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Report to Congressional Committees

October 2004

MEDICARE

Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs

GAO-05-72

October 2004

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Highlights

Highlights of GAO-05-72, a report to congressional committees

MEDICARE

Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs

Why GAO Did This Study

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) revised the payment formula for most of the outpatient drugs, including inhalation therapy drugs, covered under Medicare part B. Under the revised formula, effective 2005, Medicare's payment is intended to be closer to acquisition costs. The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, also pays suppliers of inhalation therapy drugs a $5 per patient per month dispensing fee. Suppliers have raised concerns that once drug payments are closer to acquisition costs, they will no longer be able to use overpayments on drugs to subsidize dispensing costs, which they state are higher than $5. As directed by MMA, GAO (1) examined suppliers' acquisition costs of inhalation therapy drugs and (2) identified costs to suppliers of dispensing inhalation therapy drugs to Medicare beneficiaries.

What GAO Recommends

GAO recommends that the Administrator of CMS evaluate the costs of dispensing inhalation therapy drugs and modify the dispensing fee, if warranted, to ensure that the fee appropriately accounts for the costs necessary to dispense the drugs. CMS agreed with GAO's recommendation.

www.gao.gov/cgi-bin/getrpt?GAO-05-72.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Laura A. Dummit at (202) 512-7119.

What GAO Found

Using cost data obtained from 12 inhalation therapy suppliers that accounted for more than 42 percent of 2003 Medicare inhalation therapy payments, GAO found that 2003 acquisition costs for the three inhalation therapy drugs representing approximately 98 percent of Medicare inhalation therapy drug expenditures varied widely. For example, per unit acquisition costs for ipratropium bromide, the inhalation therapy drug with the highest Medicare expenditures, ranged from $0.23 to $0.64. Although costs varied, they were not always lower for the 4 largest suppliers. The lowest acquisition cost for ipratropium bromide was obtained by one of the small suppliers, and the highest by one of the large suppliers. GAO estimated that the 2003 Medicare payment rate per patient, per month was between $119 to $129 higher than suppliers' acquisition costs for a typical monthly supply of albuterol sulfate and between $162 to $187 higher for a typical monthly supply of ipratropium bromide.

GAO estimated 2003 per patient monthly dispensing costs of $7 to $204 for the 12 inhalation therapy suppliers, which included patient care costs, such as pharmacy and shipping, and administrative and overhead costs, such as billing. Large suppliers did not necessarily have lower dispensing costs. Because Medicare payments for drugs have been much higher than suppliers' acquisition costs, suppliers indicated they were able to provide services that benefited both beneficiaries and their physicians, a fact that raises questions about the services necessary to dispense inhalation therapy drugs. For example, several suppliers reported that they incur substantial costs to ship drugs overnight to beneficiaries; most did so on an as-needed basis, although one did so routinely. All suppliers in GAO's sample made phone calls to beneficiaries to ask them if they needed medication refills, to coordinate a refill delivery, and to check on the beneficiaries' compliance with their prescribed drug regimens. Most suppliers made these calls on a monthly basis, but one reported that it did so twice a month.

Contents

Abbreviations

AAHomecare	American Association for Homecare
ASP	average sales price
AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
DME	durable medical equipment
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
VA	Department of Veterans Affairs

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Accountability * Integrity * Reliability

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

October 12, 2004

Congressional Committees

In response to substantial Medicare overpayments for outpatient drugs,[1] Congress enacted a revised payment formula in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) beginning January 1, 2005.[2] For the limited number of drugs covered under part B of the Medicare program,[3] payments had been substantially higher than acquisition costs generally available to the suppliers of the drugs. Under the revised payment formula, Medicare's payment is intended to be much closer to acquisition costs.

Medicare-covered outpatient drugs include those that are an integral and necessary part of covered durable medical equipment (DME), such as those delivered through nebulizers for inhalation therapy.[4] The Centers for Medicare & Medicaid Services (CMS), the agency that administers Medicare, makes three separate payments for inhalation therapy. Inhalation therapy drug suppliers, which are required to be licensed pharmacies,[5] receive a payment for the drug as well as a per patient monthly dispensing fee of $5 for costs such as pharmacy, shipping, and billing. In addition, Medicare pays for the nebulizer and the supplies associated with it. Suppliers have stated that payments for inhalation therapy drugs, which have been higher than the prices suppliers paid to purchase them, have helped subsidize monthly dispensing costs. They have raised concerns that once drug payments are closer to acquisition costs, they will no longer be able to cover their current dispensing costs.

[1]H.R. Conf. Rep. No. 108-391, at 582-84 (2003), reprinted in 2003 U.S.C.C.A.N. 1808, 1950-51.

[2]Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2233-55 (2003).

[3]Medicare part B provides coverage for certain physician, outpatient hospital, laboratory, and other services to beneficiaries who pay monthly premiums.

[4]A nebulizer is a device driven by a compressed air machine. It allows the patient to take medication in the form of a mist (wet aerosol) more directly into the lungs.

[5]42 C.F.R. § 424.57(b)(4) (2003).

MMA directed us to study the adequacy of Medicare's payment for inhalation therapy.[6] Specifically, we (1) examined suppliers' acquisition costs of inhalation therapy drugs and (2) identified costs to suppliers of dispensing inhalation therapy drugs to Medicare beneficiaries.

To address these issues, we analyzed 2003 cost and utilization data collected from 12 inhalation therapy suppliers. We assessed the reliability of the supplier-reported data by comparing certain data elements for consistency with information from Securities and Exchange Commission annual reports for publicly traded companies, data from a similar 2003 industry study, and the 2003 Medicare DME claims, the latest claims data available. We found these data suitable for our purposes. Our sample of 12 suppliers accounted for more than 42 percent of Medicare inhalation therapy payments in 2003. From the supplier-reported cost data, we calculated per unit acquisition costs (net of rebates and discounts) for the three inhalation therapy drugs most frequently billed to Medicare, representing approximately 98 percent of Medicare inhalation therapy drug expenditures in 2003. We also calculated per patient monthly dispensing costs, which include patient care costs, such as pharmacy and shipping, and administrative and overhead costs, such as billing. We reported the range of these costs across all 12 suppliers and separately for the 4 largest suppliers in our sample, each of which had payments accounting for at least 3 percent of all Medicare inhalation therapy payments in 2003, and all other suppliers in our sample, which we refer to as small suppliers.

We interviewed officials from CMS; three DME regional carriers, the contractors responsible for processing and paying DME and inhalation therapy drug claims; and the Department of Veterans Affairs (VA) to gather comparative information on how VA pays for inhalation therapy. We also interviewed officials from an industry association representing suppliers; two patient advocacy organizations; two associations of health care professionals who care for inhalation therapy patients; and two manufacturers and a wholesaler of inhalation therapy drugs. These interviewees helped us identify 20 inhalation therapy suppliers representing national, regional, and local homecare and mail-order pharmacies of various sizes and geographic locations. Appendix I contains

[6]Pub. L. No. 108-173, § 305(b), 117 Stat. 2066, 2255-56 (2003). MMA specified that this report was to be issued no later than 1 year after the date of enactment, December 8, 2003. This report may inform CMS as it is considering Medicare payments for inhalation therapy drug suppliers.

a more complete description of our methodology. We conducted our work from May through October 2004 in accordance with generally accepted government auditing standards.

Background

Inhalation therapy consists of drugs, including bronchodialators such as albuterol sulfate, taken through a nebulizer to alleviate severe respiratory problems. In the Medicare population, this therapy is primarily used to treat chronic obstructive pulmonary disease, which includes diseases such as asthma, emphysema, and chronic bronchitis. Once beneficiaries begin receiving inhalation therapy, they are likely to receive it for the remainder of their lives.

Inhalation therapy drugs are covered by Medicare because the nebulizer, which is covered as DME, is only useful in conjunction with the drugs. Under the DME benefit, Medicare payment for nebulizers covers the cost to suppliers of purchasing the equipment, delivering it to the beneficiary, and ensuring that the beneficiary knows how to use and care for the equipment. Medicare regulations specify that DME suppliers must document that they or another qualified party provided the beneficiary with the necessary information and instructions on using the equipment, but suppliers do not have to provide that education themselves.[7] DME suppliers receive no additional payment if they provide the patient education; however, physicians can bill Medicare if they or their staff provide the patient training.

MMA changed Medicare's payment method beginning in 2005 for most drugs covered under part B, including inhalation therapy drugs, from one based on the average wholesale price (AWP)[8] to one based primarily on the average sales price (ASP)[9] plus 6 percent. This new payment method is expected to result in payment rates that are closer to drug acquisition

[7]42 C.F.R. § 424.57(c)(12) (2003).

[8]Often described as a "sticker price" or "list price," AWP is the average price that a manufacturer suggests wholesalers charge pharmacies.

[9]ASP is defined for each drug as a manufacturer's sales to all purchasers in a given quarter, net of discounts and rebates and excluding certain government and other purchasers, divided by the total number of units of the drug sold by the manufacturer in that quarter. Pub. L. No. 108-173, § 303(c), 117 Stat. 2066, 2240-41 (2003).

costs.[10] The change was in response to substantial Medicare overpayments for outpatient drugs. For example, in a 2001 report, we found that the widely available acquisition prices for the two most common inhalation therapy drugs were 15 and 22 percent of AWP,[11] while payment was 95 percent of AWP.[12]

Although most Medicare-covered outpatient drugs are provided in a physician's office, inhalation therapy drugs are different. A physician prescribes the drugs, but beneficiaries receive the drugs from inhalation therapy drug suppliers, such as homecare companies and mail-order and retail pharmacies. The four largest suppliers are for-profit homecare companies that accounted for almost 41 percent of Medicare inhalation therapy payments in 2003. In addition to supplying the drugs, most companies also provide beneficiaries with a nebulizer and other related supplies.

Under the AWP-based payment system, suppliers received drug payments that were substantially higher than their acquisition costs. Suppliers indicated that they used these excess payments to offer services that benefited both beneficiaries and their physicians, such as shipping the drugs overnight, making monthly phone calls to remind beneficiaries to refill their prescriptions, and operating 24-hour hotlines to respond to beneficiary questions.[13] Several inhalation therapy suppliers and two physician organizations we spoke with indicated that suppliers also used excess payments to market their services to physicians to gain market share.

Currently, Medicare pays a dispensing fee of $5 monthly per patient for inhalation therapy drugs. In August 2004, CMS published a proposed rule in which the agency noted that it believed a dispensing fee is appropriate to cover a supplier's costs in delivering inhalation therapy drugs to patients, although it did not propose a specific dollar amount for 2005. CMS solicited comments on the services and costs associated with providing

[10]H.R. Conf. Rep. No. 108-391, at 582-84 (2003), reprinted in 2003 U.S.C.C.A.N. 1808, 1950-51.

[11]GAO, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118 (Washington, D.C.: Sept. 21, 2001).

[12]In implementing MMA, CMS set payments for inhalation therapy drugs furnished in 2004 at 80 to 85 percent of AWP.

[13]These services are not required by Medicare.

inhalation therapy drugs and an appropriate amount for such a dispensing fee.[14] In addition, CMS proposed to allow suppliers to dispense a 90-day supply of drugs to Medicare beneficiaries, an increase from the current limit of a 30-day supply.[15] A final rule is scheduled for publication in November 2004.

Results in Brief

The 2003 acquisition costs for the three inhalation therapy drugs most frequently billed to Medicare varied widely. For example, per unit acquisition costs for ipratropium bromide, the inhalation therapy drug with the highest Medicare expenditures, ranged from $0.23 to $0.64. In addition, acquisition costs were not always lower for the largest suppliers. The lowest acquisition cost for ipratropium bromide was obtained by one of the small suppliers, and the highest acquisition cost was obtained by one of the large suppliers. For the two drugs for which we could estimate an average monthly supply cost, the 2003 acquisition costs were considerably lower than the 2003 Medicare payment rates, resulting in substantial excess payments.

We estimated per patient monthly dispensing costs ranging from $7 to $204 for the suppliers in our sample. In addition, large suppliers did not necessarily have lower dispensing costs. Some of the variation may be due to the range of services offered by suppliers, which raises questions about the services necessary to dispense inhalation therapy drugs. For example, several suppliers reported that they incur substantial costs to ship drugs overnight to beneficiaries; most did so on an as-needed basis, although one did so routinely. Because Medicare payments for drugs have been much higher than suppliers' acquisition costs, suppliers indicated they were able to provide services that benefited both beneficiaries and their physicians. We found that dispensing a 90-day, rather than a 30-day, supply of drugs would reduce overall dispensing costs; the cost of dispensing a 90-day supply was less than twice the cost of a 30-day supply.

We recommend that the Administrator of CMS evaluate the costs of dispensing inhalation therapy drugs and modify the dispensing fee, if warranted, to ensure that the fee appropriately accounts for the costs necessary to dispense the drugs. In commenting on a draft of this report,

[14]69 *Fed. Reg.* 47,488, 47,549 (2004).

[15]69 *Fed. Reg.* 47,488, 47,549 (2004).

CMS agreed with our recommendation. An industry representative commenting on a draft of this report also agreed with our recommendation.

Suppliers' Acquisition Costs Of Inhalation Therapy Drugs Varied Widely

We found that 2003 per unit acquisition costs for the three inhalation therapy drugs most frequently billed to Medicare varied widely among the 12 suppliers in our sample (see table 1). For ipratropium bromide, excluding the 3 suppliers with the highest costs and the 3 with the lowest costs, the remaining 6 suppliers in our sample had acquisition costs that ranged from $0.26 to $0.44. For albuterol sulfate, excluding the 3 suppliers with the highest costs and the 3 with the lowest costs, the remaining 6 suppliers had costs that ranged from $0.05 to $0.06. Although costs varied, they were not always lower for large suppliers. For example, the lowest acquisition cost for ipratropium bromide was obtained by one of the small suppliers, and the highest acquisition cost was obtained by one of the large suppliers. Because the three primary drugs used in inhalation therapy are available as generic drugs, purchasers may choose from more than one source to buy these drugs, potentially leading to greater competition and lower prices.

Table 1: Supplier Per Unit Acquisition Costs for Selected Inhalation Therapy Drugs by Size of Supplier, 2003

Suppliers	Range of per unit average acquisition cost
Ipratropium bromide	
All (n=12)	$0.23 - $0.64
Large (n=4)	0.26 - 0.64
Small (n=8)	0.23 - 0.46
Albuterol sulfate[a]	
All (n=12)	$0.04 - $0.08
Large (n=4)	0.04 - 0.06
Small (n=8)	0.05 - 0.08
Budesonide[b]	
All (n=12)	$0.04 - $4.35
Large (n=4)	0.04 - 3.69
Small (n=8)	0.24 - 4.35

Source: GAO analysis of data from 12 inhalation therapy suppliers.

Note: A large supplier is one whose payments were at least 3 percent of all Medicare inhalation therapy payments in 2003.

[a]These costs are for generic albuterol sulfate and do not include the costs of Xopenex®, a brand-name form of albuterol sulfate.

[b]Budesonide is also available in a powder form, which is much less costly than the solution form of the drug. The lower cost suppliers could have purchased the powder form of the drug and compounded it into the solution themselves.

Industry representatives we spoke with stated that, typically, inhalation therapy drug suppliers purchase drugs from wholesalers or distributors. We found that three of the four large suppliers in our sample purchased inhalation therapy drugs directly from manufacturers. For these companies, the large volume of drugs that they purchase may have allowed them to receive competitive prices negotiated directly with manufacturers, avoiding any price markups from wholesalers. The other large supplier purchased drugs from a mail-order pharmacy that is also an inhalation therapy drug supplier. Most of the small suppliers in our sample stated that they purchased their drugs from a wholesaler or distributor, and a few indicated they used group purchasing organizations to negotiate prices with manufacturers. Two small inhalation therapy suppliers stated they purchased their drugs from both manufacturers and distributors, one noting that they use different sources for different drugs.

Under the previous AWP-based payment system, there was a considerable difference between the prices widely available to purchasers and Medicare's payment for the drugs. Using the lowest and highest per unit acquisition costs reported by our suppliers for 2003, we estimated a difference of $119 to $129 per patient, per month between what suppliers received in payment from Medicare at a rate of 95 percent of AWP and the acquisition costs they incurred for a typical monthly supply of albuterol sulfate. For ipratropium bromide, we estimated that the difference between the 2003 payment rate and lowest and highest acquisition costs was $162 to $187 per patient per month for a typical monthly supply. Because patients receiving inhalation therapy may receive more than one inhalation therapy drug, the excess payments to suppliers for many patients would have been larger.

Large Variation In Suppliers' Dispensing Costs Raises Questions About Services Necessary To Dispense Inhalation Therapy Drugs

Among the suppliers in our sample, there was wide variation in the monthly costs associated with dispensing inhalation therapy drugs. We also found that larger suppliers did not necessarily have lower dispensing costs. Because Medicare payments for drugs greatly exceeded suppliers' acquisition costs, suppliers indicated they were able to provide services that benefited both beneficiaries and their physicians. For example, while most suppliers stated that they shipped drugs overnight to beneficiaries on an as-needed basis, one supplier reported doing so routinely. We found that providing a 90-day supply of drugs could reduce suppliers' costs; the cost for dispensing a 90-day supply was less than twice the cost for dispensing a 30-day supply.

Total per patient monthly dispensing costs varied widely among the suppliers in our sample. Using 2003 data obtained from 12 inhalation therapy suppliers, we estimated that the cost of dispensing inhalation therapy drugs ranged from $7 to $204 per patient per month. Excluding the 3 suppliers with the highest and the 3 with the lowest dispensing costs, the remaining 6 suppliers in our sample had estimated dispensing costs that ranged from $53 to $116 per patient per month. Large inhalation therapy drug suppliers did not necessarily realize economies for inhalation therapy drug dispensing costs; estimated per patient monthly costs ranged from $53 to $138 for large suppliers and from $7 to $204 for small suppliers.

The estimated per patient monthly costs for each individual dispensing cost category varied widely across suppliers, with some suppliers incurring much higher costs than others (see table 2). Examples of substantial costs that suppliers incurred in dispensing inhalation therapy drugs include

patient care services, such as pharmacy, packaging and shipping, personal delivery, and medication refill and compliance phone calls, as well as billing and collection costs and bad debt.

Table 2: Estimated Per Patient Monthly Inhalation Therapy Drug Dispensing Costs, 2003

Cost Category	Range of per patient monthly costs
Patient care costs	
Pharmacy	$0.10 - $123.73
Packaging and shipping	0.32 - 32.61
Delivery	0.00 - 17.39
Medication refill and compliance phone calls	0.12 - 17.64
Other patient care[a]	0.00 - 24.04
Administrative and overhead costs	
Billing/collection	$2.00 - $9.68
Rent/mortgage/lease/or other payment for space	0.26 - 7.19
Insurance	0.00 - 4.10
Depreciation	0.28 - 3.88
Utilities	0.13 - 3.67
Storage	0.00 - 2.96
Licensing	0.06 - 2.39
Training	0.00 - 0.80
Taxes	0.00 - 30.92
Bad debt	0.00 - 9.28
Other administrative and overhead[b]	0.21 - 29.84

Source: GAO analysis of data from 12 suppliers.

[a]Other patient care costs as reported by the suppliers in our sample included customer service representatives not included in another cost category and purchasing personnel.

[b]Other administrative and overhead costs as reported by the suppliers in our sample included costs such as office supplies and equipment, including computers; interest expenses; and building and equipment maintenance.

The wide range of costs associated with dispensing inhalation therapy drugs is due in part to the variation in services offered by suppliers. Because of the difference between the acquisition prices of the drugs and Medicare's payment for them, suppliers indicated that they were able to incur the costs associated with providing services that benefited both beneficiaries and their physicians. For example, 10 of 12 suppliers in our sample reported that they compounded at least some prescriptions,[16] for

which they may have incurred additional costs, including maintenance of a sterile compounding room and increased pharmacist labor. However, the 2 suppliers in our sample that did not compound drugs did not have the lowest pharmacy costs among all suppliers. All suppliers in our sample made phone calls to beneficiaries to ask them if they needed medication refills, to coordinate a refill delivery, and to check on the beneficiaries' compliance with their prescribed drug regimens. Most suppliers made these calls on a monthly basis, but one reported that it did so twice a month. Several suppliers reported that they incurred substantial costs to ship drugs overnight to beneficiaries; most did so on an as-needed basis, although one supplier did so routinely. In addition, several suppliers maintained a 24-hour on-call service for patients to speak to a trained clinician or technician with questions or problems. Inhalation therapy suppliers we spoke with reported that one of their largest costs was the cost of respiratory therapists, who often provide initial patient education and are available as a clinical resource for medication refill and compliance phone calls. Respiratory therapist costs associated with teaching patients about the use and care of a nebulizer are covered as a patient education cost under Medicare's payment for the equipment. Therefore, in our analysis we excluded respiratory therapist costs for patient education on the use of the nebulizer, but included respiratory therapist costs for medication refill and compliance phone calls.

CMS has proposed to allow pharmacy suppliers to dispense Medicare beneficiaries a 90-day, rather than a 30-day, supply of inhalation therapy drugs.[17] We determined that the cost to dispense a 90-day supply of drugs is less than twice the cost to dispense a 30-day supply of drugs (see table 3).[18] This is because certain costs, such as pharmacy, shipping, and billing, are incurred only when the drugs are dispensed; therefore, less frequent dispensing would lower overall costs.[19] For example, suppliers would bill

[16]Drug compounding is the process of mixing, combining, or altering ingredients to create a customized medication for an individual patient.

[17]69 *Fed. Reg.* 47,488, 47,549 (2004).

[18]To calculate per patient dispensing costs for a 90-day supply, we included a one-time cost for pharmacy, packaging and shipping, delivery, medication compliance and refill phone calls, other patient care, and billing and collection costs. We tripled each suppliers' reported monthly costs for all other administrative and overhead costs.

[19]In contrast, administrative and overhead costs generally are not dependent on the frequency with which the drugs are dispensed.

Medicare only once for a 90-day supply of drugs, whereas they would have to bill Medicare three times over that same period if they were dispensing a 30-day supply to beneficiaries. Allowing for a 90-day supply of drugs could reduce both Medicare's and suppliers' costs because suppliers could dispense, ship, and bill for drugs less frequently and Medicare would process fewer claims.

Table 3: Estimated Inhalation Therapy Drug Dispensing Costs, Per 30-Day and 90-Day Supply, 2003

Duration of Supply	Range of costs
Per patient 30-day costs with 30-day supply	$6.96 - $203.75
Per patient 90-day costs with 90-day supply[a]	12.61 - 267.91

Source: GAO analysis of data from 12 suppliers.

[a]To calculate per patient dispensing costs for a 90-day supply, we included a one-time cost for pharmacy, packaging and shipping, delivery, medication compliance and refill phone calls, other patient care, and billing and collection costs. We tripled each suppliers' reported monthly costs for all other administrative and overhead costs.

Conclusions

The inhalation therapy suppliers in our sample exhibited a wide range of drug acquisition costs. The suppliers' costs of dispensing inhalation therapy drugs were quite variable as well. Higher dispensing costs incurred by some suppliers were covered by the excess payments for these drugs under the AWP-based payment system. Our analysis gives a range of the costs suppliers were incurring for dispensing inhalation therapy drugs, a starting point for determining a dispensing fee amount. The appropriate amount of a Medicare dispensing fee must take into account how excess payments for drugs affected dispensing costs. Some costs incurred by suppliers are necessary to dispense inhalation therapy drugs to Medicare beneficiaries, for example, maintaining a licensed pharmacy and billing Medicare. These necessary costs may no longer be covered when Medicare drug payments are closer to acquisition costs with the implementation of the ASP-based payment system. Other costs suppliers incurred may not be necessary to dispense the drugs.

Recommendation for Executive Action

We recommend that the Administrator of CMS evaluate the costs of dispensing inhalation therapy drugs and modify the dispensing fee, if warranted, to ensure that the fee appropriately accounts for the costs necessary to dispense the drugs.

Agency and External Reviewer Comments

In commenting on a draft of this report, CMS agreed with our recommendation. CMS noted the variation we found in inhalation therapy suppliers' costs of dispensing these drugs to Medicare beneficiaries and stated it would carefully consider our analysis as it determines an appropriate dispensing fee for 2005. CMS stated that it would work with those concerned with inhalation therapy to understand the variability in dispensing costs. The agency also acknowledged the variation in the acquisition costs of inhalation therapy drugs. CMS noted our finding that acquisition costs were not necessarily related to the size of the supplier and stated it intends to further explore the factors influencing drug acquisition costs. CMS's written comments appear in appendix II.

We received oral comments on a draft of this report from the American Association for Homecare (AAHomecare), which represents homecare companies, including those that provide inhalation therapy drugs. The association agreed with our recommendation. AAHomecare noted that respiratory therapists provide services that are associated with dispensing inhalation therapy drugs, as well as with the use of nebulizers, and, therefore, the exclusion of all costs associated with respiratory therapists from our analysis was not appropriate. We have clarified the discussion of our methodology to indicate that we excluded respiratory therapist costs related to patient education on the use of the nebulizer but we included respiratory therapist costs related to the medication refill and compliance phone calls. AAHomecare also made technical comments, which we incorporated where appropriate.

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

If you or your staffs have any questions, please call me at (202) 512-7119 or Nancy A. Edwards at (202) 512-3340. Other major contributors to this report include Beth Cameron Feldpush, Joanna L. Hiatt, and Andrea E. Richardson.

Laura A. Dummit
Director, Health Care—Medicare Payment Issues

List of Committees

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

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

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

Scope and Methodology

In conducting this study, we analyzed data from 12 inhalation therapy suppliers. We interviewed officials from the Centers for Medicare & Medicaid Services (CMS), three durable medical equipment (DME) regional carriers, and the Department of Veterans Affairs (VA) to gather comparative information on how VA pays for inhalation therapy. We also interviewed representatives from the American Association for Respiratory Care; American Association for Homecare; American College of Chest Physicians; Emphysema Foundation for Our Right to Survive; and National Association for Medical Direction in Respiratory Care; and two manufacturers and a wholesaler of inhalation therapy drugs. These interviewees helped us identify 20 inhalation therapy suppliers that we interviewed. We conducted a site visit at an inhalation therapy pharmacy and DME supply branch location, and interviewed officials at these facilities.

To obtain information on suppliers' costs of purchasing and providing inhalation therapy drugs to Medicare beneficiaries, we asked the 20 inhalation therapy suppliers we interviewed to report cost data to us on worksheets we provided. We analyzed 2003 cost information from 12 of these suppliers. We assessed the reliability of the cost data in several ways. For publicly traded companies, we compared certain submitted data, such as net revenue and income tax, to data reported in their annual reports filed with the Securities and Exchange Commission. In addition, we calculated the average percentage of total drug acquisition and dispensing costs accounted for by certain cost factors and compared our findings to a similar 2003 industry study. We also compared each supplier's reported data to statements they made during our interviews. We collected data on personnel costs by service (pharmacy) on one worksheet, and by type of personnel (pharmacist) on another. For each supplier, we compared total reported personnel costs on each of these worksheets. Using 2003 Medicare DME claims, we calculated each supplier's total Medicare inhalation therapy revenue and compared it to the total they reported on the worksheets. Although we initially received data from 13 suppliers, we excluded the data of one small, retail pharmacy supplier, as we considered its data unreliable. This pharmacy did not complete one of the personnel worksheets, and, therefore, we could not compare and verify its reported personnel costs. This pharmacy also reported drug acquisition costs that were inconsistent with other suppliers' acquisition costs, in some cases over 25 times higher. We determined that the data from the remaining suppliers were reliable for our purposes.

Our sample of 12 suppliers represents national, regional, and local homecare and mail-order pharmacies. All suppliers have other service lines in addition to inhalation therapy, such as the provision of DME, infusion drugs, and oxygen. These 12 suppliers accounted for more than 42 percent of 2003 Medicare inhalation therapy payments. Although these suppliers represent companies with a wide range of service volumes and geographic locations, they are not a statistically representative sample of all inhalation therapy suppliers.

In our analysis, we excluded certain costs. We excluded sales and marketing costs, as they are not allowed by Medicare, as well as "other" costs that a supplier did not specifically describe. We excluded suppliers' costs for patient education on the use of the nebulizer because they are covered under Medicare's payment for the equipment.

To analyze suppliers' costs of purchasing inhalation therapy drugs, we divided total 2003 acquisition costs (net of rebates and discounts) for each drug by the total number of billing units to obtain a per unit acquisition cost for each drug for each supplier. We analyzed costs for the 4 largest suppliers, each of which had payments accounting for at least 3 percent of all Medicare inhalation therapy payments in 2003, and all other, or small, suppliers. To identify costs associated with dispensing and delivering inhalation therapy drugs, we analyzed 2003 costs associated with dispensing and delivering these drugs for each of the 12 suppliers. We determined the portion of inhalation therapy costs related to drugs using the percent of inhalation therapy revenue accounted for by inhalation therapy drug revenue. For pharmacy and medication refill and compliance phone calls, we used 100 percent of inhalation therapy costs, as these costs are related only to providing the drugs. For each supplier, we divided inhalation therapy drug dispensing costs by the number of reported inhalation therapy patient-months to determine per patient monthly drug dispensing costs. We also determined per patient drug dispensing costs with 90-day delivery by including only once the costs that would be incurred one time per dispensing and by tripling all other costs. We included pharmacy, packaging and shipping, delivery, medication refill and compliance phone calls, other patient care costs, and billing and collection costs only once in this analysis.

We calculated the difference between the 2003 Medicare payment rates and the lowest and highest acquisition costs for albuterol sulfate and ipratropium bromide reported by our suppliers by multiplying both the payment rates and acquisition costs by the number of milligrams in the

typical monthly supply of albuterol sulfate or ipratropium bromide and subtracting the cost from the payment.

We conducted our work from May through October 2004 in accordance with generally accepted government auditing standards.

Comments From the Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Service

Administrator
Washington, DC 20201

DATE: OCT - 8 2004

TO: Laura A. Dummit
Director, Health Care—Medicare Payment Issues

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: General Accounting Office Draft Report (GAO), *MEDICARE: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs*. (GAO-05-72)

Thank you for the opportunity to review and comment on the GAO's draft report entitled, "*MEDICARE: Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs*."

We are committed to ensuring that our beneficiaries have appropriate access to inhalation drugs and understand the vital role these medications play in the care of patients with respiratory illnesses. Lung diseases such as chronic obstructive pulmonary disease (COPD) affect large numbers of Medicare beneficiaries. The COPD is the fourth largest cause of death in America behind heart disease, certain cancers, and stroke. We hope to reduce the number of new COPD cases by educating Americans about the disease, its causes, and ways to prevent it. We hope to improve the lives of Medicare beneficiaries and improve beneficiary access to treatment for those who already suffer from these conditions.

Depending on an individual's age and health, a number of steps can be taken to treat or prevent COPD. Because approximately 85 percent of those with COPD are smokers, the first step to avoid the disease is to stop smoking. Smoking has been linked to a large number of health problems and is a leading cause of cancer and pulmonary disease. The Department of Health and Human Services (HHS) has been actively encouraging Americans to quit smoking through its smoking cessation initiatives. Americans who quit smoking will enjoy longer, healthier lives and avoid diseases such as COPD.

We have also recently approved services to address the needs of Americans suffering from COPD, including lung-volume reduction surgery, which, performed in more serious cases, removes the diseased lung tissue, allowing the rest of the lung to function better. Specifically, effective January 1, 2004, Medicare expanded coverage of lung volume reduction surgery to include patients who either have severe, upper-lobe emphysema, or have severe, non-upper-lobe emphysema with low exercise capacity.

A number of drugs are available to treat the persons with asthma or who develop COPD. These include drugs, often inhaled, that expand the bronchial tubes and allow the patient to breathe more freely. Depending on the needs of the individual patient, these medications can be delivered using nebulizers or metered dose inhalers (MDIs). While nebulizers have long been covered under Medicare Part B, the Medicare Modernization Act (MMA) expanded access to MDIs beginning in 2006 through the new Medicare Part D drug benefit.

We recognize many patients require the use of nebulizers and that nebulizers will continue to play an important role in inhalation therapy even after coverage of MDIs begins in 2006. We, therefore, agree with the GAO recommendation that we evaluate the costs of dispensing inhalation therapy drugs used in nebulizers and modify the dispensing fee, if warranted, to ensure that the fee appropriately accounts for the costs necessary to dispense these drugs.

We note the extreme variation that the GAO found in the costs of dispensing these nebulized drugs to Medicare beneficiaries: GAO found that the 2003 per patient monthly costs of dispensing these medications ranged from a low of $7 to a high of $204. We believe that before a final determination can be made as to the dispensing fee for inhalation drugs, we need to more fully understand the reasons behind the current variability in the dispensing of these drugs. We intend to work with those concerned with inhalation therapy and our partners in the Department of Health and Human Services to explore this issue more fully.

In the interim, the GAO's analysis has provided us with information that we will carefully consider with the comments we received from the public on our August 5, 2004 proposed rule policy on inhalation dispensing fees. A number of commenters on our proposed rule cited an industry-sponsored study on the costs of delivering inhalation drug services. Other comments and publicly available cost information were also available to us. After reviewing the comments and the information from the GAO survey and other public sources, we believe that $55.00 to $64.00 per month is a reasonable range for a 2005 fee.

We also appreciate the GAO's work in surveying the acquisition cost of the suppliers of the inhalation drugs. As with dispensing costs, the GAO found that the acquisition cost of these drugs varied widely. The GAO found that acquisition costs of the two most widely utilized drugs, ipratropium bromide and albuterol sulfate, ranged from $0.23 to $0.64 for ipratropium bromide and from $0.04 to $0.08 for albuterol sulfate. The 2005 Medicare payments for ipratropium bromide and albuterol sulfate will be based on manufacturers' quarterly submissions of average sales price data. The Medicare payment each quarter will be based on the average sales price data plus 6 percent. When we compare the acquisition costs of ipratropium bromide and albuterol sulfate to the Medicare payment rates based on the submission of manufacturer's average sales price

data for the second quarter of 2004, we find that the Medicare payment rates would be solidly inside the acquisition cost range found by the GAO.

The GAO also found that acquisition cost was not necessarily related to the size of the supplier. As we seek to encourage prudent purchasing under the ASP+6 percent payment system, we intend to further explore the factors influencing drug acquisition costs.

We look forward to working with the GAO as we address these important issues and ensure appropriate access to inhalation drugs for our beneficiaries who need them.

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