Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF SERVICES PROVIDED BY INHALATION DRUG SUPPLIERS

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EXECUTIVE SUMMARY

OBJECTIVE

To determine the nature and extent of dispensing services that Medicare beneficiaries receive from inhalation drug suppliers.

BACKGROUND

In 2003, about 1 million beneficiaries received Medicare-covered inhalation drugs. Medicare paid suppliers about $1.4 billion for the drugs and an additional $35.5 million in dispensing fees. In 2005, reductions in payments for inhalation drugs mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 took effect. This resulted in up to a 90 percent drop in payment for some of these drugs from their 2003 level. To cover the cost of services necessary to dispense inhalation drugs, the Centers for Medicare & Medicaid Services (CMS) raised the dispensing fee from $5 to $57 for a 30-day drug supply and offered $80 for a 90-day supply. We estimate that payments for dispensing fees will total about $400 million in 2005.

Yet, it is unclear what services suppliers provide and, therefore, how much Medicare should pay in its dispensing fee. While the Medicare Program Integrity Manual requires suppliers to contact beneficiaries before providing drug refills, neither Congress nor CMS has stated what additional services the dispensing fee covers. In its 2004 final rule setting the interim fee, CMS stated the need to learn more about the services inhalation drug suppliers provide to Medicare beneficiaries.

We drew a stratified random sample of 480 beneficiaries who had Medicare claims for inhalation drugs in 2003. We mailed surveys to the 203 suppliers who provided these beneficiaries with their drugs and requested that the suppliers report and provide supporting documentation for all services they provided to the beneficiaries during 2003. We received responses for 96 percent of the beneficiaries in our sample, yielding data on 11,777 services. We excluded undocumented services and others outside of the scope of this inspection, such as drug deliveries and billing activities. Our analysis considered 4,130 services.

FINDINGS

The most common service beneficiaries received in 2003 was contact for drug refills. Sixty percent of beneficiaries received this service at least once in 2003. Thirty-one percent of beneficiaries who should have been contacted for a refill were not contacted by their

suppliers, contrary to the Medicare Program Integrity Manual. Suppliers contacted physicians' offices for about half of beneficiaries to get physicians' orders, consult on medication changes, and for other reasons. Less than a third of beneficiaries had their medication compliance reviewed by their suppliers. Few beneficiaries received more intensive services such as education, response to an inquiry, care plan revision, or respiratory assessment. Among beneficiaries who had 2 months or more of drug claims, 16 percent received no services at all.

Other services were less common. Contact for drug refills accounted for 56 percent of services. The next most common services, medication compliance reviews and contacting physicians' offices, composed 15 percent and 12 percent of services, respectively.

The most common way beneficiaries received services was by telephone. Beneficiaries received 73 percent of services by telephone. Fourteen percent of services involved no supplier contact with beneficiaries. Home visits were rare; only about 1 in 10 beneficiaries received a home visit any time during 2003.

Beneficiaries were three times more likely to receive a service beyond a refill contact if their supplier also provided their respiratory equipment. When beneficiaries' inhalation drug suppliers also provided them with Medicare-covered respiratory equipment, those beneficiaries were far more likely to receive services beyond a refill contact. Those beneficiaries' average monthly service level was higher than that of beneficiaries who only received inhalation drugs from their suppliers.

Service levels dropped off after the first month suppliers billed for drugs. On average, services beneficiaries received fell from 1.96 services in the first month suppliers billed for drugs to between 1.01 and 1.18 services in the second through eighth months of service.

CONCLUSION

CMS set the interim dispensing fee for inhalation drugs based, in part, on an assumption that beneficiaries receive numerous, important services from their drug suppliers. This inspection shows that beneficiaries, on average, receive little service from their inhalation drug suppliers beyond contacting them to ask if they need a drug refill. We provide this information to CMS to assist it in setting a new dispensing fee for inhalation drugs.

AGENCY COMMENTS

In its comments on the draft report, CMS expressed appreciation for the Office of Inspector General's efforts to provide information on services that inhalation drug suppliers provide to Medicare beneficiaries. CMS stated that it will carefully consider this information as it develops a new dispensing fee policy.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate CMS's comments and consideration of the information in the report.

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OBJECTIVE

To determine the nature and extent of dispensing services that Medicare beneficiaries receive from inhalation drug suppliers.

BACKGROUND

Medicare Coverage of Inhalation Drugs

About 1 million beneficiaries received Medicare-covered inhalation drugs in 2003. These drugs, such as albuterol sulfate and ipratropium bromide, help beneficiaries to ease shortness of breath caused by emphysema, chronic bronchitis, and other ailments collectively known as chronic obstructive pulmonary disease. Because this is an incurable, progressive disease, long term use of inhalation drugs is often required.[1]

Until full implementation of Medicare Part D in 2006 as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Medicare benefits typically do not cover outpatient prescription drugs. However, Medicare does pay for drugs that are necessary for the effective use of covered durable medical equipment (DME). In this case, Medicare covers inhalation drugs because it covers a type of DME called a nebulizer, which beneficiaries use in home-care settings to administer the drugs. Nebulizers aerosolize medications so that patients can inhale them into their lungs.

Under the DME benefit, Medicare coverage of nebulizers includes the cost of renting/purchasing the equipment, delivering it to beneficiaries, and educating beneficiaries in its proper use and maintenance. Medicare regulations require that DME suppliers document proof of delivery and that they or another qualified party provide beneficiaries with the necessary information and instructions on how to use Medicare-covered items safely and effectively.[2] Medicare pays suppliers separately for the inhalation drugs used with the nebulizer and a separate drug dispensing fee.

Medicare Reimbursement for Inhalation Drugs

In 2003, Medicare payments to suppliers totaled $1.4 billion for inhalation drugs and, under a fee structure of $5 per month per drug dispensed, $35.5 million in dispensing fees.

About one-quarter of the suppliers that billed Medicare for inhalation drugs in 2003 also billed the program for nebulizers, oxygen equipment, and respiratory supplies. These suppliers received several streams of

Medicare payment for each beneficiary they serviced, enabling them to achieve economies of scale in their service delivery, for example, by attending to both equipment and drug issues during one service call.

Reduction in Medicare Reimbursement for Inhalation Drugs

In 2005, MMA-mandated reductions in reimbursement for inhalation drugs took full effect, resulting in cuts of up to 90 percent for some of these drugs from their 2003 payment level.[3] This change followed numerous studies by the Office of Inspector General (OIG) and the Government Accountability Office (GAO) that found Medicare's payment for inhalation drugs was up to five times suppliers' acquisition cost, far exceeding the payment rate of Medicaid and others.[4] In 2002 alone, Medicare overpaid suppliers nearly $650 million for albuterol sulfate and ipratropium bromide, the two most commonly used inhalation drugs. Of this amount, about $130 million, or 20 percent, was paid by Medicare beneficiaries through copayments.[5]

Suppliers contend that the difference between their acquisition costs and Medicare payment helps them provide important services to beneficiaries, in addition to providing their inhalation drugs. A 2004 report written for the American Association for Homecare (AAH) stated that suppliers commit significant resources to compliance monitoring, beneficiary/caregiver education, care plan management, and other services. It also stated that suppliers spend 23 minutes on average per patient, per month conducting home visits. The report estimated that these services compose over 60 percent of the monthly cost of providing inhalation drugs.[6]

Interim Dispensing Fee

Because it was concerned that lower, MMA-mandated drug payments would not cover suppliers' cost of furnishing inhalation drugs, CMS raised the dispensing fee on an interim basis for 2005.[7] Under the interim fee, payment for providing a 30-day drug supply increased from $5 to $57. CMS also offered to pay suppliers $80 for providing a 90-day drug supply.[8] Under these two fee structures, we estimate dispensing fees for inhalation drugs will total about $400 million in 2005.[9] To calculate the interim dispensing fee, CMS relied largely on the services and costs described in the AAH report, but excluded sales and marketing expenses, bad debt, and an explicit profit margin.[10, 11]

Uncertainty Over Services Provided

Yet, it is unclear what services suppliers provide when furnishing inhalation drugs, and, therefore, how much Medicare should pay in its

dispensing fee. An October 2004 GAO report found that suppliers' services varied widely and that their dispensing costs ranged from $7 to $204 per month. GAO also found that some costs reported by suppliers might not be necessary to dispense drugs, such as overnight shipping costs.[12]

CMS established the dispensing fee in January 1994.[13] Since then, neither Congress nor CMS has provided guidance in either statute, regulation, or program memorandum concerning what services the dispensing fee should cover. However, the Medicare Program Integrity Manual does require that suppliers contact beneficiaries prior to dispensing refills.[14]

New Dispensing Fee for 2006

In August 2005, CMS published a proposed rule stating its intention to set a new dispensing fee for 2006. Pursuant to the proposed rule, the fee should be ". . . adequate to cover the costs of those services that appropriately fall within the scope of a dispensing fee . . . ." To that end, CMS requested ". . . data and information on the various services inhalation drug suppliers are currently providing to Medicare beneficiaries . . . ."[15]

METHODOLOGY

We based this inspection on a review of services provided by inhalation drug suppliers to a stratified random sample of Medicare beneficiaries.

Scope

This inspection is national in scope and focuses on customer service activities that inhalation drug suppliers provide to Medicare beneficiaries. This inquiry does not estimate the cost of providing these services, nor does it imply an appropriate level or composition of services. This inquiry does not address pharmacy, delivery, billing, and other activities that suppliers perform to provide drugs and that also drive their cost of doing business. We excluded these activities because they must take place for suppliers to provide drugs and get reimbursed. We also excluded services related to equipment because Medicare pays suppliers separately for equipment and equipment-related services. Our analysis of services considered only those services that suppliers could support with documentation.

Sample Selection

We based our findings on a review of services provided by inhalation drug suppliers to a stratified random sample of 480 Medicare

beneficiaries who had paid claims for inhalation drugs in Medicare's National Claims History File in calendar year 2003. Our sample population comprises 966,966 beneficiaries. We stratified our sample to enable us to test for differences related to longevity on the drugs and oxygen use. This approach resulted in 4 strata of 120 beneficiaries each. Our analysis showed that oxygen use does not affect service levels, and we do not report on it in our findings. See Table 1 in Appendix A for the strata definitions and sample design.

Data Collection

To determine the services provided to beneficiaries in our sample, we surveyed the suppliers that provided them with inhalation drugs during 2003. We requested that suppliers report all services they provided to the beneficiaries during 2003 and provide documentation supporting each service. We received responses from 186 of the 203 suppliers we surveyed. These suppliers provided data on 461 of the 480 beneficiaries in our sample, yielding a 96 percent response rate.

Data Analysis

We captured data on a total of 11,777 services, including 500 services that suppliers failed to report but were evident in supporting documentation. Of these, we excluded 5,097 services related to drug delivery, billing, and pharmacy because they were outside of the scope of our inquiry and 441 equipment-related services. We eliminated 1,505 services that suppliers could not support with documentation.[16] We also excluded 181 unsuccessful service attempts because no service was provided, 344 duplicate reports of services, 68 services related to drugs not covered by Medicare, and 11 services for other reasons. After these exclusions, the total number of services in our analysis was 4,130.

See Appendix A for a full discussion of our methodology.

This inspection was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency.

The most common service beneficiaries received in 2003 was contact for drug refills

Sixty percent of beneficiaries received this service at least once in 2003. This service involved salespeople, respiratory therapists, or other supplier staff contacting beneficiaries to ask if they need a new monthly supply of medication (beneficiaries sometimes initiate this contact as well). Occasionally, beneficiaries would request refills by sending preprinted postcards to their suppliers.

Among beneficiaries with 2 months or more of drug claims in 2003, 31 percent had no refill contacts during the entire year. Pursuant to the Medicare Program Integrity Manual, these beneficiaries should have been contacted at least once by their suppliers that year.

Suppliers contacted physicians' offices for about half of beneficiaries

Fifty-two percent of beneficiaries received this service in 2003. Suppliers contacted physicians' offices to get physicians' orders, to consult on medication changes, and for other reasons. The Medicare Program Integrity Manual requires that suppliers get a physician's order before billing for inhalation drugs.[17] Fifty percent of these contacts occurred in the first month that suppliers billed for drugs; the contacts dropped off significantly in subsequent months.[18]

Less than a third of beneficiaries had their medication compliance reviewed by their suppliers

Twenty-seven percent of beneficiaries received a compliance review from their supplier at least once in 2003. Supplier staff conducted compliance reviews to determine whether beneficiaries were using their medication in accordance with the instructions of their physicians. Compliance reviews ranged from those using a telephone call script with questions on the beneficiary's drug use, side effects, and outcomes, to reviews that consisted of a note made in a refill call log stating how often the beneficiary used the drugs (e.g., "using as needed"). Eighty-nine percent of all compliance reviews occurred while supplier staff were calling beneficiaries to ask if they needed a drug refill.

Few beneficiaries received more intensive services such as education, response to an inquiry, care plan revision, or respiratory assessment

Sixteen percent of beneficiaries received an educational service from their supplier at least once in 2003. Educational services included printed fact sheets on the prescribed drugs, printed information about the supplier, and training on how to use the drugs. Eight percent of

beneficiaries made an inquiry to their suppliers during the year, typically by telephone. Inquiries included requests for emergency refills and reporting problems with medications. Five percent of beneficiaries received care plan revisions and less than 3 percent received respiratory assessments. Care plan revisions involved changing beneficiaries' medication or frequency of use. To conduct respiratory assessments, supplier staff visited beneficiaries in their homes to check clinical indicators of breathing functions. See Table 6 in Appendix B for the percentage of beneficiaries who received different services.

Sixteen percent of beneficiaries received no services at all

Because some beneficiaries were beginning or ending their treatment regimens outside of 2003, we do not expect that all of them would have received a service during the year. However, among beneficiaries with 2 months or more of drug claims in 2003, 16 percent received no services at all during the entire year.

Other services were far less common

Of all services provided in 2003, 56 percent were refill contacts. With 15 percent of services, medication compliance reviews were the second most common service beneficiaries received. Contacting physicians' offices composed 12 percent of services. The next most common service was beneficiary/caregiver education at 7 percent of services, followed by clinical intake, which composed 4 percent of services. Two percent of services were responding to beneficiary inquiries. Other services, including respiratory assessments and care plan revisions, together composed about 5 percent of services. See Table 7 in Appendix B for a list and frequency count of services.

The most common way beneficiaries received services was by telephone

Beneficiaries received 73 percent of services by telephone in 2003. Contacting beneficiaries for a refill and medication compliance reviews, the two most frequent services, were performed almost entirely by telephone. Fourteen percent of services involved contacting physicians' offices and other activities that required no beneficiary interaction. Service delivery methods also included U.S. mail, third-party delivery services such as FedEx, and in-person at retail locations. See Table 8 in Appendix B for a list and frequency count of service delivery methods.

Home visits were rare

Only about 1 in 10 beneficiaries received a home visit from their suppliers at least once in 2003. These visits involved supplier delivery people or other staff visiting beneficiaries in their homes to perform services such as education and respiratory assessments. About 2 percent of all services were provided by home visits. See Table 9 in Appendix B for the percentage of beneficiaries who received different service delivery methods.

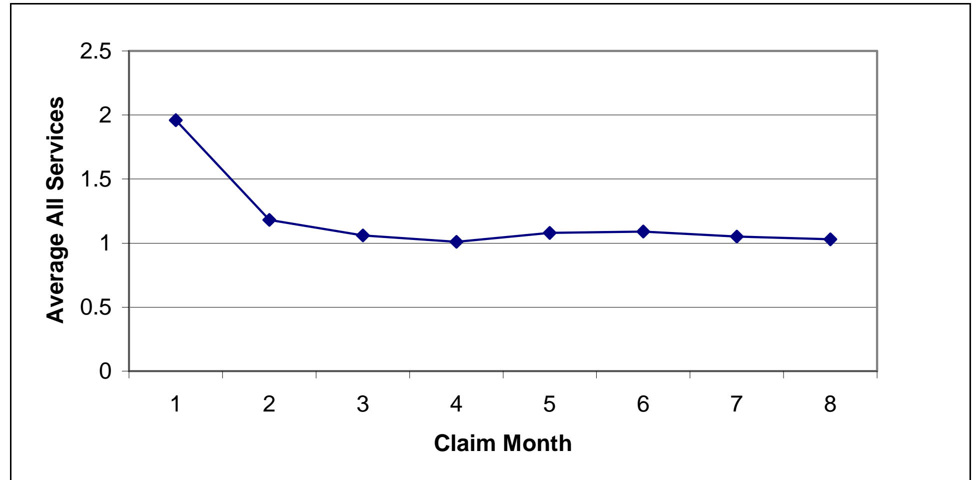
Beneficiaries were three times more likely to receive a service beyond a refill contact if their supplier also provided their respiratory equipment

When beneficaries' inhalation drug suppliers also provided them with their nebulizers, oxygen equipment, or other Medicare-covered respiratory equipment, those beneficiaries were far more likely to receive services beyond a refill contact.[19] Also, those beneficiaries' average service level was higher than that of beneficiaries who only received inhalation drugs from their suppliers.[20] Seventy-four percent of beneficiaries receiving inhalation drugs also got Medicare-covered respiratory equipment or supplies from their drug suppliers.

Service levels dropped off after the first month suppliers billed for drugs

Services fell from 1.96 services in the first month that suppliers billed for drugs to between 1.01 and 1.18 services in the second through eighth months of service.[21] (See Chart 1 on page 8.) On average, beneficiaries received 1.2 services per month throughout 2003.[22] Excluding contacts for drug refills, this service level fell to 0.71 services per month.

Chart 1: Average Number of Services per Month Received by Medicare Beneficiaries from Inhalation Drug Suppliers During 2003, by Month of Service



Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

For 2005, CMS set a revised, interim dispensing fee for inhalation drugs in response to significant cuts in drug payments mandated by the MMA. The fee is to remain in place while CMS gathers more information on the services that drug suppliers provide to Medicare beneficiaries. CMS plans to set a new dispensing fee for 2006.

To set the interim fee, CMS relied primarily on a report commissioned by AAH, a trade group representing the respiratory therapy industry. The report stated that, in addition to providing drugs, inhalation drug suppliers provide numerous, important services to Medicare beneficiaries. According to the report, services such as home visits, compliance monitoring, beneficiary/caregiver education, and care plan management compose 60 percent or more of the monthly cost of servicing each beneficiary.

CMS set the interim dispensing fee for inhalation drugs based, in part, on an assumption that beneficiaries receive these services from their drug suppliers. However, this inspection shows that beneficiaries, on average, receive little service from their inhalation drug suppliers beyond contacting them to ask if they need a refill.

We provide this information to CMS to assist it in setting a new dispensing fee for inhalation drugs.

AGENCY COMMENTS

In its comments on the draft report, CMS expressed appreciation for the OIG's efforts to provide information on services that inhalation drug suppliers provide to Medicare beneficiaries. CMS stated that it will carefully consider this information as it develops a new dispensing fee policy. For CMS's complete comments, see page 26 of this report.

OFFICE OF INSPECTOR GENERAL RESPONSE

We appreciate CMS's comments and consideration of the information in the report.

ENDNOTES

[1] Global Strategy for Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease, Executive Summary based on April 1998 National Heart, Lung, and Blood Institute/World Health Organization workshop. Global Initiative for Chronic Obstructive Pulmonary Disease, updated 2004.

[2] 42 C.F.R. § 424.57(c)(12) (2003).

[3] Medicare now pays for inhalation drugs at 106 percent of the average sales price. The average sales price reflects the actual average price at which manufacturers sell inhalation drugs.

[4] See:

Department of Health and Human Services, Office of Inspector General, *Update: Excessive Medicare Reimbursement for Albuterol*, OEI-03-03-00510, January 2004.

Department of Health and Human Services, Office of Inspector General, *Update: Excessive Medicare Reimbursement for Ipratropium Bromide*, OEI-03-03-00520, January 2004.

Government Accountability Office, *Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118, September 2001.

[5] Department of Health and Human Services, Office of Inspector General, *Update: Excessive Medicare Reimbursement for Albuterol*, OEI-03-03-00510, January 2004.

Department of Health and Human Services, Office of Inspector General, *Update: Excessive Medicare Reimbursement for Ipratropium Bromide*, OEI-03-03-00520, January 2004.

[6] Muse & Associates, *The Costs of Delivering Inhalation Drug Services to Medicare Beneficiaries*, August 2004.

[7] 69 Fed. Reg. 47,549 (August 5, 2004).

[8] 69 Fed. Reg. 66,338 (November 15, 2004).

[9] We base this estimate on about 7,100,00 dispensing fees paid in 2003 at a blend of the 2005 interim amounts of $57 and $80.

[10] 70 Fed. Reg. 45,848 (August 8, 2005).

[11] 69 Fed. Reg. 66,338 (November 15, 2004).

[12] Government Accountability Office, *Appropriate Dispensing Fee Needed for Suppliers of Inhalation Therapy Drugs*, GAO-05-72, October 2004.

[13] Authority for a dispensing fee for inhalation drugs is based on § 1842(o)(2) of the Social Security Act which reads, "If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologics under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy."

[14] Medicare Program Integrity Manual Rev. 71, 04-09-04 § 4.26.1.

[15] 70 Fed. Reg. 45,848 (August 8, 2005).

[16] Of these, about half were medication compliance reviews and about a third were contacts for drug refills.

[17] Medicare Program Integrity Manual Rev. 100, 01-21-05 § 5.1.1.

[18] The average decrease in physician contacts from month 1 to months 2 through 8 was 0.61, with $p<.01$.

[19] We performed logistic regression to determine the relationship between beneficiaries receiving respiratory equipment from their inhalation drug suppliers and receiving a service beyond a refill contact. The regression determined that, compared to beneficiaries receiving only drugs from their suppliers, beneficiaries receiving equipment were 3.14 times more likely to receive a service beyond a refill contact. This effect is statistically significant at $p<.05$; the upper and lower 95 percent confidence intervals are 1.73 and 5.70, respectively.

[20] Beneficiaries who also received Medicare-covered respiratory equipment and supplies received 1.31 services per month on average. Beneficiaries who only received inhalation drugs from their supplier received 0.83 services per month, on average. A statistical test of differences shows that the difference between these means is statistically significant with $t=3.25$ and $p<.01$.

[21] The average decrease in services from month 1 to months 2 through 8 was 0.93, with $p<.01$.

[22] Including undocumented services reported by suppliers, this service level is 1.59 services per month.

METHODOLOGY

We based this inspection on a review of services provided by inhalation drug suppliers to a stratified random sample of Medicare beneficiaries.

Scope

This inspection is national in scope and focuses on customer service activities that inhalation drug suppliers provide to Medicare beneficiaries. This inquiry does not estimate the cost of providing these services, nor does it imply an appropriate level or composition of services. This inquiry does not address pharmacy, delivery, billing, and other activities that suppliers perform to provide drugs and that also drive their cost of doing business. We excluded these activities because they must take place for suppliers to provide drugs and get reimbursed. We also excluded services related to equipment because Medicare pays suppliers separately for equipment and equipment-related services. Our analysis considered only those services that suppliers could support with documentation from patient records and other sources. See Table 6 in Appendix B for the list of services we included in our analysis.

Sample Selection

We based our findings on a review of services provided by inhalation drug suppliers to a stratified random sample of 480 Medicare beneficiaries who had Medicare-paid claims for inhalation drugs in calendar year 2003. We chose 2003 as our reference year because it was the latest year with complete and available Medicare claims data when we drew our sample. We excluded Medicare beneficiaries from Puerto Rico and U.S. territories. We used CMS's year 2003 100 percent National Claims History file to identify beneficiaries who had paid Medicare claims for 1 of 32 inhalation drugs covered for use in a nebulizer. Our sample population comprises 966,966 beneficiaries.

We stratified our sample to determine if beneficiaries beginning inhalation drug use and those who use oxygen receive different amounts or types of services.

- Stratum 1: Beneficiaries who began using inhalation drugs in 2003 and had 8 or more months of drug claims during the year from the same supplier and were not using oxygen.
- Stratum 2: All other beneficiaries who had a claim for inhalation drugs in 2003 and were not using oxygen.

- Stratum 3: Beneficiaries who began using inhalation drugs in 2003 and had 8 or more months of drug claims during the year from the same supplier and were using oxygen.
- Stratum 4: All other beneficiaries who had a claim for inhalation drugs in 2003 and were using oxygen.

Our analysis showed that oxygen use does not affect service levels, and we do not report on it in our findings.

To identify which stratum members of our sample population belonged to, we used CMS's Enrollment Data Base and 2002 - 2003 100 percent National Claims History files. See Table 1 for more information on the strata populations.

Table 1: Population and Response Rate for OIG Survey of Inhalation Drug Suppliers, by Strata

Strata	N (Population)	n (Sample)	Number of Cases Received	Percent of Cases Received
Stratum 1	13,827	120	118	98
Stratum 2	473,867	120	119	99
Stratum 3	13,918	120	113	94
Stratum 4	465,354	120	111	93
Overall Total	**966,966**	**480**	**461**	**96**

Data Collection Instrument

Drawing on work by GAO, private researchers, CMS staff, and other research, we developed a list of possible services that suppliers might provide to beneficiaries and the ways they might interact with beneficiaries in doing so. (See Table 2 on page 15.)

Next, we incorporated our lists of service types and interaction types into a 1-page data collection form. We designed the form to be photocopied and completed by suppliers for each service they provided to beneficiaries in our sample during 2003. The form captured the date suppliers provided the service, the type of service provided, how suppliers interacted with the beneficiary to provide the service, and whether documentation to support the service was attached. We vetted the form within OIG and with staff at CMS.

Table 2: Service and Interaction Types

Service Types	Interaction Types
Delivered Supply of Drugs	By U.S. Postal Service
Responded to Patient Inquiry About Drugs	By a Delivery Service (e.g., FedEx)
Responded to Patient Inquiry About Equipment	By Company Delivery Person
Performed Equipment Maintenance	By Telephone
Performed Patient Education	By Company Staff Visiting in Patient's Home
Performed Clinical Intake	In Person at Retail Location
Reviewed Medication Compliance	No Interaction
Contacted Patient for a Refill	Other Interaction
Contacted Patient's Physician	
Revised Plan of Care	
Compounded Drugs	
Other Service	

Data Collection

To determine the services suppliers provided to beneficiaries in our sample, we contacted the suppliers that provided them with inhalation drugs in 2003. For beneficiaries in Strata 2 and 4, we contacted every supplier the beneficiaries had during the year. For each beneficiary in Strata 1 and 3, we only contacted the supplier that provided that beneficiary with 8 or more months of inhalation drugs. Using this approach, we identified 203 suppliers that were associated with the beneficiaries in our sample.

To conduct our survey, we sent each supplier via express delivery a packet with a cover letter, a supplier information form, a beneficiary roster, instructions, and at least one copy of the data collection instrument. Our instructions asked that suppliers report and document all services they provided during 2003 to the beneficiaries on the roster. We attempted to contact suppliers three times in writing over 8 weeks. We also attempted to contact unresponsive suppliers by telephone. We received responses from 186 suppliers. These suppliers provided data

on 461 out of the 480 beneficiaries in our sample, yielding a 96 percent response rate. (See Table 1 on page 14.) See Appendix C for a nonrespondent analysis.

Data Analysis

We reviewed each completed form and the corresponding supporting documentation suppliers submitted to attempt to verify the service the supplier provided and how the supplier interacted with the beneficiary. We captured data on 11,777 services, including 500 services that suppliers failed to report to us but were evident in the supporting documentation for other services. During data entry, we added 13 additional service types and 2 additional interaction types to categorize information suppliers reported to us. About 1,800 services fell into these additional categories. See Table 3 below for detail on how we defined service delivery methods and Table 4 on page 17 for how we defined services.

Table 3: Definitions of Service Delivery Methods

Service Delivery Methods	Definition
By U.S. Postal Service	U.S. mail
By a Delivery Service	Third-party delivery service (e.g., FedEx, United Parcel Service)
By Company Delivery Person	Driver/delivery person employed by drug supplier
By Telephone Contact	Supplier spoke with beneficiary or caregiver by telephone
By Company Staff Visiting in Patient's Home	Supplier staff travel to and work inside beneficiary's home
In Person at Retail Location	Beneficiary or caregiver went to retail pharmacy
No Interaction	Supplier did not interact with beneficiary or caregiver
Left Message/Voicemail*	Supplier telephoned beneficiary and left a message
Telephone/No Answer*	Supplier telephoned beneficiary and received no answer or voicemail
Other	Supplier reported a service delivery type that does not fit in these categories

* Service delivery methods excluded from our analysis.

Table 4: Definitions of Services

Service	Definition
Delivered Supply of Drugs*	Supplier provided the beneficiary with nebulizer drugs
Responded to Patient Inquiry About Drugs	Beneficiary or caregiver contacted the supplier with a drug-related question and the supplier answered it
Responded to Patient Inquiry About Equipment*	Beneficiary or caregiver contacted the supplier with an equipment-related question and the supplier answered it
Performed Equipment Maintenance*	The supplier performed maintenance on or replaced the beneficiary's nebulizer, oxygen concentrator, or other respiratory equipment
Performed Patient Education	Supplier educated beneficiary or caregiver about drugs
Clinical Intake	Supplier captured beneficiary's demographic and/or clinical information
Reviewed Medication Compliance	Supplier asked beneficiary or caregiver how often beneficiary is using drugs and/or about effectiveness, side effects
Contacted Patient for a Refill	Supplier corresponded with beneficiary or caregiver to determine if beneficiary needed a refill shipment of drugs
Contacted Physician's Office	Supplier contacted physician's office for prescription, doctor's order, etc.
Revised Plan of Care	Changed beneficiary's medication or frequency of use
Compounded Drugs*	Pharmacist mixed two or more drugs together into single vial, or mixed drug from powder
Billing Activity*	Medicare billing activity (e.g., verified insurance, mailed assignment of benefits form)
Patient Education about Equipment*	Supplier educated beneficiary or caregiver about nebulizer or oxygen equipment
Delivered Equipment*	Supplier delivered nebulizer, oxygen, or respiratory equipment to beneficiary
Respiratory Assessment	Supplier performed clinical assessment of beneficiary's respiratory functions
Quality Control/Quality Assurance*	Supplier staff verified drug order, tested drug batch, etc.
Notified Patient of Impending Delivery	Supplier contacted beneficiary or caregiver to confirm delivery date
Patient Tracking	Supplier changed beneficiary mailing address due to vacation, beneficiary moving; supplier terminated service
Internal Order Processing*	Supplier processed drug order (e.g., sent order from call center to pharmacy)
Pharmacist Filled/Dispensed*	Pharmacy-related work needed to fill order
Stat Dose	Supplier arranged for initial drug supply to be picked up at local retail pharmacy
Other Service	Service that does not fit into these categories

* Services excluded from our analysis.

We excluded services outside of our scope from our analysis. We also excluded undocumented services, duplicate reporting of services, and unsuccessful service attempts, such as attempted phone calls with no answer. After all exclusions, the total number of services in our analysis was 4,130. See Table 5 for a breakdown of the services we excluded from our analysis.

Table 5: Services Excluded From Analysis, by Category

Service Category	Number of Services Excluded
Equipment-related	441
Drug delivery	3,520
Billing activity	61
Pharmacy activity	1,516
Duplicate service	344
Undocumented service	1,505
Unsuccessful service attempt	181
Related to non-Medicare drug	68
Other reason	11
Total services outside the scope of analysis	**7,647**

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

We based our analysis of average services per month on the count of documented services each beneficiary received in each month. We included a month in our analysis if the supplier reported any documented drug-related service, including delivery, during that month. This approach allowed us to include months with services even if there was no Medicare claim billed in those months. For example, when a beneficiary begins using inhalation drugs, his or her supplier could provide services such as clinical intake and contacting the beneficiary's physician's office before billing Medicare for drugs. Our approach enabled us to include these services in our analysis.

Our analysis of the percentage of beneficiaries who got a particular service is based on a count of those that received the service at least

once during 2003 divided by the total number of beneficiaries for whom we received a survey response.

The numbers of beneficiaries in our analysis changed depending on whether we were analyzing our data at the beneficiary level or at the service level and whether or not we were focusing on subgroups of beneficiaries or services. We excluded beneficiaries whose suppliers reported no documented services, including delivery, from all analysis except that projecting the overall percentages of beneficiaries that received services. We excluded beneficiaries whose suppliers only reported documented drug deliveries from all analysis except our calculations of average services per month and our projections of the overall percentages of beneficiaries that received services.

We weighted the results of our analysis to account for our sample design.

Confidence intervals and point estimates are provided in Table 10 in Appendix B.

DATA TABLES

Table 6: Number of Medicare Beneficiaries Receiving Different Services from Inhalation Drug Suppliers in 2003*

Service	Frequency of Beneficiaries	Estimated Population of Beneficiaries	Percent of Beneficiaries Who Received Service
Contacted for a Refill	303	555,357	59.9
Contacted Physician's Office	268	486,361	52.5
Reviewed Drug Compliance	140	251928	27.2
Clinical Intake	170	228,350	24.6
Performed Education	103	152,321	16.4
Responded to Inquiry	48	73,838	8.0
Revised Plan of Care	38	45,991	5.0
Patient Tracking	21	40,547	4.4
Delivery Followup	18	32,463	3.5
Delivery Notification	26	29,696	3.2
Other Service	13	24,290	2.6
Stat Dose	13	24,218	2.6
Respiratory Assessment	12	24,174	2.6
Delivery Confirmation	8	4,757	0.5

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

* Beneficiaries may receive more than one service.

Table 7: Frequency and Percent of Services Provided to Medicare Beneficiaries by Inhalation Drug Suppliers in 2003

Service	Sample Frequency of Services	Estimated Population of Services	Percent of All Services
Contacted for a Refill	2,316	3,675,554	55.9
Reviewed Drug Compliance	570	952,208	14.5
Contacted Physician's Office	500	801,099	12.2
Performed Education	289	485,108	7.4
Clinical Intake	183	245,114	3.7
Responded to Inquiry	76	115,126	1.8
Delivery Followup, Patient Tracking, Revised Plan of Care, Respiratory Asessment, Delivery Notification, Other Service, Stat Dose, Delivery Confirmation	196	299,578	4.6
Overall Total	**4,130**	**6,573,787**	**100**

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

Table 8: Number of Services Delivered by Inhalation Drug Suppliers in 2003 by Method of Service Delivery

Service Delivery Method	Frequency of Services	Estimated Population of Services	Percent of All Services
By Telephone Contact with Beneficiary	3,044	4,809,297	73.2
No Interaction	614	943,125	14.4
By a Delivery Service	197	361,033	5.5
By U.S. Postal Service	129	154,883	2.4
By Company Staff Visiting in Beneficiary Home	71	144,862	2.2
In Person at Retail Location, By Company Delivery Person, Other Service Delivery Type, Could Not Verify Service Delivery Type	75	160,586	2.4
Overall Total	**4,130**	**6,573,786**	**100**

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

Table 9: Number of Medicare Beneficiaries Receiving Services from Inhalation Drug Suppliers in 2003 by Method of Service Delivery*

Service Delivery Method	Frequency of Beneficiaries	Estimated Population of Beneficiaries	Percent of Beneficiaries Who Received Service Delivery Method
By Telephone Contact with Beneficiary	313	590,517	63.7
No Interaction	280	514,298	55.5
By a Delivery Service	34	80,100	8.6
By U.S. Postal Service	47	73,647	7.9
By Company Staff Visiting in Beneficiary Home	44	69,405	7.5
In Person at Retail Location, By Company Delivery Person, Other Service Delivery Type	14	28,239	3.1

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

* Beneficiaries may receive multiple services through multiple methods.

Table 10: Confidence Intervals

Statistic	Point Estimate	n	95 Percent Confidence Interval
Percent of beneficiaries who received a refill contact	59.9%	461	54% - 66%
Percent of beneficiaries with 2 months or more of drug claims who did not get a refill contact during the year	30.8%	377	24% - 37%
Percent of beneficiaries whose doctors were contacted by their supplier	52.4%	461	46% - 59%
Percent of physician contacts that occur in the first month suppliers bill for drugs	49.8%	146	44% - 56%
Drop in doctor contacts from month 1 to subsequent months	0.61	212	0.51 - 0.72
Percent of beneficiaries who received a compliance review	27.2%	461	22% - 33%
Percent of compliance reviews done over the telephone during a refill call	89.1%	142	84% - 95%
Percent of beneficiaries who got education	16.4%	461	12% - 21%
Percent of beneficiaries who had an inquiry answered by their supplier	8.0%	461	5% - 11%
Percent of beneficiaries who had their care plan revised	5.0%	461	2% - 8%
Percent of beneficiaries who got a respiratory assessment	2.6%	461	1% - 5%
Percent of beneficiaries who got no services	16.3%	409	12% - 21%
Percent of all services that were refill contacts	55.9%	377	52% - 59%
Percent of services that were medication compliance reviews	14.5%	377	11% - 18%
Percent of services that were contacting physician offices	12.2%	377	10% - 14%
Percent of services that were beneficiary/caregiver education	7.4%	377	4% - 10%
Percent of services that were clinical intake	3.7%	377	3% - 5%
Percent of services that were responding to beneficiary inquiries	1.8%	377	1% - 3%
Percent of services that were other services including respiratory assessments and care plan revisions	4.6%	377	3% - 6%
Percent of services provided by telephone	73.2%	377	69% - 77%
Percent of refill contacts done by telephone	93.5%	303	90% - 97%
Percent of compliance reviews done by telephone	96.0%	142	92% - 100%
Percent of services with no beneficiary interaction	14.4%	377	12% - 17%
Percent of beneficiaries who got a home visit	8.8%	461	5% - 12%
Percent of services provided by home visit	2.4%	377	1% - 4%
Percent of beneficiaries who got drugs and respiratory equipment from their inhalation drug supplier	74.1%	461	69% - 80%
Number of services in first month	1.96	215	1.75 - 2.18
Low number of services received in months 2 - 8	1.01	203	0.87 - 1.16
High number of services received in months 2 - 8	1.17	192	1.01 - 1.35
Average number of services beneficiaries received in 2003	1.20	444	1.08 - 1.32
Excluding refill contacts, average number of services beneficiaries received in 2003	0.71	444	0.60 - 0.82

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005

NONRESPONDENT ANALYSIS

A consideration in surveys or data collection efforts of this type is whether the results may be biased by significant differences between respondents and nonrespondents. To determine whether significant differences exist in this data collection effort, we compared respondents and nonrespondents by whether or not beneficiaries got respiratory equipment from their inhalation drug suppliers and by the average months of inhalation drug claims beneficiaries had in Medicare's National Claims History file.

We achieved a 96 percent response rate with respect to the beneficiaries sampled. As a result, we had 461 responses and 19 nonresponses to use for this analysis.

Our analysis suggests that our survey results were not biased with regard to these variables.

Analysis by Whether the Beneficiary Also Received Equipment

A chi-square test showed no relationship between respondents and nonrespondents with respect to beneficiaries receiving respiratory equipment from their inhalation drug suppliers. (See Table 11.)

Table 11: Analysis by Whether the Beneficiary Also Received Equipment

	Received Equipment (Number)	Received Equipment (Percent*)	Did Not Receive Equipment (Number)	Did Not Receive Equipment (Percent*)
Sample (n=480)	369	73.1	111	26.9
Respondents (n=461)	359	73.3	102	26.7
Nonrespondents (n=19)	10	69.1	9	30.9

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

* Percents were weighted based on the sample design.

Chi-square=0.08 (not significant)

Analysis by Average Months of Claims

We performed a t-test to compare the average months of inhalation drug claims between respondents and nonrespondents. The difference was not statistically significant. (See Table 12.)

Table 12: Analysis by Average Months of Claims

Sample (n=480)	Average Months of Claims*
Respondents (n=461)	4.97
Nonrespondents (n=19)	6.10

Source: Office of Inspector General Survey of Inhalation Drug Suppliers, 2005.

* Average claims were weighted based on the sample design.

t=1.09 (not significant)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

SEP 2 2 2005

TO: Daniel R. Levinson
Inspector General
Office of Inspector General

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

SUBJECT: Office of Inspector General (OIG) Draft Report: "Review of Services Provided by Inhalation Drug Suppliers" (OEI-01-05-00090)

Thank you for the opportunity to comment on the above-referenced OIG draft report. We appreciate OIG's efforts to provide information about the types of services being provided by inhalation drug suppliers to Medicare beneficiaries.

As indicated in the report, with implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare reimbursement for inhalation drugs changed. In 2005, Medicare began reimbursing inhalation drugs at 106 percent of the average sales price. At the same time, Medicare increased the dispensing fee paid to inhalation drug suppliers from the prior $5 per month to $57 per 30-day supply and $80 per 90-day supply of inhalation drugs for 2005.

The OIG report examines the nature and extent of services Medicare beneficiaries receive from inhalation drug suppliers. The OIG review addresses an important issue that the Centers for Medicare & Medicaid Services is currently seeking comment on in its physician fee schedule proposed rule. The proposed rule, published in the *Federal Register* on August 8, seeks comment on an appropriate dispensing fee payment amount for 2006. In order to shape this issue, the proposed rule also solicits comment on a number of related issues, such as what services inhalation drug suppliers are currently providing to beneficiaries. The OIG report provides helpful information on this topic. We will carefully consider the OIG report together with the public comments we receive, as we develop the final rule dispensing fee policy.

Thank you for your efforts to produce this timely report.

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A C K N O W L E D G M E N T S

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