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The Honorable Pete Stark
Ranking Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

The Honorable Charles E. Grassley
Ranking Member
Committee on the Judiciary
United States Senate

Subject: *Medicare: Issues for Manufacturer-Level Competitive Bidding for Durable Medical Equipment*

In 2009, Medicare—a federal health insurance program that serves about 46.3 million beneficiaries¹—spent approximately \$8.1 billion on durable medical equipment (DME), prosthetics, orthotics, and related supplies for 10.6 million beneficiaries.² DME includes items such as wheelchairs, hospital beds, and walkers. Medicare beneficiaries typically obtain DME items from suppliers, who submit claims for payment for these items to Medicare on behalf of beneficiaries. The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services (HHS), has responsibility for administering the Medicare program. Both we and HHS's Office of Inspector General (OIG) have reported that

¹Medicare is the federal health insurance program for people age 65 and older, individuals under age 65 with certain disabilities, and individuals diagnosed with end-stage renal disease.

²DME is 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. Prosthetic devices (other than dental) are defined as devices needed to replace body parts or functions such as artificial limbs, enteral nutrition, and cardiac pacemakers. Orthotic devices are defined as providing rigid or semirigid support for weak or deformed body parts or restricting or eliminating motion in a diseased or injured part of the body, such as leg, arm, back, and neck braces. Medicare-reimbursed supplies are items that are used and consumed with DME, such as drugs used for inhalation therapy, or that need to be replaced frequently (usually daily), such as surgical dressings.

Medicare and its beneficiaries—through their out-of-pocket costs—have sometimes paid higher than market rates for various medical equipment and supplies.³

To achieve Medicare savings for DME and to address DME fraud concerns, Congress, through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),⁴ required CMS to phase in a competitive bidding program (CBP)⁵ for DME suppliers in selected competitive bidding areas (CBA). In CBP, suppliers submit bid prices in the amounts they are willing to accept as payment to provide DME items to Medicare beneficiaries. CMS then enters into contracts with select DME suppliers to provide DME items at the prices determined by CBP. CBP is a fundamental departure from CMS's usual method of paying for DME, in which CMS pays any qualified supplier a set fee schedule. CBP also provides an incentive for DME suppliers to accept lower Medicare payment amounts in exchange for the ability to serve beneficiaries and to potentially increase their Medicare market share.

CMS began implementing CBP in 2007 and 2008—referred to as round 1. Concerns about CBP's round 1 bid submission and contract award processes were raised during two congressional hearings in May 2008. CBP's round 1 was stopped by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA),⁶ which terminated the contracts already awarded to suppliers, delayed the program's restart, and required CMS to repeat the competition.⁷ To compensate for the loss of the projected savings from the CBP delay, beginning January 1, 2009, MIPPA reduced Medicare payments by 9.5 percent nationally for items in the 10 product categories that had been included in the CBP round 1. The CBP competition—referred to as the round 1 rebid—was repeated in 2009 and 2010. On January 1, 2011, CBP began with 356 suppliers awarded contracts to provide DME items in

³GAO, *Medicare: CMS has Addressed Some Implementation Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program for the Round 1 Rebid*, [GAO-10-1057T](#) (Washington, D.C.: Sept. 15, 2010); GAO, *Medicare: Competitive Bidding for Medical Equipment and Supplies Could Reduce Program Payments, but Adequate Oversight Is Critical*, [GAO-08-767T](#) (Washington, D.C.: May 6, 2008); GAO, *Medicare: Past Experience Can Guide Future Competitive Bidding for Medical Equipment and Supplies*, [GAO-04-765](#) (Washington, D.C.: Sept. 7, 2004); Daniel R. Levinson, Inspector General, Department of Health and Human Services, *Medicare's Competitive Bidding Program for Durable Medical Equipment: Implications for Quality, Cost, and Access*, testimony before the House of Representatives Committee on Energy and Commerce, Subcommittee on Health, 111th Cong., 2nd sess., Sept. 15, 2010; Department of Health and Human Services Office of Inspector General, *A Comparison of Prices for Power Wheelchairs in the Medicare Program*, OEL-03-03-00460 (April 2004); and 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., June 12, 2002.

⁴Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 302(b), 117 Stat. 2066, 2224-29 (2003) (codified as amended at 42 U.S.C. § 1395w-3). MMA established a competitive acquisition program for certain Medicare-covered items of DME, prosthetics, orthotics, and supplies referred to as DMEPOS. CMS refers to this program as the Medicare DMEPOS competitive bidding program. The items and services covered by the competition were DME and related supplies, off-the-shelf orthotics, and enteral nutrients and related equipment and supplies.

⁵For this report, the term CBP is used to refer to CMS's supplier-level Medicare DMEPOS competitive bidding program, and the term DME refers to durable medical equipment, prosthetics, orthotics, and related supplies.

⁶Pub. L. No. 110-275, § 154, 122 Stat. 2494, 2560-68 (2008) (amending 42 U.S.C. § 1395w-3).

⁷In a November 2009 report, we documented round 1 implementation problems, including, for example, that CMS had not provided suppliers with timely and clear bid submission information. GAO, *Medicare: CMS Working to Address Problems from Round 1 of the Durable Medical Equipment Competitive Bidding Program*, [GAO-10-27](#) (Washington, D.C.: Nov. 6, 2009).

nine DME product categories⁸ in nine CBAs.⁹ CMS stated that the CBP payment amounts are projected to result in an average savings of 32 percent as compared to the current Medicare fee schedule payments for the same items.

In contrast to CBP's supplier-level approach, some health care purchasers use a manufacturer-level approach to buy DME items directly from DME manufacturers to obtain savings by leveraging their purchasing power. CMS has not been required to develop a manufacturer-level approach, and there are no current proposals for it to do so. You expressed interest in obtaining information on health care purchasers that currently use a manufacturer-level approach and on issues that would need to be addressed if CMS implemented such an approach.¹⁰ In this report, we describe (1) efforts used by some non-Medicare purchasers to reduce DME spending by contracting with DME manufacturers or using purchasing intermediaries, and (2) issues that CMS might face if required to implement a DME manufacturer-level approach with broad authority to do so.

To describe how some non-Medicare purchasers¹¹ reduce spending on DME items, we interviewed government and private purchasers that contract with DME manufacturers or use purchasing intermediaries to reduce DME spending. We selected purchasers for further study that reflected a wide range of manufacturer-level purchasing approaches. We interviewed officials from the Department of Veterans Affairs (VA), which provided care to more than 5.6 million patients in fiscal year 2010, to identify how VA competitively purchases DME directly from manufacturers and how VA contracts with suppliers to provide services such as delivery and setup of DME items. To compare the costs of certain DME items, we compared VA's national contract prices for DME items in 2010 with Medicare's 2010 payments for those same items. We also interviewed Medicaid¹² officials about program operations and lessons learned from either attempting to, or successfully contracting with,

⁸A product category is a grouping of related DME items that are used to treat a similar medical condition. The nine DME product categories and their items selected by CMS for bidding were generally high-volume and high-cost items. The product categories are: oxygen supplies and equipment; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories (limited to group 2—power wheelchairs with power options); mail-order diabetic supplies; enteral nutrients, equipment, and supplies; continuous positive airway pressure devices, and respiratory assist devices, and related supplies and accessories; hospital beds and related accessories; walkers and related accessories; and support surfaces (limited to group 2 mattresses and overlays—pressure reducing support surfaces for persons with or at high risk for pressure ulcers—in the Miami CBA only). The enteral nutrition product category—equipment and supplies to provide nutrition through a tube into the stomach or small intestine—is covered under the Medicare prosthetic device benefit for beneficiaries.

⁹The CBAs were required to be selected from the largest metropolitan statistical areas (MSA). The nine selected CBAs are: Charlotte (Charlotte-Gastonia-Concord, North Carolina and South Carolina); Cincinnati (Cincinnati-Middletown, Ohio, Kentucky, and Indiana); Cleveland (Cleveland-Elyria-Mentor, Ohio); Dallas (Dallas-Fort Worth-Arlington, Texas); Kansas City (Kansas City, Missouri and Kansas); Miami (Miami-Fort Lauderdale-Pompano Beach, Florida); Orlando (Orlando-Kissimmee, Florida); Pittsburgh (Pittsburgh, Pennsylvania); and Riverside (Riverside-San Bernardino-Ontario, California).

¹⁰Actual implementation issues presented by such a program, however, would depend on whether and how Congress may design the program and the nature of the authority Congress provides to CMS for implementation.

¹¹In this report, we use the term “purchaser” to refer both to those who obtain DME and provide it to beneficiaries, such as the Department of Veterans Affairs (VA), and to those who pay for DME obtained by beneficiaries, such as CMS.

¹²Medicaid is the joint federal-state program that finances medical services for certain low-income adults and children.

manufacturers.¹³ To identify additional approaches to reducing spending, we interviewed officials from selected entities that negotiate favorable prices from manufacturers through purchasing intermediaries. We interviewed officials from one group purchasing organization (GPO)—a purchasing intermediary that negotiates contracts between its customers and vendors of medical products. This GPO administers DME benefits on behalf of health insurers. We also interviewed officials from a third-party administrator (TPA)—a group that, under a service contract, processes claims and also provides certain administrative services to a health insurer—which negotiates discounts from diabetic supply manufacturers on behalf of some state Medicaid programs.

To describe the issues CMS could face if it were to implement a competitive bidding program at the manufacturer-level for Medicare DME, we reviewed competitive bidding studies and interviewed stakeholders in the DME industry to learn about the structure of the industry and how a manufacturer-level competitive bidding program could affect their business. Specifically, we interviewed representatives from trade associations representing both DME suppliers and DME manufacturers,¹⁴ representatives from selected DME suppliers and DME manufacturers, and officials from a CMS contractor responsible for processing Medicare DME claims. On the basis of these interviews, we compared the issues CMS considered in the current Medicare DME CBP with the issues CMS could consider if the agency were to implement a manufacturer-level competitive bidding program.

We conducted this performance audit from March 2010 to May 2011 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings based on our audit objectives.

Results in Brief

Some government and private health care purchasers leverage their buying power to reduce spending on DME (durable medical equipment) by contracting with DME manufacturers or using purchasing intermediaries. VA requires its medical centers to purchase certain DME items directly from manufacturers through one of three mechanisms. By offering manufacturers the opportunity to serve VA's medical centers, VA leverages its buying power when negotiating for lower prices for high-volume and recurring-need DME items. VA can purchase DME items through the Federal Supply Schedule (FSS), where contracts are awarded to an unlimited number of manufacturers offering VA what are known as most-favored customer pricing—prices at least as low as those given to the manufacturers' most-favored commercial customers. To purchase items that are widely used on a recurring basis, VA may use blanket purchase agreements (BPA) and national contracts. VA enters into these agreements and contracts with a limited number of manufacturers—offering to increase the manufacturers' VA market share for certain DME items in exchange for prices that must be

¹³We contacted Medicaid officials and an official from an association of state public health and human services departments to identify states whose Medicaid programs attempted to or were using competitive bidding programs for certain DME items. We interviewed Medicaid officials from California, Florida, Michigan, Nevada, New Hampshire, New York, Rhode Island, South Carolina, and Texas.

¹⁴We interviewed representatives from the American Association for Homecare, which is an organization of DME suppliers, the Advanced Medical Technology Association, which is an organization of DME and medical device manufacturers, and the National Association for the Support of Long Term Care, which is an organization of DME manufacturers and DME suppliers that provide medical supplies to long-term care facilities and home care providers.

lower than those listed on the FSS. Like VA, some Medicaid programs contract with manufacturers for DME items. These programs select either a single or limited number of manufacturers to provide a particular DME item, enabling them to leverage their buying power in exchange for price discounts from DME manufacturers on items requiring little or no servicing. Purchasers can also leverage their buying power by negotiating favorable prices from DME manufacturers through purchasing intermediaries. For example, several private insurers may use one GPO to administer their DME benefits and negotiate favorable manufacturer pricing on their behalf. Similarly, some Medicaid programs use a TPA to negotiate rebates from diabetic supply manufacturers on their behalf.

CMS could face issues both similar to those that it addressed in implementing CBP at the supplier level and specific to competitive bidding involving manufacturers if it were required to implement a Medicare DME manufacturer-level approach and were given broad authority to do so. Key issues similar to those CMS considered for CBP could include choosing which DME items to competitively bid that would result in the most Medicare savings, determining whether to operate the program for some items at a national level, and considering the range of Medicare beneficiary choices for DME items. CMS could also consider key issues specific to competitive bidding at the manufacturer level. For example, CMS currently has a minimal relationship with DME manufacturers unless they are also Medicare suppliers, and it might need to strengthen its regulatory relationship with DME manufacturers for competitive bidding. CMS could also consider whether a new Medicare payment system would need to be created that could separate payments for the cost of a manufacturer's item from the cost for an item's services provided by suppliers.

In commenting on a draft of this report, HHS stated that the report provides useful information about other ways the Medicare program, and its beneficiaries, can obtain better value for DMEPOS items and services. HHS also noted that the report demonstrates how other payers use various acquisition strategies to receive better prices than Medicare for the same DMEPOS items and services, despite the fact that Medicare often pays for a larger quantity of items and services.

Background

Medicare is the federal program that helps pay for a variety of health care services for about 46.3 million beneficiaries—people age 65 and older, certain disabled individuals, and those with end-stage renal disease. Most Medicare beneficiaries participate in Medicare Part B, which helps pay for DME items and supplies, such as oxygen, wheelchairs, hospital beds, walkers; orthotics, prosthetics, and supplies if they are medically necessary and prescribed by a physician.¹⁵ Part B also covers certain outpatient prescription drugs used with DME or that are not usually self-administered by the patient; some of these drugs, such as inhalation therapy drugs, are classified as supplies.

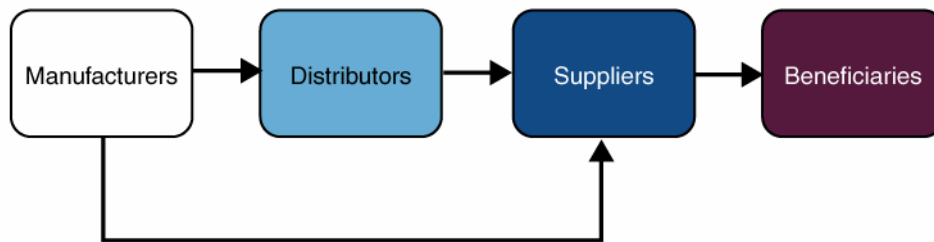
¹⁵Medicare Part B helps pay for certain physician, outpatient hospital, laboratory, and other services, and medical equipment and supplies. Beneficiaries are required to pay a monthly premium for Part B coverage, an annual deductible, and coinsurance.

Medicare and DME Suppliers and Manufacturers

Medicare beneficiaries typically obtain their DME items from suppliers, who submit claims for payment to Medicare on the beneficiary's behalf. To be able to bill Medicare, DME suppliers must enroll in Medicare and must meet certain requirements, such as accreditation to ensure that they meet minimum quality standards, in order to reduce the risk of enrolling suppliers intent on defrauding or abusing Medicare.¹⁶ Suppliers can include DME retail establishments, and outpatient providers, such as physicians, home health agencies, and physical therapists. Suppliers may also provide DME items, such as diabetic testing supplies, directly to a beneficiary's residence through a common carrier, such as the U.S. Postal Service or shipping or courier services.

Suppliers purchase DME items from DME manufacturers or from distributors that sell items from multiple manufacturers to suppliers.¹⁷ (See fig. 1.) Suppliers may negotiate—either directly or indirectly through a third party—with manufacturers to obtain item prices lower than the Medicare payment for that item. Suppliers have an incentive to negotiate DME price discounts, as they may retain the difference between the negotiated item price and its Medicare payment. In general, the larger a supplier is, the more it can leverage its buying power to negotiate price discounts.

Figure 1: How Medicare Beneficiaries May Receive DME Items



Source: GAO.

Note: Medicare beneficiaries can receive DME items directly from entities that are enrolled as Medicare suppliers. If enrolled as Medicare suppliers, other entities such as manufacturers, distributors, and pharmacies, and providers such as hospitals, nursing homes, and home health agencies, may also furnish items to beneficiaries.

¹⁶For a list of Medicare enrollment standards applying to DME suppliers, see 42 C.F.R. § 424.57(c) (2010). For a list of quality standards applying to DME suppliers, see <http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOS AccreditationStandards.pdf> (downloaded on Jan. 20, 2011).

¹⁷A distributor generally transfers DME items from one or more DME manufacturers to suppliers who then provide the items to Medicare beneficiaries. A distributor is not regulated by CMS unless it enrolls in Medicare as a supplier and then provides items directly to Medicare beneficiaries.

Medicare DME Payments

Medicare pays for most DME through fee schedules based on suppliers' historical charges to Medicare.¹⁸ The Medicare payment is generally equal to 80 percent of the lesser of either the supplier's actual charge or the Medicare fee schedule for a particular item or service. Medicare beneficiaries are responsible for paying the supplier the remaining 20 percent.¹⁹

The Medicare fee schedules classify most DME, prosthetics, orthotics, and supplies (DMEPOS) items into six payment categories, for example the inexpensive or other routinely purchased items category includes items such as standard walkers and canes. Depending on the category, the items may be paid as a lump sum—onetime—payment, or as rental payments—monthly payments over a set time period—and may or may not include payment for repair, maintenance, and delivery of the item.²⁰ (See enc. I.)

In submitting claims for Medicare payments, suppliers use a standardized coding system—the Healthcare Common Procedure Coding System (HCPCS). The codes identify a category of like DME items or services, for example hospital beds, rather than specific products or brand or trade names. Medicare's DME fee schedule has nearly 3,000 HCPCS codes. 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.²¹ To handle DME payment claims processing, including coverage and payment determinations, CMS contracts with DME Medicare administrative contractors.

History of DME Competitive Bidding

The Balanced Budget Act of 1997 required CMS to test competitive bidding as a new way to set payment rates for Medicare Part B items and services selected by CMS.²² CMS conducted three DME CBP demonstration projects, two in Florida (1999–2002) and one in Texas (2000–2002). About a year after the demonstrations ended, the MMA was enacted, requiring CMS to implement a broader CBP beginning in 2007. Changing the long-standing policy that any qualified supplier be allowed to enroll in Medicare, the MMA provided that generally only

¹⁸Medicare adjusts fee schedules for DME for each state, reflecting geographic price differences that are subject to national floor and ceiling limits. The applicable state fee schedule is determined by the Medicare beneficiary's residence, not the DME supplier's location.

¹⁹For suppliers, Medicare assignment—accepting Medicare's reimbursement amount for an item as payment in full and limiting the amount the beneficiary can be billed for that item—is optional. If a supplier agrees to assignment, then Medicare generally pays 80 percent of the amount to the supplier and the Medicare beneficiary is responsible for paying the supplier the remaining 20 percent—referred to as the coinsurance payment, once the beneficiary's annual deductible has been met. If the supplier does not accept assignment, the supplier is not limited to charging the beneficiary 20 percent of the Medicare reimbursement for that item or service and the beneficiary can be billed for whatever balance is due. For CBP items, Medicare assignment is mandatory for suppliers.

²⁰Repairs are paid separately only if the item is being purchased or is already owned by the beneficiary, and the repair is necessary to make the item serviceable. For some DME items, manufacturers are responsible for warranty repair work; repairs made under warranty are not a covered Medicare service and no Medicare payment is made. Maintenance is also paid only if the item is being purchased or is already owned by the beneficiary, and if the maintenance is extensive amounting to repairs that require the services of skilled technicians. Routine maintenance and periodic servicing are not covered by Medicare payment.

²¹For example, 82 products are listed under the HCPCS code E0260 "Hospital Bed, Semi-Electric (Head and Foot Adjustment), With Any Type Side Rails, With Mattress."

²²Pub. L. No. 105-33, § 4319(a), 111 Stat. 251, 392-94 (1997) (adding 42 U.S.C. § 1395w-3).

suppliers who were awarded CBP contracts could be paid by Medicare for providing CBP-covered Part B DME items and services in selected CBAs.

In 2007 and 2008, CMS began the phase-in of CBP—round 1—with suppliers submitting price bids for items in 10 product categories²³ in 10 CBAs.²⁴ Through CBP, CMS established competitively determined Medicare payments for the bid items and competitively selected a limited number of suppliers to provide items to Medicare beneficiaries residing in the CBAs.²⁵ Suppliers submitted bids for supplying 1 or more of the 10 product categories in 1 or more of the 10 CBAs. The MMA imposed certain CBP criteria including, for example, that the total amount to be paid to winning suppliers be less than would otherwise be paid by Medicare under existing fee schedules and that the ability of suppliers to meet the anticipated needs of beneficiaries in a CBA be considered in choosing the CBP suppliers.

MIPPA imposed additional requirements for how CMS should conduct later CBP rounds, including the round 1 rebid and the subsequent rounds that will expand CBP to additional CBAs. CMS began the CBP round 1 rebid with nine product categories in nine CBAs in 2009,²⁶ it announced its winning suppliers in November 2010, and the contracts awarded through the CBP round 1 rebid and its Medicare payments were effective January 1, 2011.

Some Non-Medicare Purchasers Contract with DME Manufacturers or Use Purchasing Intermediaries to Reduce DME Spending

To reduce DME spending, some non-Medicare government purchasers—both federal and state—leverage their buying power by contracting with manufacturers for DME items. Other private purchasers leverage their buying power through purchasing intermediaries such as group purchasing organizations (GPO) and third-party administrators (TPA) that negotiate favorable prices from DME manufacturers on their behalf. (See enc. II for a summary of DME purchasing approaches.)

Contracting with Manufacturers

To reduce spending, some non-Medicare government purchasers—both federal and state—leverage their buying power by contracting with DME manufacturers. VA is both a purchaser and provider of DME items and services, and is able to leverage its DME buying power by having its medical centers purchase DME items from those manufacturers who have entered into VA contracts or agreements through one of three mechanisms. Some Medicaid programs

²³The 10 DME product categories—a grouping of related items used to treat a similar medical condition—selected by CMS for bidding were generally high-volume and high-cost items. The product categories were the same as the CBP round 1 rebid, except that round 1 also included the negative pressure wound therapy pumps and related supplies and accessories category.

²⁴To begin the program's national phase-in, 10 CBAs were chosen from the largest MSAs. In CBP's round 1 rebid there were 9 CBAs. For round 2, the Patient Protection and Affordable Care Act (PPACA) provided for competition to occur in 91 of the largest MSAs. Pub. L. No. 111-148, § 6410, 124 Stat. 119, 773 (2010).

²⁵To submit CBP bids, CMS required eligible suppliers to have met Medicare enrollment, quality, and financial standards, obtained the state licenses required to provide the relevant services, and have been accredited by a CMS-approved accrediting organization. The competitive bidding process had several steps: bidder registration, bid submission, bid review, winner selection, setting CBP Medicare payments—referred to as single payment amounts—for each item in a product category in each CBA, and awarding contracts to winning suppliers.

²⁶In CBP's round 1 rebid, the product categories were revised to delete the negative pressure wound therapy category and to exclude group 3 complex rehabilitative power wheelchairs from the entire CBP, and the San Juan, Puerto Rico, CBA was deleted.

have also reported reducing their DME spending by contracting, either on their own or with other state Medicaid programs, with manufacturers for DME items requiring little or no servicing.

VA Contracting Mechanisms

VA leverages its DME buying power by requiring that its medical centers purchase DME items through one of three mechanisms: the Federal Supply Schedule (FSS),²⁷ blanket purchase agreements (BPA), and national contracts. The discount VA is able to achieve off the manufacturer's retail price for DME items depends, in part, on the exclusivity provided to the manufacturer under each mechanism and the type of DME item involved. To determine the most appropriate mechanism to use for each DME item that VA purchases, VA staff conduct product research, including VA purchasing history for the particular DME item.

VA can purchase DME items through contracts with manufacturers that have agreed to provide an uninterrupted supply of an item at a given price to federal agencies through the FSS program.²⁸ Under this program, VA awards contracts to multiple vendors—manufacturers in the case of DME items—for commercially available goods and services; federal agencies—in this case VA—place orders under these contracts. To obtain best prices, VA negotiates for the best price that a vendor—or manufacturer in the case of DME—provides to its most-favored customer prior to awarding a contract.²⁹ VA maintains the best prices through a price-reduction clause in FSS contracts that allows VA to receive a lower contract price if the vendor lowers its price to a similarly situated commercial customer.³⁰

²⁷The General Services Administration (GSA) directs and manages the FSS program, which government agencies use to procure commonly used goods and services. The GSA, for example, is responsible for acquiring vehicles for government agencies to use in the federal fleet. See GAO, *Federal Energy and Fleet Management: Plug-in Vehicles Offer Potential Benefits, but High Costs and Limited Information Could Hinder Integration into the Federal Fleet*, [GAO-09-493](#) (Washington, D.C.: June 9, 2009). The GSA has delegated authority to VA to operate the FSS schedules and contract for medical supplies and services, including DME, for federal agencies. The GSA has not delegated VA the authority to prescribe the policies and procedures that govern the FSS program.

²⁸Contracts awarded through the FSS program are indefinite delivery-indefinite quantity contracts. These contracts allow the federal agency to order unspecified quantities, within stated limits, of products or services during a fixed period when the agency cannot predetermine its needs.

²⁹Most-favored customers are customers or categories of customers that receive the best price from vendors. See 48 C.F.R. §§ 538.270(a), 538.271, and 538.272 (2010). The pursuit of most-favored customer pricing is consistent with the objective of negotiating a fair and reasonable price. See 62 Fed. Reg. 44,518, 44,519 (Aug. 21, 1997).

³⁰See 48 C.F.R. § 538.272 (2010). Previous GAO work has shown that some of the tools for obtaining the best price are used on a limited basis, which hinders the ability of the government to determine whether the FSS program is achieving its goal of obtaining best prices. See GAO, *Contracting Strategies: Data and Oversight Problems Hamper Opportunities to Leverage Value of Interagency and Enterprisewide Contracts*, [GAO-10-367](#) (Washington, D.C.: Apr. 29, 2010).

VA generally uses BPAs to fill a recurring need by an agency for supplies or services and to seek pricing lower than listed on the FSS.³¹ Agencies may award BPAs to one vendor—known as a single award BPA—or to more than one vendor—known as multiple award BPAs,³² and then issue individual orders against BPAs to fulfill requirements for supplies as the need arises. The Federal Acquisition Regulation requires federal agencies to seek reductions from vendors' FSS prices when negotiating BPAs because the use of BPAs limits the number of vendors from whom items are purchased, thus granting greater exclusivity to those vendors.³³ For example, the price under a VA BPA for a 50-count box of blood glucose strips for one manufacturer is \$11.06, compared to the same manufacturer's FSS price of \$13.07.³⁴

According to VA officials, VA generally negotiates national contracts with a single manufacturer to exclusively provide particular DME items to VA medical centers, including with manufacturers that are not listed on the FSS. VA typically uses these contracts for items it needs in large quantities, such as hospital beds.³⁵ Manufacturers bid competitively to provide the DME item, and VA conducts best-value determinations³⁶ to select the manufacturer that would provide the greatest overall benefit. For example, VA's national contract price in 2010 for power lifts used to transfer patients included a 70 percent discount off the manufacturer's suggested retail price. (See table 1 for a summary of VA contracting mechanisms.)

³¹VA can only award a BPA to a manufacturer that is already participating in the FSS program. BPAs are not contracts, but rather agreements between federal agencies and vendors with terms and conditions, including prices, for future use. When the need arises, agencies enter into contracts with vendors by issuing individual orders against BPAs. Previous GAO work has identified a number of issues with federal agencies' use of BPAs. See GAO, *Contract Management: Agencies Are Not Maximizing Opportunities for Competition or Savings under Blanket Purchase Agreements despite Significant Increase in Usage*, [GAO-09-792](#) (Washington, D.C.: Sept. 9, 2009).

³²Multiple award BPAs provide an opportunity to benefit from further competition when placing orders because vendors compete against other BPA vendors for a particular product.

³³VA has BPAs in place for a number of DME items, including continuous positive airway pressure (CPAP) machines and accessories, which are used to treat sleep problems.

³⁴In order to purchase the strips at the lower BPA price, all VA medical centers must sign a letter of participation and agree to purchase at least 90 percent of their test strips from this manufacturer.

³⁵Among the CBP DME items for which VA has national contracts are enteral nutrients, standard power wheelchairs, scooters, and related accessories.

³⁶The best-value determination, in addition to price, considers nonprice factors such as the past performance record of the bidder and whether the business is considered to be a small business.

Table 1: Summary of Three VA Contracting Mechanisms for DME Items

Contracting mechanism	Relationship to Federal Supply Schedule (FSS)	Number of awards	How the DME item price is determined	What VA medical centers can purchase
Federal Supply Schedule (FSS)	VA operates two schedules that include DME. ^a	No limit to the number of contract awards for a single item; the manufacturer must be able to provide an uninterrupted supply of the item.	Price is no greater than the manufacturer's most-favored commercial customer price.	Any item on FSS.
Blanket purchase agreement (BPA) ^b	Manufacturers that already participate in the FSS can compete to provide the item.	Generally, no more than three BPAs are awarded.	Price must be lower than the manufacturer's FSS price.	The BPA-included item from any one of the selected manufacturers.
National contract	Manufacturers do not have to participate in the FSS.	One contract award.	Price is determined through competitive bidding and a best-value determination that includes a trade-off of price and nonprice factors. ^c	The item from the winning manufacturer.

Source: GAO analysis based on the Federal Acquisition Regulation and interviews with VA officials.

Notes: VA medical centers are required to purchase items first from a national contract, second from a BPA, and third from an FSS. Only when items are not available from these sources can the Veterans Integrated Service Networks (VISN) or VA medical centers enter into local contracts with local manufacturers or suppliers. See 48 C.F.R. § 808.002 (2010).

^aThe GSA directs and manages the FSS program and has delegated authority to VA to operate FSS 65 (medical and surgical supplies) and FSS 66 (laboratory) which include DME items from manufacturers, distributors, and resellers that are contractually required to provide an uninterrupted supply of items.

^bBPAs are not contracts, but rather agreements between federal agencies and vendors with terms and conditions, including prices, for future use. When the need arises, agencies enter into contracts with vendors by issuing individual orders against BPAs.

^cThe best-value determination, in addition to price, considers nonprice factors such as the past performance record of the bidder and whether the business is considered to be a small business.

According to VA officials, VA may also use local contracts to obtain servicing for the DME items that the department purchases and are not available under the FSS program, BPAs, or national contracts. Each Veterans Integrated Service Network (VISN)³⁷ or VA medical center may competitively award these local service contracts to suppliers. Under these contracts, local DME suppliers may be responsible for delivering, setting up, and servicing DME items at beneficiaries' homes. For example, we reviewed one VISN's contract with a DME supplier to store, deliver, set up, and service DME items, such as hospital beds and wheelchairs, in that VISN's region.³⁸ This 1-year contract, awarded in 2007 with four 1-year option periods for renewal, had a value of approximately \$177,000.

VA has been able to negotiate for lower prices than Medicare for certain DME items. For example, in 2002, the HHS OIG reported that, compared to Medicare, VA's median prices for 15 selected DME items were 31 to 88 percent less than Medicare's fee schedule prices.³⁹ In

³⁷The VA healthcare system is organized into 21 regional networks, which are called VISNs. VA has delegated to VISNs decision-making authority regarding financing and service delivery for health care services, including most budget and management responsibilities concerning VA medical center operations.

³⁸This contract had a series of requirements for the DME supplier, including that the supplier respond to service calls within 48 hours under normal circumstances and to an emergency call within 8 hours.

³⁹Rehnquist, *Medicare Reimbursement for Medical Equipment and Supplies*.

addition, we recently reported that, had Medicare applied average VA payment rates for home oxygen equipment to estimated Medicare utilization, Medicare spending for this category could have been 38 percent lower in 2009.⁴⁰ We also found some examples where VA has been able to obtain lower prices than Medicare. (See table 2.) We found that VA’s national contract price in 2010 for a fully electric hospital bed was \$396.85, while Medicare’s payment for the same bed was \$1,638.38. According to VA officials, VA’s contract price does not include service components that are included in the Medicare payment, such as delivery and set up of these hospital beds, which could reduce the difference between VA and Medicare.

Table 2: Examples of Medicare Payments and VA National Contract Prices for Select DME Items, 2010

General item description	Item name	Medicare payments ^a	VA national contract price
Power Wheelchair	Jazzy Power Chair	\$3,855.50 ^b	\$2,004.98
Dry Pressure Mattress	CareGuard 101	187.97	103.01
Hospital Bed, Total Electric	Full-Electric Bed 5410IVC	1,638.38 ^b	396.85

Source: GAO analysis of VA and CMS data.

Notes: While these Medicare payments include servicing and delivery of DME items, these VA national contract prices may not include servicing and delivery.

^aThis Medicare payment is the average payment across states. Medicare has a separate fee schedule for each state based on the average charges that Medicare allowed in the state in 1986 and 1987.

^bThese two items are categorized by Medicare as capped rental DME. Capped rental DME is a category of DME for which Medicare contractors pay DME suppliers a fee schedule amount that is “capped” after a certain number of continuous months of rental by a Medicare beneficiary. We determined the Medicare payment by using the Medicare formula to calculate how much these items would cost if a beneficiary rents long enough to own them, which occurs after 13 months of rental. Therefore, the least expensive purchase price is equal to 13 months of rental payments.

Medicaid Programs

We examined the Michigan and New Hampshire Medicaid programs and found that these states also contract with manufacturers and select either a single or limited number of manufacturers of DME items through a competitive bidding process.⁴¹ This process enables these Medicaid programs to offer their purchasing power in exchange for price discounts on certain DME items requiring little or no servicing. These Medicaid programs pay manufacturers the negotiated contract rate for the DME item and may make a separate payment to DME suppliers for dispensing the item and for providing follow-up services. A Medicaid official from Michigan told us that limiting the number of manufacturers has allowed the state to achieve both administrative efficiencies and cost savings. For example, Michigan has a contract with a single manufacturer to provide eligible beneficiaries both eyeglass frames and lenses.⁴² According to program officials, Michigan’s program saves

⁴⁰GAO, *Medicare Home Oxygen: Refining Payment Methodology Has Potential to Lower Program and Beneficiary Spending*, GAO-11-56 (Washington, D.C.: Jan. 21, 2011). We also calculated that this difference between VA and Medicare costs would be reduced if we accounted for the assumed lower administrative costs for serving VA patients.

⁴¹Medicare and Medicaid do not always cover the same DME items.

⁴²According to the contract, the Michigan Department of Community Health has been authorized to contract for volume purchase of eyeglasses since 1979. Since 1980, 10 contracts have been awarded ranging in length from 18 months to 5 years. Medicare only covers eyeglass frames and lenses for beneficiaries who have had cataract surgery.

approximately \$73 per complete set of eyeglasses compared to retail chain prices.⁴³ Michigan also has a volume purchase contract with one distributor of incontinence supplies that enables Medicaid beneficiaries to receive incontinence supplies by mail.⁴⁴ Officials told us Michigan's program saves about \$50,000 to \$55,000 per month on incontinence supplies. For hearing aids, Michigan entered into a multistate contract with 13 manufacturers in 2009 along with Minnesota and Wisconsin, allowing all three states to leverage their buying power and purchase the hearing aids from any of the 13 manufacturers at reduced prices.⁴⁵

Officials from New Hampshire's Medicaid program told us that New Hampshire also contracted with a single DME distributor that was selected through a competitive process to obtain high-volume discounts for incontinence supplies. The distributor provides incontinence supplies from multiple manufacturers to either Medicaid DME suppliers or directly to beneficiaries by mail. All Medicaid suppliers must obtain incontinence supplies through this distributor at the contracted rate set by the state through competitive bidding unless there is a medical exception.⁴⁶ The state reimburses Medicaid suppliers for these products at the established Medicaid fee-for-service payment, which includes the contracted rate and an additional markup for administrative and dispensing costs. For Medicaid beneficiaries selecting the mail-order option, the distributor must provide incontinence supplies by mail at the same Medicaid fee-for-service payment paid to other Medicaid suppliers. According to the New Hampshire Medicaid officials, contracting with a single distributor has allowed New Hampshire to secure high-volume discounts, stabilize the product line to obtain quality control, and ease the administrative burden of dealing with multiple distributors. Officials also told us that contracting with a single distributor has produced program savings of more than 50 percent—with the state's average payment per unit for incontinence supplies down to \$0.42 from \$0.90.

Negotiations with Manufacturers through Purchasing Intermediaries

Some purchasers of DME leverage their buying power through purchasing intermediaries that negotiate favorable prices from manufacturers on their behalf. For example, we contacted one GPO and one TPA that negotiate with DME manufacturers on behalf of the purchasers in order to reduce their DME spending.

Group Purchasing Organization (GPO)

One GPO⁴⁷ we contacted acts as a purchasing intermediary by negotiating DME item discounts from manufacturers on behalf of its clients—private health insurers. The GPO

⁴³Michigan's Medicaid program obtains both eyeglass frames and lenses for about \$27 per complete set under its vision services contract. Michigan officials told us that chain vision suppliers' prices of approximately \$100 per set indicates the savings Michigan achieved for the same quality and styles available in retail optical stores.

⁴⁴According to state officials, Michigan has been contracting with distributors of incontinence supplies under its Medicaid Diaper and Incontinence Supply Program since 1997. Medicare does not include incontinence supplies in its DME benefit.

⁴⁵Medicare does not cover hearing aids or the exam for fitting hearing aids.

⁴⁶New Hampshire's Medicaid program grants a medical necessity exception—for example, if a beneficiary is obese or has a specific skin condition—to the requirement that suppliers obtain only those products on the state's approved list of incontinence supplies from the distributor. The medical necessity exception also applies to beneficiaries who receive supplies directly from the distributor.

⁴⁷A GPO official told us that the entity also describes itself as a durable medical equipment benefits manager. In addition to DME, the GPO also manages orthotic and prosthetic services.

maintains a network of DME suppliers for these insurers and leverages the network's purchasing power to obtain manufacturer discounts, thus lowering the insurers' DME spending. For each major DME product category, the GPO typically contracts with one competitively selected preferred manufacturer, although items are also available at lesser discounts from approximately another 20 to 25 manufacturers. According to a GPO official, manufacturers give the GPO DME item discounts in exchange for access to its large supplier network and may give additional discounts depending on supplier purchasing volume. Once contracts are established with DME manufacturers, the GPO establishes a discounted fee schedule for each insurer by adding estimated DME item service costs⁴⁸ to an average manufacturer price for that item.⁴⁹ Suppliers in the network procure DME items directly from these manufacturers at the discounted rates and submit claims for payment to the GPO.⁵⁰ The GPO—acting as a benefit manager for the insurers—then makes a fee schedule payment to suppliers for providing the DME items to beneficiaries.⁵¹ Suppliers that join the GPO's network gain access to these high-volume discounts in exchange for accepting the reduced payments.⁵² A GPO official told us that in addition to a discounted DME fee schedule, the GPO provides utilization-management services for its clients—such as requiring preauthorization for certain DME items—and achieves additional administrative cost savings. The official also told us that the GPO's fee schedule rates are about 70 percent of Medicare fee schedule rates, saving insurers between 20 percent and 30 percent compared to Medicare—an amount roughly equivalent to CMS's projected CBP round 1 rebid savings of 32 percent. According to the official, the savings the GPO is able to achieve for insurers varies by product category.

Third-Party Administrator (TPA)

Some Medicaid programs, including those that use both managed care and fee-for-service (FFS) plans,⁵³ use a TPA to negotiate with certain manufacturers of diabetic supplies on their behalf before they contract with these manufacturers.⁵⁴ A TPA official told us that these programs operate a rebate program by having the TPA that is already operating their pharmacy benefits negotiate rebate amounts with manufacturers of diabetic supplies. This is similar to Medicaid's supplemental rebate program⁵⁵ for preferred drugs—where the TPA

⁴⁸The profit margin points—reflecting DME item service costs—that the GPO adds to the average item price in calculating its fee schedule would be lower for items requiring little or no servicing than for items requiring the supplier to deliver the item to the beneficiary's home, educate the beneficiary about its use, and intermittently service the item.

⁴⁹To set average prices for each DME item on the fee schedule, the GPO collects information on the average cost of standard and basic DME items from three to four leading manufacturers.

⁵⁰A GPO official told us that in the event a network supplier is able to purchase DME at a lower cost than under a GPO contract, they are free to do so.

⁵¹The GPO we interviewed is also accredited for utilization management and claims management by the Utilization Review Accreditation Committee.

⁵²When selecting DME suppliers for its network, the GPO we interviewed checks a supplier's accreditation status to ensure the supplier is enrolled in Medicare and also checks to make sure the supplier has been in business for a certain number of years.

⁵³States generally cover Medicaid services for beneficiaries through two major payment approaches: FFS, in which the Medicaid program directly pays suppliers for care provided to beneficiaries, and capitated managed care, in which the state prospectively pays managed care organizations a fixed monthly fee per enrollee to provide or arrange for most health care services.

⁵⁴Diabetic supplies include blood-glucose monitors and test strips.

⁵⁵Medicaid drug supplemental rebates are in addition to rebates already received under the Medicaid national drug agreement.

negotiates supplemental rebates for participating states from pharmaceutical manufacturers based on their placement on a state's preferred drug list (PDL).⁵⁶ According to TPA and Medicaid officials, states determine the rebate amounts based on the number of manufacturers they select to be on their preferred list. For example, the rebate is higher if a state has only one manufacturer instead of three manufacturers on its preferred list because it provides a larger market share to that manufacturer. However, states may select more than one manufacturer to provide beneficiaries with greater item choice. Officials from the rebate program said that diabetic supplies work for this approach because they can be easily substituted—one manufacturer's blood-glucose monitor can be interchanged with that of another manufacturer.⁵⁷ Medicaid programs file rebate claims quarterly with the DME manufacturer based on the utilization of the specific manufacturer's products.

CMS Could Face a Number of Issues If Required to Implement a Medicare DME Competitive Bidding Program at the Manufacturer-Level

CMS could face several issues regarding competitive bidding if it developed a DME manufacturer-level competitive bidding program. Some of these issues would be similar to those CMS faced in implementing CBP while others would be specific to implementing a manufacturer-level program.

Several Issues CMS Faced When Implementing CBP Could Again Be Issues for a Medicare Manufacturer-Level Competitive Bidding Program

If CMS is given broad authority to implement a manufacturer-level competitive bidding program, it would face issues similar to those it addressed in implementing CBP. These program issues are, among others, which DME items to include, the geographic level on which to operate, the potential effect on small businesses, the range of beneficiary choice, and the implementation time including program demonstrations.

DME items to include. For CBP, CMS chose the DME items to include—generally those with the highest utilization and cost with the largest savings potential—organized by product category, which is a grouping of related items used to treat a similar medical condition.⁵⁸ DME suppliers must provide all DME items in a CBP product category.⁵⁹ If a manufacturer-level program is implemented, CMS could face the issue of whether to conduct the program at the item level because manufacturers do not always produce all items within a Medicare-covered product category.⁶⁰ Also, some experts and stakeholders we interviewed suggested that commodity-type items—items considered to be standard and interchangeable—may be

⁵⁶To contain prescription drug program costs, Medicaid's PDL programs encourage physicians to prescribe drugs on the list, which are deemed functionally safe and equivalent to more expensive drugs in the same drug class. Nonpreferred drugs are available through prior medical authorization.

⁵⁷There are specialized blood-glucose monitors, such as voice synthesized monitors for the visually impaired that are exempted from this program.

⁵⁸CMS chose the CBP items to include from (1) DME in four categories—inexpensive or routinely purchased items, items requiring frequent and substantial servicing, oxygen and oxygen equipment, and other capped rental DME items; (2) supplies necessary for the effective use of DME; (3) enteral nutrients, equipment, and supplies; and (4) off-the-shelf orthotics.

⁵⁹In CBP, winning suppliers must provide all items in the product category for which they are awarded a contract, and must provide the same items to Medicare beneficiaries and non-Medicare customers.

⁶⁰While CMS also chose to begin CBP by including high-cost and high-volume DME product categories, these same product categories may not provide the same savings under a manufacturer-level program, if the item's cost is a small portion of the total Medicare payment.

preferable to include in a manufacturer-level program. Examples of commodity-type items include diabetic monitors,⁶¹ walkers, and canes. A CMS official told us that commodity items that do not need to be delivered by a supplier to a beneficiary's home, or replacement items such as diabetic supplies that can be mailed from a manufacturer to a beneficiary, could be considered. Furthermore, industry stakeholders also told us that CMS would need to consider the number of major manufacturers producing a particular item in the market. For example, if one manufacturer dominates the market for a particular item, that manufacturer may not have sufficient incentive to discount its prices if it believes Medicare must include its item to meet beneficiary demand.

Geographic level to operate. For CBP, CMS determined which of the largest MSAs to include as the CBAs for the competitive bidding rounds.⁶² CMS could consider at what geographic level—for example, by region or nationally—to operate a manufacturer-level program. It may be possible for CMS to implement a manufacturer-level competitive bidding program on a national basis, which would limit the number of bid competitions needed as compared to CBP. DME manufacturers generally use distributors to provide their items to DME suppliers throughout the country, which could allow for national competitions. An industry stakeholder told us, however, that some DME manufacturers only provide their items locally. If these local manufacturers are to be included, a more regionalized competitive bidding approach may be needed.

Small-business consideration. To protect small DME suppliers in CBP, CMS established a target that at least 30 percent of the winning suppliers be small suppliers, and also allowed small suppliers to bid together as networks under certain conditions.⁶³ For a manufacturer-level program, CMS could consider whether to allow for special consideration of smaller manufacturers. A trade association told us that there are small DME manufacturers, including specialty manufacturers that may produce only one item, such as wheelchair seat cushions, and therefore may not be able to compete with larger, national DME manufacturers that produce a range of items under a Medicare competitive bidding program.

Range of beneficiary choice. When developing CBP, CMS determined it would award contracts to enough suppliers to both meet projected demand and to ensure that beneficiaries would have a choice of suppliers. For CBP, CMS established a minimum of two winning suppliers in each product category for each CBA and sought to have at least five suppliers in each category.⁶⁴ For a manufacturer-level program, CMS could consider the trade-off between limiting the number of manufacturers to achieve more savings and ensuring access to a wide array of DME items for Medicare beneficiaries. As demonstrated by other DME purchasing programs, leveraging purchasing power by limiting the number of

⁶¹The CBP round 1 rebid includes a mail-order diabetic supplies product category that includes replacement supplies. Mail-order for the round 1 rebid is defined as items that are ordered remotely, for example, by phone or e-mail, and that are delivered to a beneficiary's residence by a common carrier.

⁶²MMA required that CBP first be implemented in 10 of the largest MSAs, and that CMS would choose which MSAs would be used as CBAs. MIPPA designated the round 1 rebid CBAs. PPACA increased the number of MSAs for round 2. CMS also has discretion to operate CBP regionally or nationally for items furnished by mail.

⁶³For CBP, a network is defined as a group of between 2 to 20 small suppliers that meet certain requirements, including that they cannot independently furnish all items in the product category for which the network is submitting a bid to beneficiaries throughout the entire CBA, and that they collectively submit a bid as a single entity.

⁶⁴When there are not five suppliers, at least two suppliers are selected. The mail-order diabetic supply product category in regional and national CBAs was exempted from the five-supplier minimum.

manufacturers participating in a program generally allows for greater cost savings. The more limited the participation would be for manufacturers in a manufacturer-level program, the more savings CMS could likely achieve as manufacturers may be willing to provide greater discounts in return for a greater Medicare market share. However, greater exclusivity would limit the array of DME items that Medicare beneficiaries would be allowed to choose. Additionally, CMS could consider including a process to allow beneficiaries to have DME items not produced or carried by contracted manufacturers in cases of medical necessity. As required by federal law,⁶⁵ CMS has a similar medical necessity process for CBP—referred to as the physician authorization process.

Implementation and demonstrations. CMS might consider whether demonstrations would be necessary to test a manufacturer-level program and the length of time and associated costs needed to develop a program. For CBP, CMS began work in 1995 and conducted three supplier-level program demonstrations over 4 years—1999 through 2002—to test how the program’s design would work; the demonstrations were subsequently evaluated. CMS’s first attempt to implement CBP on a nondemonstration basis—round 1—ended when MIPPA, enacted in July 2008, terminated the CBP contracts awarded during that round. Contracts awarded as a result of CBP’s round 1 rebid began operating in January 2011.

Table 3 summarizes the key issues CMS could face if it were required to implement a manufacturer-level competitive bidding program and how these issues were resolved in CBP.

⁶⁵See 42 U.S.C. § 1395w-3(a)(5)(A).

Table 3: Comparison of Key Issues in Supplier-Level Competitive Bidding Program and a Possible Manufacturer-Level Competitive Bidding Program

Issue	Supplier-level competitive bidding program (CBP)	Possible manufacturer-level competitive bidding program
DME items to include	<p>CBP began with nine product categories^a generally including high-utilization and high-cost items with the potential for the most Medicare savings.</p> <p>CBP winning suppliers must provide all items within a product category.</p>	<p>High-utilization and high-cost items may not provide the most savings if the item cost is a small proportion of total Medicare payment. Commodity items may be preferable.</p> <p>Manufacturers may need to bid by item rather than product category because one manufacturer may not be able to provide all items within a product category.</p>
Geographic level to operate	<p>CBP was phased in beginning with 9 competitive bidding areas (CBA); competition is to occur in 91 of the largest MSAs in round 2.</p>	<p>May be possible to conduct a program at the national level.</p>
Small-business consideration	<p>CBP has a target that a minimum of 30 percent of winning suppliers be small suppliers. Small suppliers can bid together as networks under certain conditions.</p>	<p>Small specialty manufacturers may find it difficult to compete against larger manufacturers.</p>
Range of beneficiary choice	<p>CBP tried to have five winning suppliers—a minimum of at least two—for each product category in each CBA to provide Medicare beneficiaries with a choice of suppliers.</p>	<p>Limiting the number of winning manufacturers may limit the range of item models available to Medicare beneficiaries.</p>
Implementation and demonstrations	<p>Work began on a supplier-level competitive bidding demonstration in 1995. CBP's round 1 rebid was effective January 1, 2011.</p>	<p>Time would be needed to possibly conduct demonstrations, and to establish a new manufacturer-level competitive bidding program.</p>

Source: GAO analysis.

^aThe nine product categories were: oxygen, oxygen equipment, and supplies; standard power wheelchairs, scooters, and related accessories; complex rehabilitative power wheelchairs and related accessories (group 2—power wheelchairs with power options); mail-order diabetic supplies; enteral nutrition, equipment, and supplies; continuous positive airway pressure devices, respiratory assist devices, and related supplies and accessories; hospital beds and related accessories; walkers and related accessories; and support services (group 2 mattresses and overlays) in only one CBA.

Additional Issues CMS Could Face with a Manufacturer-Level Competitive Bidding Program

Depending on how a manufacturer-level competitive bidding program might be designed, CMS could face issues other than those it faced for CBP. These issues include establishing a more direct relationship between CMS and DME manufacturers, changing Medicare's DME payment system, and changing the DME coding system used for billing.

CMS relationship with DME manufacturers. CMS currently has a minimal relationship with DME manufacturers unless they are also Medicare suppliers.⁶⁶ For example, DME manufacturers that are not Medicare suppliers submit their products to a CMS contractor for HCPCS code assignment, which is needed for suppliers to bill Medicare and other health

⁶⁶Manufacturers that make DME items that meet the definition of a device are subject to regulation by the Food and Drug Administration (FDA). FDA defines a home health care medical device as any product or equipment that is used in the home environment by people who are ill or have disabilities including, for example, ventilators and nebulizers, wheelchairs, infusion pumps, and blood-glucose meters. For more information, see GAO, *Medical Devices: Shortcomings in FDA's Premarket Review, Postmarket Surveillance, and Inspections of Device Manufacturing Establishments*, [GAO-09-370T](#) (Washington, D.C.: June 18, 2009).

insurers. DME manufacturers generally do not have systems to submit claims to Medicare or other health insurers. DME suppliers must meet a set of Medicare enrollment requirements, be accredited, and obtain a unique supplier number to be able to bill Medicare.⁶⁷ For CBP, CMS had additional regulatory requirements that suppliers had to meet, for example, having all required state licenses for items and services in the bid. Suppliers also had to submit financial documentation, such as a balance sheet and a credit rating score with their bids. Once participating in Medicare, DME suppliers have systems and standards for billing Medicare.

The extent of the relationship needed between CMS and DME manufacturers would depend on how a manufacturer-level competitive bidding program might be designed. If the program were designed like the VA or Medicaid programs, under which a specific manufacturer or set of manufacturers is chosen to exclusively provide DME items to beneficiaries, then CMS could consider developing product specifications that manufacturers would need to meet and create committees to review the DME items that manufacturers propose to provide through their bids. VA, for instance, includes product requirements in its requests for bids for BPAs and national contracts, and has clinical staff that review DME samples during the bidding process. CMS also could consider the need to accredit DME manufacturers, as it does DME suppliers, or to review DME manufacturer financial information, as it does for DME suppliers in CBP.

Changes to DME payment system. If CMS implemented a manufacturer-level competitive bidding program that required separate payments for the item and the supplier's service, a new payment system for suppliers might be needed to account for the service component associated with each DME item that requires servicing. Currently, the Medicare payment to the DME supplier generally includes the cost of both the items and services provided to beneficiaries. Under some other payers' competitive bidding programs, the service component is separated from the payment for the DME item. This is the case, for instance, with items provided by the VA, such as hospital beds, that require local service contracts for delivery and setup in the patient's home, and for the hearing aids provided by a Medicaid program that includes separate dispensing fees for the hearing-aid supplier. The service component payment would likely need to vary by DME item because some DME items, such as home oxygen, require more service by a DME supplier than others. According to a CMS official, previous attempts by the agency to separate the item cost component and the service cost component for DME items have not been successful. During the 1990s, Congress required the agency to examine how a split payment for DME, which would include one payment for the cost of an item and one payment for the servicing associated with an item, would work. According to CMS officials, DME suppliers would not provide the agency with the information necessary to respond to the mandate.

⁶⁷To ensure suppliers meet these requirements, suppliers must be accredited by a CMS-deemed accrediting organization. CMS published a final rule in the *Federal Register*, effective September 27, 2010, to clarify and expand the existing enrollment requirements suppliers must be in compliance with to obtain and retain their Medicare billing privileges; there are 30 supplier standards, including, for example, that the supplier meets all state licensure and regulatory requirements to furnish certain DME items or services. 75 Fed. Reg. 52,629 (Aug. 27, 2010) (amending 42 C.F.R. § 424.57(c)). As of October 2009, suppliers were required to obtain and submit a surety bond in the amount of at least \$50,000. See 42 U.S.C. § 1395m(a)(16)(B). A surety bond is issued by an entity guaranteeing that erroneous Medicare payments that result from a supplier's fraudulent or abusive billing practices can be recouped by means of the bond.

However, CMS was able to establish a separate servicing payment in one non-DME program—the Competitive Acquisition Program for Part B drugs, which was in effect from July 1, 2006, through December 31, 2008.⁶⁸ Under this program, CMS competitively contracted with a specialty pharmacy to supply a designated basket of Part B drugs to physicians, whose participation in the program was voluntary. The specialty pharmacy billed Medicare for the predetermined cost of the drug—which was determined as part of the bid process—and the physician billed Medicare for the administration of the drug.

Changes to DME coding system. If CMS implemented a manufacturer-level competitive bidding program that required the identification of the manufacturer of the item provided, like the existing Medicaid rebate programs for diabetic supplies, the coding system for DME might need to be changed to include manufacturer information. Under a rebate program, the amount that the manufacturer pays in the form of the rebate is determined by the number of the manufacturer’s items that are purchased, which means claims need to identify the manufacturer. HCPCS, which is currently used by Medicare to code DME items, does not allow for identification of the manufacturer of a DME item or the model of an item being provided to the beneficiary. A DME administrative contractor official also noted there are limitations to the number of fields on the current Medicare claim form that could also be a problem due to the number of different models that exist within the DME industry.⁶⁹ As an example, according to the CMS contractor that assigns HCPCS codes to DME items, 506 different products produced by 55 different manufacturers have been assigned the HCPCS code E0143, which is for folding walkers with wheels. CMS officials told us another way to accomplish the same goal would be to modify the DME claim form to identify a product’s manufacturer.

We provided a draft of this report for comment to HHS. HHS provided written comments, which are summarized below, and reprinted in enclosure III. HHS also provided technical comments that we incorporated as appropriate.

In its comments, HHS stated that the report provides useful information about other ways the Medicare program, and its beneficiaries, can obtain better value for DMEPOS items and services. HHS also noted that the report demonstrates how other payers use various acquisition strategies to receive better prices than Medicare for the same DMEPOS items and services, despite the fact that Medicare often pays for a larger quantity of items and services. Given Medicare’s scarce resources, the department noted the importance of considering various ways to leverage Medicare’s buying power to achieve savings.

As we agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution of it until 30 days from its date. We are sending copies of this report to the Secretary of Health and Human Services. The report will also be available at no charge on our Web site at <http://www.gao.gov>.

⁶⁸Medicare covers drugs typically provided in a physician’s office under Part B. Section 303(d)(2) of MMA required CMS to implement the Competitive Acquisition Program.

⁶⁹Under a contract with CMS, DME administrative contractors process and pay Medicare DME claims.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or kingk@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in enclosure IV.

A handwritten signature in black ink that reads "Kathleen M. King". The signature is written in a cursive style with a large initial 'K' and a long, sweeping tail on the 'g'.

Kathleen M. King
Director, Health Care

Enclosures – 4

**Six Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)
Medicare Fee Schedule Categories**

Fee schedule category	DMEPOS example	Medicare payment
Inexpensive or other routinely purchased items.	Inexpensive equipment that has a purchase price that does not exceed \$150. Other routinely purchased equipment that is bought—rather than rented—at least 75 percent of the time.	Depending on the beneficiary’s choice, equipment may be paid as a lump-sum purchase of new or used equipment, or as rental equipment. The total payment amount may not exceed the actual charge or the fee schedule for a purchase.
Items requiring frequent and substantial servicing.	Ventilators and intermittent positive pressure breathing machines, and continuous passive motion machines.	Equipment is only paid on a rental basis. Payments are based on the monthly fee schedule amounts until the beneficiary’s medical necessity ends. No payments are made for the purchase of equipment, for maintenance and servicing, or for replacement of items. Supplies and accessories are not allowed separately.
Certain customized items.	Items uniquely constructed or substantially modified for a specific beneficiary prescribed by a physician.	The coverage and allowable amounts for custom equipment is decided by individual evaluation based on medical indications and is paid as a lump-sum payment.
Other prosthetic and orthotic devices.	All prosthetic and orthotic devices except items requiring frequent and substantial servicing, certain customized items, parenteral and enteral nutritional supplies and equipment, and intraocular lenses.	Payment is on a lump-sum purchase basis.
Capped rental items.	Electric wheelchairs.	Payment is on a monthly rental basis not to exceed a 13-month period of continuous use for rentals beginning on or after January 1, 2006. ^a After the 13th month, the equipment is owned by the beneficiary.
Oxygen and oxygen equipment.	Stationary and portable oxygen system.	Payment for oxygen equipment is on a rental basis only. The total number of continuous rental months is capped at 36 months. The costs of oxygen contents, maintenance, and repairs are bundled into the rental payment. After 36 months, rental payments cease but Medicare will pay separately for oxygen contents and nonroutine maintenance.

Source: GAO analysis of Centers for Medicare & Medicaid Services data.

Notes: The data are from the Medicare claims processing manual and DME Medicare Administrative Contractor supplier manuals.

^aPrior to January 1, 2006, the monthly rentals are not to exceed a period of continuous use of 15 months or on a purchase option basis not to exceed a period of continuous use of 13 months.

Summary of Durable Medical Equipment (DME) Purchasing Approaches

Purchasing approaches		DME Items purchased	How prices are set	How manufacturers are selected
Contracting with manufacturers	Department of Veterans Affairs (VA) federal supply schedule (FSS)	Any item on FSS	VA contracts directly with manufacturers and price is no greater than the manufacturer's most-favored commercial customer price.	Any manufacturer offering VA their best item price.
	VA blanket purchase agreements (BPA) ^a	<ul style="list-style-type: none"> Continuous positive airway pressure (CPAP), Bi-level positive airway pressure (BPAP), Auto positive airway pressure (APAP) equipment^b Masks, headgear, filters^b 	VA enters into agreements directly with manufacturers listed on the FSS, and prices must be lower than the manufacturer's FSS price for that item.	VA enters into agreements with one manufacturer in a single award BPA and with more than one manufacturer in a multiple award BPA.
	VA national contracts	<ul style="list-style-type: none"> Enteral nutrients^b Standard power wheelchairs, scooters, and related accessories^b Hospital beds, related accessories^b 	VA contracts with one manufacturer and price is determined through best-value determinations, which include a trade-off of price and nonprice factors.	Typically a single manufacturer is chosen based on the lowest bid for the item through a competitive bidding process.
	Medicaid programs	<ul style="list-style-type: none"> Incontinence supplies Hearing aids Eyeglasses 	Some Medicaid programs directly contract with one or a limited number of manufacturers, and prices are set based on bids submitted by the manufacturers.	Medicaid programs contract with one or a limited number of manufacturers.
Negotiations through purchasing intermediaries	Group Purchasing Organization (GPO)	All covered DME	One GPO contracts with manufacturers on behalf of private insurers to establish a discounted fee schedule for its national network of suppliers, and prices are set by the GPO, which calculates service costs that are added onto an average manufacturer price for that item.	GPO selects manufacturers to provide DME to its network of suppliers.

Enclosure II

Purchasing approaches	DME Items purchased	How prices are set	How manufacturers are selected
Third-Party Administrator (TPA)	Diabetic supplies	One TPA operates a rebate program on behalf of certain state Medicaid programs, and prices are set based on bids submitted to the TPA by manufacturers.	States select one or a limited number of manufacturers to provide diabetic supplies based on a list provided by the TPA.

Source: GAO's analysis of information from VA, Medicaid programs, and purchasing intermediaries.

^aBPAs are not contracts, but rather agreements between federal agencies and vendors with terms and conditions, including prices, for future use. When the need arises, agencies enter into contracts by issuing individual orders against BPAs.

^bExamples include only items in the competitive bidding program's round 1 rebid product categories.

Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

APR 29 2011

Kathleen King
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Ms. King:

Attached are comments on the U.S. Government Accountability Office's (GAO) draft correspondence entitled: "Medicare: Issues for Manufacturer-level Competitive Bidding for Durable Medical Equipment" (GAO-11-337R).

The Department appreciates the opportunity to review this correspondence before its publication.

Sincerely,

A handwritten signature in cursive script that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT CORRESPONDENCE ENTITLED, "MEDICARE: ISSUES FOR MANUFACTURER-LEVEL COMPETITIVE BIDDING FOR DURABLE MEDICAL EQUIPMENT" (GAO-11-337R)

The Department appreciates the opportunity to review and comment on this draft correspondence.

This exploration of manufacturer-level competitive bidding provides useful information about other ways the Medicare program, and its beneficiaries, can obtain better value for quality durable medical equipment prosthetics, orthotics, and supplies (DMEPOS) items and services. It is important to consider the various ways that Medicare's buying power could be used to leverage savings for overpriced DMEPOS items and preserve scarce Medicare resources.

This correspondence demonstrates how other payers employ various acquisition strategies to receive better prices than Medicare for the same DMEPOS items and services, despite the fact that Medicare, in many cases, pays for a considerably higher quantity of items and services than other payers. In general, there are a number of important issues identified in this report that might need to be addressed if manufacturer-level bidding is considered as an alternative for reforming how Medicare items and services are acquired. In particular, GAO points out that the idea of manufacturer-level bidding might have more potential for commodity items such as diabetic test strips that can be shipped directly to the beneficiary without an extensive local distribution network and without in home equipment set up requirements. However, the possibility of bidding at the manufacturer level for other items should not be dismissed and could have merit.

Enclosure IV

GAO Contact and Staff Acknowledgments

Contact

Kathleen M. King at (202) 512-7114 or kingk@gao.gov

Staff Acknowledgments

In addition to the contact named above, key contributors to this report were: Martin T. Gahart, Assistant Director; Lori Achman; Krister Friday; Thomas Han; Erica Pereira; Hemi Tewarson; and Opal Winebrenner.

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