair or replace free of charge Medicare-covered items that are under warranty.
7	A supplier must maintain a physical facility on an appropriate site.
8	A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards. The supplier location must be accessible to beneficiaries during reasonable business hours and must maintain a visible sign and posted hours of operation.
9	A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll-free number available through directory assistance. The exclusive use of a beeper, answering machine, or cell phone as the primary business telephone number is prohibited.
10	A supplier must have comprehensive liability insurance in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items, this insurance must also cover product liability and completed operations.
11	A supplier must agree not to initiate telephone contact with beneficiaries, with a few exceptions allowed. This standard prohibits suppliers from calling beneficiaries in order to solicit new business.
12	A supplier is responsible for delivery and must document that it, or another qualified party, instructed beneficiaries on the use of Medicare-covered items, and maintain proof of delivery.
13	A supplier must answer questions and respond to complaints of beneficiaries, and maintain documentation of such contacts.
14	A supplier must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.
15	A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.

(Continued From Previous Page)

Standard number	Standard description
16	A supplier must disclose these supplier standards to each beneficiary to whom it supplies a Medicare-covered item.
17	A supplier must disclose to the government any person having ownership, financial, or controlling interest in the supplier.
18	A supplier must not convey or reassign a supplier number; that is, the supplier may not sell or allow another entity to use its Medicare billing number.
19	A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20	Complaint records must include the name, address, telephone number, and health insurance claim number of the beneficiary; a summary of the complaint; and any actions taken to resolve it.
21	A supplier must agree to furnish CMS with any information required by the Medicare statute and implementing regulations.

Source: GAO analysis of 42 C.F.R. § 424.57(c) (2003).

Comments from the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: AUG 5 2004

TO: Leslie G. Aronovitz
Director, Health Care – Program
Administration and Integrity Issues

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator

SUBJECT: General Accountability Office's Draft Report: *MEDICARE: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies* (GAO-04-765)

Thank you for the opportunity to review and comment on the above referenced General Accountability Office's (GAO) draft report. The Centers for Medicare & Medicaid Services (CMS) recognizes the many complexities of implementing national durable medical equipment (DME) competitive bidding. The CMS is beginning to explore various approaches and policy options for effectively implementing national DME competitive bidding. The CMS has formed a cross-component internal workgroup that has begun meeting to address the many facets of implementation of DME competitive bidding. We have also contracted with the Research Triangle Institute to provide technical and advisory assistance to us throughout this process. Additionally, we are establishing the Program Advisory and Oversight Committee, as provided for in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Our first meeting is tentatively scheduled for October 2004.

The CMS appreciates the GAO's efforts in preparing this report. The CMS agrees with the majority of the recommendations and will give serious consideration to the GAO report throughout the development and implementation of national competitive bidding. We believe, based on the evaluation of the competitive bidding demonstration and the GAO report, that we will be able to increase the potential savings, streamline implementation, ensure that Medicare is paying appropriately for items, and to promote beneficiary satisfaction.

Attached are CMS' detailed comments to GAO's recommendations.

Attachment

Centers for Medicare & Medicaid Services' Comments to the GAO Draft Report: *MEDICARE: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies* (GAO-04-765)

GAO Recommendation

Consider conducting competitive bidding for demonstration items and items that represent high Medicare spending that were not included in the competitive bidding demonstration;

CMS Response

The CMS concurs with the recommendation. This recommendation is consistent with the statute, which states that competitive bidding "may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential." Although a list of items has not been decided, we concur that the list should include items that have the largest savings potential. The CMS is currently working with the Research Triangle Institute to develop a list of items to phase in beginning in 2007.

GAO Recommendation

Develop a standardized approach for competitive bidding for use at multiple locations;

CMS Response

We concur with the recommendation. It is CMS' intention to develop a regulation that will outline the approach that we will take to implement competitive bidding.

GAO Recommendation

Use of mail delivery for items that can be provided directly to beneficiaries in the home, as a way to implement a national competitive bidding strategy;

CMS Response

The CMS will explore the feasibility of this approach. On pages 13 and 14 of the draft, please clarify whether the GAO is recommending that for items which have a significant national market through mail order delivery that only those companies that have nationwide mail order businesses would be allowed to bid. A similar clarification is needed on page 22 to explain GAO's third recommendation.

GAO Recommendation

Evaluate individual [Healthcare Common Procedure Coding System] HCPCS codes to determine if codes need to be subdivided because the range in prices of items included under the individual codes is too broad;

Page 2 - Attachment

CMS Response

We do not concur with this recommendation. The current Healthcare Common Procedure Coding System is designed to identify and group similar and equivalent items based upon function and operation, rather than price. We believe subdividing codes according to price ranges would lead to Medicare setting codes for particular brand names in circumstances where a manufacturer has established high prices for its products but when these price differences do not reflect meaningful clinical differences or higher quality.

GAO Recommendation

Periodically obtain specific identifying information on selected high-cost items to monitor the characteristics of competitively bid items provided to beneficiaries, such as manufacturers, make, and model number;

CMS Response

We concur with the recommendation. The CMS is developing a regulation that will outline the process that we will use to ensure the quality of the products provided to beneficiaries.

GAO Recommendation

Monitor beneficiary satisfaction with items and services provided;

CMS Response

We concur with the recommendation. The CMS will develop a process to monitor the beneficiary satisfaction with the quality and service being provided under the competitive bidding process.

GAO Recommendation

Seek input from individuals with technical knowledge about the items and services suppliers provide to beneficiaries.

CMS Response

We concur with the recommendation. Pursuant to the Medicare Prescription Drug , Improvement, and Modernization Act of 2003 (MMA), CMS will convene a panel of experts, the Program Advisory and Oversight Committee, to assist us with implementation of the competitive bidding. This panel will be charged with making recommendations on the quality service standards that will be applied to items and services that are provided to the beneficiaries under the competitive bidding process.

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