

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**QUESTIONABLE BILLING FOR
BRAND-NAME INHALATION
DRUGS IN SOUTH FLORIDA**



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OBJECTIVES

1. To identify changes in billing among South Florida durable medical equipment (DME) suppliers for budesonide and arformoterol after payment controls were put in place to detect and deny excessive budesonide claims.
2. To determine whether the amount of arformoterol billed by South Florida DME suppliers and paid under Medicare Part B exceeded the amount of the drug distributed for sale in the area between January 2008 and June 2009.

BACKGROUND

Medicare Part B covers inhalation drugs when they are used in conjunction with DME. Beneficiaries typically obtain DME items, including inhalation drugs, through suppliers, which then submit claims to Medicare on behalf of the beneficiaries. The Centers for Medicare & Medicaid Services (CMS) contracts with four geographically defined DME Medicare Administrative Contractors to process and pay DME claims. CMS also contracts with Program Safeguard Contractors to administer benefit integrity functions and conduct medical reviews.

CMS may establish national coverage determinations for DME items. National coverage determinations specify whether certain medical items, services, treatment procedures, or technologies are eligible for Medicare payment. When a national coverage determination does not exist or when there is need for further definition, a local coverage determination (LCD) may be established by a CMS contractor. An LCD for nebulizers and related inhalation drugs (L5007), originally effective on April 1, 1997, establishes coverage limitations, such as the maximum milligrams per month of a drug that may reasonably be billed for a beneficiary. Through this LCD, a utilization edit to detect and deny claims that exceed utilization guidelines was implemented for the inhalation drug budesonide in September 2008.

In 2008, Medicare was billed \$426 million for the inhalation drug budesonide (brand name Pulmicort Respules) and \$75 million for the inhalation drug arformoterol (brand name Brovana). During that year, Medicare spent \$297 million for budesonide and \$47 million for arformoterol. Both brand-name-only drugs have relatively high Medicare payment amounts when compared to the payment amounts for inhalation drugs with generic versions. Billing and spending on

budesonide and arformoterol for beneficiaries in South Florida (Miami-Dade, Broward, and Palm Beach Counties) were much greater when compared to billing and spending for beneficiaries in the rest of the country.

We used the Medicare National Claims History File to identify all budesonide and arformoterol claims in 2008 and the first half of 2009. We also obtained sales data from arformoterol's manufacturer, Sepracor, for the same period. Sepracor provided sales data for any direct sales and sales by the three largest wholesalers (approximately 70 percent to 75 percent of sales).

For budesonide and arformoterol, we analyzed the claim files to identify billing differences by South Florida suppliers before and after the utilization edit was implemented on September 19, 2008. We calculated the number of South Florida suppliers that (1) billed Medicare for units provided before the edit but did not bill after the edit, (2) did not bill for units before the edit but began billing after the edit, and (3) billed for units provided both before and after the edit. Using the arformoterol sales data provided by Sepracor, we compared the total number of arformoterol units sold to South Florida suppliers by the manufacturer and the three largest wholesalers to the number of units paid based on the Medicare claims files. We also compared the dollar amount submitted by South Florida suppliers to the amount distributed for sale in the region.

FINDINGS

After a utilization edit was implemented for budesonide, Medicare payments for the drug to South Florida suppliers were reduced by almost half. In the 6 months after the edit was implemented, there was a 46-percent decrease in Medicare payments for budesonide to South Florida suppliers (\$13 million less than in the 6 months before the edit). In fact, 39 high-dollar South Florida suppliers either completely stopped or reduced billing for budesonide after the edit was put in place.

Medicare payments for arformoterol to South Florida suppliers more than doubled after a utilization edit for budesonide was implemented. In the 6 months after the budesonide edit was put in place, arformoterol billings by South Florida suppliers increased by 53 percent and Medicare payments for the drug to South Florida suppliers increased by 138 percent compared to billings and payments from 6 months prior. After the September 2008 budesonide edit, decreases in Medicare expenditures for

budesonide were offset by increases in expenditures for arformoterol. In fact, 169 South Florida suppliers either started billing or had billing increases for arformoterol within the 6 months after the edit was implemented.

We estimate that in 2008 and the first half of 2009, Medicare paid South Florida suppliers for up to 10 times more units of arformoterol than were distributed for sale in the area. In 2008 and the first half of 2009, Medicare paid for 7 million units of arformoterol, but the manufacturer and the 3 largest wholesalers sold only 750,000 units to suppliers in the area. As a result, Medicare paid South Florida suppliers for nearly 10 times more units of arformoterol than the drug's manufacturer and the 3 largest wholesalers sold to South Florida suppliers. Even when factoring in the 25 percent to 30 percent of missing sales data (i.e., sales from sources other than the manufacturer and the three largest wholesalers), it is highly unlikely that South Florida suppliers provided beneficiaries with this volume of arformoterol.

Based on data for the manufacturer and the 3 largest wholesalers, Florida suppliers billed Medicare for up to 17 times more than the amount that could have legitimately been billed. Had all South Florida sales reported by Sepracor and the three largest wholesalers gone to beneficiaries, the program would have spent \$3.7 million on arformoterol in the area in 2008 and the first half of 2009. Instead, South Florida suppliers billed Medicare for \$62 million, of which the program paid \$34 million.

The majority (65 percent) of the Miami-Dade County suppliers billing for arformoterol in 2008 and the first half of 2009 never purchased arformoterol from the drug's manufacturer or the three largest wholesalers in this period. In fact, three-fourths of the suppliers with the most arformoterol billings in Miami-Dade County did not purchase a unit of the drug from arformoterol's manufacturer and the three largest wholesalers.

RECOMMENDATIONS

South Florida is known for its susceptibility to Medicare fraud, particularly by DME suppliers. A previous Office of Inspector General (OIG) report identified potential fraud related to billings for budesonide by South Florida suppliers. In September 2008, a CMS contractor implemented an automated edit to detect and deny claims that exceed

the maximum milligrams that a physician can safely prescribe to a beneficiary for budesonide. Our findings indicate that this edit did in fact decrease budesonide billings by and Medicare payments to South Florida DME suppliers. However, South Florida suppliers instead began billing for another brand-name inhalation drug, arformoterol. The substantial difference between the sales data provided by arformoterol's manufacturer and the claims data for South Florida suppliers suggests that these suppliers were billing for drugs that may not have been actually purchased. Therefore, we recommend that CMS:

Require DME contractors to implement utilization edits in high-fraud areas as soon as Medicare begins paying for a brand-name drug.

Monitor utilization changes among brand-name inhalation drugs.

Strengthen initial claim review processes to focus on prevention of improper payments.

Perform site visits and request documentation from South Florida suppliers to support budesonide and arformoterol billings.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all four of our recommendations (one of the concurrences included a caveat) and described steps that the agency has taken to resolve problematic billings for brand-name inhalation drugs by DME suppliers in South Florida and in certain other areas of the country. CMS generally concurred with our recommendation about utilization edits for brand-name inhalation drugs, but included the caveat that certain procedures, such as developing and issuing an LCD, would need to be followed before implementing these edits. OIG acknowledges the importance of CMS's requirements; however, budesonide and arformoterol had utilization guidelines in an LCD years before prepayment edits were implemented. CMS agreed with our recommendations to monitor utilization changes and strengthen initial claim review processes. CMS stated that to address the latter it would recommend that its contractors include late-billing suppliers as an additional risk indicator. Finally, CMS concurred with our recommendation to review problematic suppliers and provided details about its planned actions.

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BACKGROUND

Medicare payments for DME have consistently been vulnerable to fraud and abuse. In particular, the South Florida region has been identified by the Office of Inspector General (OIG), the Centers for Medicare & Medicaid Services (CMS), and other agencies as a high-risk area for fraudulent billings to Medicare by DME suppliers.

A 2009 OIG report found that brand-name inhalation drugs appear to be especially prone to aberrant billings by South Florida DME suppliers, which could lead to improper Medicare payments.¹ For example, in the second half of 2007, 75 percent of South Florida beneficiaries who received the brand-name drug budesonide had paid claims that exceeded the drugs' utilization guideline for a 90-day period. A CMS contractor implemented an edit in September 2008 to detect and deny budesonide claims that exceed the utilization guideline.

Another previous OIG report² has shown that pricing and payment concerns may affect which inhalation drug a supplier will provide. This current report will determine how the edit affected billing and payment for budesonide and whether utilization shifted to the newer brand-name inhalation drug arformoterol. Although both drugs are prescribed to treat conditions affecting the lungs, large shifts from budesonide to arformoterol should not be expected because the drugs are not interchangeable in terms of approved use or classification.

¹ OIG, *Aberrant Claim Patterns for Inhalation Drugs in South Florida* (OEI-03-08-00290), April 2009.

² OIG, *Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B* (OEI-03-07-00440), August 2009.

Medicare Part B Coverage of Inhalation Drugs

Although Medicare Part D covers most outpatient prescription drugs, CMS continues to cover a limited number of prescription drugs and biologicals (hereinafter referred to as drugs) under its Part B benefit. These drugs generally fall into three categories: injectable drugs administered by a physician, drugs explicitly covered by statute, and drugs administered through DME.³ Inhalation drugs, a class of DME drugs requiring a nebulizer, are prescribed to treat and prevent symptoms brought on by lung diseases, such as asthma and chronic obstructive pulmonary disorder.

Beneficiaries typically obtain inhalation drugs through DME suppliers, which purchase the drugs either directly from the manufacturer or from a distributor/wholesaler (hereinafter referred to as wholesalers).⁴ DME suppliers that purchase large quantities of a drug likely receive volume discounts from the manufacturer and/or wholesaler.⁵ Three wholesalers account for around 90 percent of the prescription drug market.⁶

DME suppliers typically submit claims for DME items to Medicare on behalf of the beneficiaries. In general, DME claims should be submitted within 12 months of the service dates.⁷ For an inhalation drug to be eligible for Medicare reimbursement, the DME supplier must have a signed prescription from the treating physician and the submitted claim form must list the physician's identification number.

Once Medicare receives the claim, it has up to 30 calendar days to pay or deny it.⁸ Generally, Medicare will pay 80 percent of the authorized reimbursement amount to the DME supplier providing the inhalation drug; the beneficiary is responsible for the remaining 20 percent in the form of coinsurance. CMS has implemented several initiatives that

³ 68 Fed. Reg. 50428, 50429 (Aug. 20, 2003).

⁴ See Appendix A for a description of the DME supplier enrollment process.

⁵ OIG, *Excessive Medicare Reimbursement for Albuterol* (OEI-03-01-00410) March 2002; *Excessive Medicare Reimbursement for Ipratropium Bromide* (OEI-03-01-00411), March 2002.

⁶ Market Watch, *Growing Share of 'Big Three' Gets Federal Attention*. Accessed at <http://www.marketwatch.com> on July 23, 2009. The three wholesalers are Cardinal Health, Inc., McKesson, and AmerisourceBergen.

⁷ Social Security Act, § 1848(g)(4), 42 U.S.C. § 1395w-4.

⁸ Claims submitted by certain problem suppliers may be placed on a prepayment review and are subject to a medical review before the claims are paid. Payment in these cases may exceed the 30 calendar days allotted to pay or deny the claims.

enable contractors to conduct prepayment or postpayment reviews of certain submitted claims.⁹

CMS contracts with four geographically defined DME Medicare Administrative Contractors (MAC) to process and pay for DME claims.¹⁰ CMS also contracts with Program Safeguard Contractors (PSC)¹¹ and Zone Program Integrity Contractors (ZPIC)^{12, 13} to perform benefit integrity¹⁴ and medical review functions for each of the four DME MAC jurisdictions.

DME Coverage Determinations

CMS may establish national coverage determinations for DME items (including inhalation drugs).¹⁵ National coverage determinations specify whether certain medical items, services, procedures, or technologies are eligible for Medicare payment. DME MACs and PSCs are required to follow national coverage determinations when they exist.

However, when a national coverage determination does not exist or when there is need for further definition, DME MACs may establish or revise a local coverage determination (LCD).¹⁶ The LCD defines coverage criteria, coding rules, and documentation requirements that will be applied to DME claims processed by DME MACs. Because many DME suppliers operate nationally, CMS requires that LCDs involving DME items (including inhalation drugs) be identical among all four

⁹ For example, the National Correct Coding Initiatives Edits, Medically Unlikely Edits, and the Medical Review Program can be used to review claims prior to paying; the Comprehensive Error Rate Testing Program, Recovery Audit Contractors, and the Medical Review Program can be used for reviewing claims after payment.

¹⁰ The four DME MAC contractors are National Heritage Insurance Company for Jurisdiction A; AdminaStar Federal, Inc., for Jurisdiction B; CIGNA Government Services, LLC, for Jurisdiction C; and Noridian Administrative Services for Jurisdiction D.

¹¹ Social Security Act, § 1893.

¹² CMS, *CMS Enhances Program Integrity Efforts to Fight Fraud, Waste and Abuse in Medicare*. Accessed at <http://www.cms.hhs.gov> on July 23, 2009.

¹³ CMS is transitioning PSC work to ZPICs. There are seven ZPIC jurisdictions. Two ZPICs became operational in February 2009, and CMS expects that by the end of 2010, all PSC work will be transitioned to ZPICs. Until the transition is complete, PSCs and ZPICs will both be responsible for the benefit integrity of DME claims (as well as all Parts A and B claims).

¹⁴ Benefit integrity refers to functions that prevent, detect, and deter Medicare fraud.

¹⁵ Social Security Act, § 1862(a)(1).

¹⁶ Since March 1, 2008, DME MACs have had full responsibility for developing and revising LCDs. However, before that date, PSCs developed the LCDs and submitted them to DME MACs (or its predecessors, the DME regional carriers) for approval.

DME MACs. Therefore, coverage determinations for DME items are the same in all four DME MAC jurisdictions.

An LCD (L5007) was established for nebulizers and related inhalation drugs effective April 1997.¹⁷ One function of this LCD was to set guidelines for the maximum milligrams per month that may reasonably be billed for certain inhalation drugs.¹⁸ This LCD states that claims exceeding these guidelines will be denied as not medically necessary. As required by CMS, the LCD is effective nationally, meaning that it applies to inhalation drug claims in all four DME MAC jurisdictions. To enforce the LCD for certain drugs, CMS has implemented computerized edits to automatically detect and deny claims that exceed the utilization guidelines.

Brand-Name Inhalation Drugs: Budesonide and Arformoterol

Budesonide. Budesonide (brand name Pulmicort Respules) is an inhaled corticosteroid used in conjunction with a nebulizer. The Food and Drug Administration (FDA) approved budesonide on August 8, 2000, for the “maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years of age.”¹⁹ Physicians may legally prescribe this drug to older patients to treat respiratory disorders; however, such prescriptions would be considered an off-label use of the drug.²⁰

Over time, the Medicare payment amount for a unit (i.e., one vial of up to 0.5 milligram) of budesonide has gradually increased.²¹ In the first quarter of 2008, Medicare paid \$5.09 per unit, but paid \$5.39 in the fourth quarter of 2008 (and paid \$6.42 in the second quarter of 2010).

In 2008, DME suppliers billed Medicare \$426 million for budesonide inhalation solution, of which the program paid \$297 million. The amount billed and paid for beneficiaries in South Florida was

¹⁷ CMS, *LCD for Nebulizers*. Accessed at <http://www.cms.gov> on January 14, 2010.

¹⁸ As of its most recent update on January 1, 2010, the LCD has maximum milligram billing guidelines for 14 inhalation drugs and solutions.

¹⁹ FDA, label for Pulmicort Respules (budesonide inhalation solution). Accessed at <http://www.accessdata.fda.gov> on October 27, 2009.

²⁰ Off-label use refers to the practice of prescribing medications approved by FDA for a purpose outside the scope of the drugs’ approved label.

²¹ The Medicare payment amount for most Part B drugs, including inhalation drugs, is equal to 106 percent of the volume-weighted average sales price (ASP). Section 1847A(c) of the Social Security Act defines an ASP as a manufacturer’s sales of a drug to all purchasers in the United States in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in that same quarter, net of any price concessions.

substantially higher than the amount billed and paid for beneficiaries in counties not located in South Florida (see Table 1).

Table 1: Medicare Amounts Billed and Paid for Budesonide in 2008

Beneficiary Location	Total Billed	Total Paid
Three South Florida Counties		
Miami-Dade	\$93.9 mil	\$48.9 mil
Broward	\$5.1 mil	\$2.9 mil
Palm Beach	\$2.0 mil	\$1.4 mil
Top Three Billing Counties Not in South Florida		
Cook, IL	\$2.7 mil	\$1.8 mil
Sedgwick, KS	\$1.9 mil	\$1.4 mil
Dallas, TX	\$1.8 mil	\$1.4 mil

Source: OIG analysis of 2008 DME claims file, August 2009.

South Florida suppliers billed for 97 percent of the budesonide claims associated with area beneficiaries. These suppliers accounted for a quarter of the total amount billed to Medicare nationwide for budesonide and 18 percent of total payments for the drug. Suppliers in this region also billed over \$900 more per beneficiary for budesonide annually, on average, when compared to the amounts billed by suppliers in the rest of the country.

Utilization guidelines that define the maximum monthly dose of budesonide were added to the LCD for nebulizers and related inhalation drugs on July 1, 2007. According to staff from a CMS contractor, on September 19, 2008, an automated edit was implemented by the DME MAC and PSC covering Jurisdiction C (the region including South Florida) to detect and deny budesonide claims that exceed the guidelines.

Arformoterol. Arformoterol (brand name Brovana) functions as a long-acting bronchodilator and is approved to treat chronic obstructive pulmonary disorder (but not asthma) in adults. FDA issued a black box warning²² for arformoterol and many other long-acting bronchodilators

²² A black box warning is designed to warn of serious adverse reactions that may lead to death or serious injury. See 21 CFR § 201.57(a)(4).

because data indicated an increased incidence in asthma-related deaths in patients receiving salmeterol, the active ingredient in this class of drug.²³ FDA approved arformoterol in October 2006, and its manufacturer, Sepracor, began marketing the drug in April 2007.

On January 1, 2008, CMS established a payment amount and billing code for arformoterol.²⁴ During that quarter, the Medicare payment amount for one vial was \$4.72. This amount had increased to \$5.23 by the second quarter of 2010.

In 2008, DME suppliers billed Medicare \$75 million for arformoterol, of which the program paid \$47 million. Even though only 2 percent of Medicare beneficiaries lived in South Florida, these beneficiaries accounted for 43 percent of the amount billed nationwide and 31 percent of the amount paid by Medicare for arformoterol.²⁵ The majority (98 percent) of the claims for South Florida beneficiaries were billed by suppliers located in South Florida (see Table 2).

Table 2: Medicare Amounts Billed and Paid for Arformoterol in 2008

Beneficiary Location	Total Billed	Total Paid
Three South Florida Counties		
Miami-Dade	\$29.1 mil	\$13.0 mil
Broward	\$2.5 mil	\$1.0 mil
Palm Beach	\$554,000	\$395,000
Top Three Billing Counties Not in South Florida		
Harris, TX	\$571,000	\$183,000
Cook, IL	\$371,000	\$267,000
Los Angeles, CA	\$351,000	\$238,000

Source: OIG analysis of 2008 DME claims file, August 2009.

²³ Label for Brovana (arformoterol tartrate) Solution. Accessed at <http://www.accessdata.fda.gov> on July 17, 2009.

²⁴ Prior to 2008, suppliers would bill using a “Not Otherwise Classified Nebulizer Drug Code” and indicate on the claim form that the drug was arformoterol.

²⁵ CMS, *Medicare Enrollment Reports*. Accessed at <http://www4.cms.gov/MedicareEnrpts/> on June 3, 2010. The most recent enrollment report available was last updated on July 1, 2007.

Utilization guidelines for arformoterol were added to the LCD on July 1, 2007. As of March 2010, an automated edit for arformoterol had not been put in place.

Medicare Fraud in South Florida

OIG's numerous reports, criminal indictments, and convictions involving providers in South Florida have identified vulnerabilities that have put the Medicare program at risk for fraud and/or abuse. OIG studies have involved unannounced site visits to verify that DME suppliers meet certain supplier standards and analysis of claim patterns related to infusion therapy providers and DME suppliers.

In March 2007, a Medicare Strike Force of Federal, State, and local investigators began operating in high-fraud areas (including South Florida) to detect, prosecute, and prevent Medicare fraud by DME suppliers. As of May 31, 2010, the Strike Force's efforts have resulted in charges against over 550 defendants; over 300 convictions; the sentencing of over 250 defendants; and over \$260 million in court-ordered restitutions, fines, and penalties.²⁶

The Medicare Strike Force found that one method used to defraud Medicare involved South Florida DME suppliers' paying physicians to write fraudulent inhalation drug prescriptions and paying Medicare beneficiaries to accept the unnecessary medications or to help create the appearance that the drugs were delivered. Beneficiaries could receive up to \$150 per month or \$300 per falsified visit for use of their Medicare identification numbers. In many cases, beneficiaries have testified that they threw away the inhalation drugs upon receipt or that the DME supplier instructed them to sign fake delivery receipts even though they had not received any equipment or medication.²⁷ Physicians have also testified that they had falsely diagnosed beneficiaries and prescribed unnecessary inhalation drugs for these fictitious diagnoses.²⁸ In

²⁶ *Hearing on Reducing Fraud, Waste and Abuse in Medicare*, Hearing Before the U.S. House Committee on Ways and Means, Subcommittees on Health and Oversight, 111th Cong. (2010) (Testimony of Lewis Morris, Chief Counsel to the Inspector General, Department of Health & Human Services).

²⁷ Department of Justice (DOJ) Press Release, June 28, 2007, *Medicare Fraud Strike Force Convicts Owner of Miami Durable Medical Equipment Company of Defrauding Medicare*. Accessed at <http://www.usdoj.gov> on December 18, 2007. DOJ Press Release, March 7, 2008, *Miami Jury Convicts Physician and Three Business Owners of Medicare Fraud*. Accessed at <http://miami.fbi.gov> on April 15, 2008.

²⁸ DOJ Press Release, July 11, 2008, *Miami Doctor Sentenced to 41 Months in Prison for Medicare Fraud*. Accessed at <http://www.miami.fbi.gov> on January 22, 2010.

multiple cases, medical personnel allegedly conspired with a South Florida DME supplier to create the appearance that the beneficiary qualified for and received services and/or drugs that were not medically necessary and/or were not provided.

However, beneficiaries and physicians are not always aware that DME suppliers are using their Medicare identification numbers for fraudulent activities. For example, a Miami DME owner pleaded guilty in August 2009 to billing Medicare \$123 million in fraudulent DME claims that had not been prescribed or ordered by a physician or delivered to a beneficiary. In cases such as this, a DME supplier fraudulently obtains beneficiary identification information and uses a physician's identification number without the physician's consent or knowledge.^{29, 30}

In May 2009, efforts to fight and reduce Medicare fraud were renewed through the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative. See Appendix B for a full description of related OIG reports and governmental efforts to reduce Medicare fraud in South Florida.

METHODOLOGY

Data Sources and Collection

Medicare claims data. We used the Medicare National Claims History (NCH) file to identify all Part B claims for budesonide and arformoterol in 2008 and the first half of 2009.³¹ To identify where the supplier submitting each claim was located, we cross-referenced the supplier identification number listed in the claims file to the supplier identification number listed in the 2008 or the 2009 National Supplier Clearinghouse (NSC) file. We then selected all claims submitted by suppliers located in South Florida (i.e., Miami-Dade, Broward, or Palm Beach Counties). In 2008 and the first half of 2009, 609 South Florida suppliers submitted 204,603 claims for budesonide

²⁹ DOJ Press Release, April 1, 2008, *Miami-Dade DME and Clinic Owners Indicted for Using Stolen Patient Information in Multi-million Dollar Medicare Fraud Scheme*. Accessed at <http://www.usdoj.gov> on October 1, 2008.

³⁰ DOJ Press Release, August 14, 2009, *Miami Man Pleads Guilty to \$123 Million Medicare Fraud Scheme*. Accessed at <http://miami.fbi.gov> on August 31, 2009.

³¹ For arformoterol, we obtained an updated 2009 claims data file after our initial data request. We used this file to summarize supplier billing and payment information for all arformoterol claims in the entire year.

and 305 South Florida suppliers submitted 79,878 claims for arformoterol. See Table 3 for the total number of suppliers billing for budesonide and arformoterol in each South Florida county for the entire period.

Table 3: Number of South Florida DME Suppliers Billing for Budesonide and Arformoterol in 2008 and the First Half of 2009

County	Number of Suppliers in 2008 and First Half of 2009 Billing for Budesonide	Number of Suppliers in 2008 and First Half of 2009 Billing for Arformoterol
Broward	77	27
Miami-Dade	453	242
Palm Beach	79	36
Total	609	305

Source: OIG analysis of DME claims files, 2010.

Manufacturer sales data. We contacted arformoterol’s manufacturer, Sepracor, and asked that it provide us with the total number of vials of arformoterol sold in 2008 and 2009 to DME suppliers located in South Florida (whether directly or through a wholesaler). We also asked for information to identify the suppliers to which arformoterol was sold (e.g., suppliers’ names, any other known business names, and addresses).³²

In November 2009, Sepracor provided the requested sales data for all of 2008 and the first three quarters of 2009. Sepracor provided sales data for any direct sales activity (i.e., the manufacturer sells directly to the end user) and sales data for the three largest wholesalers.³³ Sepracor estimated that these three wholesalers accounted for approximately 70 percent to 75 percent of all arformoterol sales to wholesalers. These

³² We had also contacted budesonide’s manufacturer, AstraZeneca, and requested similar sales data for budesonide. AstraZeneca provided data in May 2010; however, the data provided were not at the level of detail necessary for an analysis of sales to South Florida suppliers.

³³ Sepracor’s only direct sales were to two Broward County suppliers. The exact number of suppliers with purchases from the three largest wholesalers could not be determined for confidentiality reasons. At a minimum, data pertaining to the 3 largest wholesalers included 123 Miami-Dade County suppliers, 55 Broward County suppliers, and 29 Palm Beach County suppliers.

data included, in addition to the number of arformoterol units sold, the transaction date, business name, and address for each sale to every South Florida supplier that purchased the drug either directly or through one of the three largest wholesalers.

Because of contractual commitments between the three largest wholesalers and certain suppliers, Sepracor was unable to provide identification information for all suppliers. Sepracor commented that the unidentified suppliers were typically large, retail, chain pharmacies. Sepracor provided only the suppliers' ZIP Codes and counties associated with these transactions.

In addition, we accessed CMS's ASP background files to obtain the total arformoterol units sold nationwide from the first quarter of 2008 through the second quarter of 2009.³⁴ The ASP background files contain manufacturer-reported sales of the drug to all purchasers in the United States (not just to Medicare beneficiaries).

Supplier data. We spoke with our Office of Investigations (OI) about certain suppliers that we identified as having questionable billing patterns. OI provided us with information regarding indictments and investigations related to the suppliers in question. In addition, staff from DOJ provided us with details of a recent NSC site visit to a South Florida supplier.

Data Analysis

Billing shifts in budesonide and arformoterol. To identify billing changes after the budesonide edit was implemented on September 19, 2008, we analyzed claims by both the dates of service and the dates the claims were received for processing.

We subset the drug's claims for services occurring up to 180 days before the edit's implementation (March 23 to September 18, 2008) and up to 180 days after the edit's implementation (September 19, 2008, to March 17, 2009). We calculated the percentage difference in billing and payments for budesonide before and after the edit. We performed this same calculation for arformoterol.

For both drugs, we used the subset files described in the above paragraph to determine the number of Florida suppliers that (1) billed Medicare for units provided before the edit but did not bill after the edit,

³⁴ Each quarter, certain manufacturers must report to CMS the ASPs of their Part-B covered drugs as well as the number of units sold in the quarter.

(2) did not bill for units before the edit but began billing after the edit, and (3) billed for units provided both before and after the edit. For suppliers in each group, we determined the extent of changes in billing and payment amounts for budesonide and arformoterol.

For arformoterol, we also used the date that the supplier actually submitted the claim for processing to analyze billing shifts. To do so, we determined the amount billed in each month in 2008 and the percentage of total 2008 dollars that were submitted after the edit using the receipt date listed on the claim (i.e., the date the DME MAC receives the claim from the supplier).

Arformoterol sales data and Medicare claims data. We first compared the number of units and total dollars paid for by Medicare in South Florida to the number of units sold in the area by the manufacturer and the three largest wholesalers. Using claims data in the NCH file for 2008 and the first half of 2009, we determined the number of arformoterol units paid per South Florida supplier by dividing the amount paid on each claim by the Medicare payment amount for the quarter when the service was provided (the Medicare payment amount represents one unit of the drug).³⁵ We summed the total number of arformoterol units paid by Medicare to suppliers in South Florida. Using the sales data Sepracor provided, we then calculated the total number of arformoterol units sold by Sepracor and the three largest wholesalers to South Florida suppliers in 2008 and the first half of 2009 (one vial is equal to one unit). We compared the total number of units sold to South Florida suppliers to the total number of units that were paid by Medicare.

We then compared the amount billed (i.e., submitted charges) to Medicare by South Florida suppliers to the amount sold by the manufacturer and the three largest wholesalers. Because Medicare claims data do not have a variable for units “billed,” we could do this comparison only by the total dollar amount billed. To estimate the dollar amount of arformoterol that could have been billed by area suppliers, we multiplied the number of units sold to South Florida suppliers (according to Sepracor’s data) by the Medicare payment amount for each quarter. We summed the quarterly figures and

³⁵ These claims data contained a total service variable; although our estimate is similar to the total services in the claims file, our method used to calculate units paid was a more conservative estimate.

compared this total figure to the total amount actually billed by South Florida suppliers and paid by Medicare during this time.

Accounting for arformoterol units not sold by the manufacturer or the three largest wholesalers. We used CMS's quarterly ASP background files to obtain the total number of arformoterol units Sepracor sold in 2008 and the first half of 2009. This figure represents total sales in the entire country and includes non-Medicare beneficiaries. To account for the 25 percent to 30 percent of sales data we were unable to obtain from Sepracor, we multiplied the total number of units sold during each quarter by 30 percent. This provided us with an estimate of the maximum number of total possible units South Florida suppliers could have purchased from an entity other than the manufacturer or the three largest wholesalers. We added this figure to the number of units sold to South Florida suppliers from Sepracor's data to get the total possible units that could have been sold to South Florida suppliers. We compared the "total possible units" figure to the number of units paid by Medicare.

Arformoterol sales data for individual DME suppliers in Miami-Dade County. We focused a portion of our sales analysis on individual suppliers in Miami-Dade County. As shown in Table 3, the 242 Miami-Dade County suppliers represented the majority (79 percent) of South Florida suppliers billing for arformoterol between January 2008 and June 2009. We linked the arformoterol units in the claims data to the units in Sepracor's sales data using the name and address for each Miami-Dade County supplier. We determined the number of suppliers billing Medicare for arformoterol that were not listed in the South Florida sales data provided by Sepracor. As previously mentioned, Sepracor was unable to provide us with the specific sales data for certain large retail pharmacies. We identified 42 large retail pharmacies with claims data that did not have sales data. The large retail pharmacies accounted for less than 1 percent of Medicare billings by all Miami-Dade suppliers and we removed them from this analysis. By doing so, we were left with 200 Miami-Dade County suppliers for which we calculated unit differences between paid Medicare claims and the total sales data for Sepracor and the three largest wholesalers. We summed the total dollar amount billed to and paid by Medicare for Miami-Dade suppliers that did not appear in Sepracor's sales data (again, excluding large retail pharmacies).

We also identified the top 20 billing suppliers in South Florida by arraying the claims data for 2008 and the first half of 2009 by the total

amount each South Florida supplier billed for arformoterol. All of the top 20 billing suppliers were located in Miami-Dade County. We compared the total number of units paid in the claims data to the number of units sold to the suppliers by Sepracor and the three largest wholesalers.

Limitations

Sepracor was able to provide information pertaining to direct sales and sales by the three largest wholesalers. Because direct sales were to two suppliers, the sales most likely accounted for a small percentage of total sales. However, Sepracor did not estimate the direct sales' percentage of total sales. Sepracor noted that the three largest wholesalers account for approximately 70 percent to 75 percent of arformoterol sales. Sepracor was unable to provide sales information for wholesalers other than the three largest wholesalers, meaning that we may be missing as much as 30 percent of the sales data for arformoterol. In addition, Sepracor's data account for all sales of the drug (e.g., Medicare, Medicaid, private payers). In other words, the data provided by Sepracor are not limited to the product that was used by Medicare beneficiaries.

Our comparisons between the sales data provided by Sepracor and the Medicare claims data do not account for units of arformoterol that were sold to a South Florida DME supplier in 2007 and then provided by the DME supplier to Medicare beneficiaries in 2008. Conversely, our comparisons also do not account for the likelihood that some of the units included in Sepracor's data that were sold to a South Florida DME supplier in the first half of 2009 would not have been provided to a Medicare beneficiary until later that year (i.e., after the period covered by our analysis).

Standards

This study was conducted in accordance with the *Quality Standards for Inspections* approved by the Council of the Inspectors General on Integrity and Efficiency.

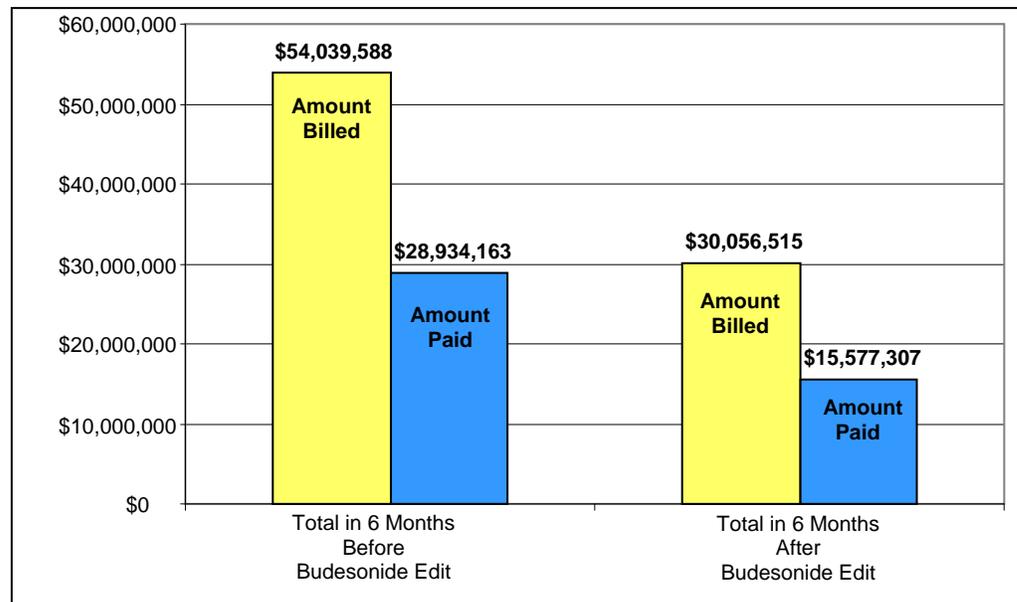
► FINDINGS

After a utilization edit was implemented for budesonide, Medicare payments for the drug to South Florida suppliers were reduced by almost half

In September 2008, a CMS contractor covering South Florida implemented an automated edit to detect and deny budesonide claims

that exceeded the drugs' utilization guideline listed in the LCD for nebulizers and related inhalation drugs.³⁶ In the 6 months after the edit's implementation, Medicare paid \$13 million less to South Florida suppliers for budesonide (for a 46-percent decrease) and these suppliers billed \$24 million less for budesonide (for a 44-percent decrease) when compared to the 6 months before the edit.³⁷ Figure 1 illustrates the changes in payment and billing behavior of South Florida suppliers before and after the edit was implemented.

Figure 1: Before and After the Budesonide Edit—Amount Billed and Paid to South Florida Suppliers for Budesonide



Source: OIG analysis of 2008 and 2009 DME claims data, 2010.

³⁶ See OEI-03-08-00290 for more detail on budesonide claim patterns in South Florida. This report found that during a 90-day period in 2007, approximately 75 percent of South Florida beneficiaries with budesonide claims exceeded this utilization guideline before the edit was implemented.

³⁷ Six months refers to the 180 days before the edit was implemented on September 19, 2008, and the 180 days after the edit was implemented. For the remainder of this finding, comparisons before the edit to after the edit refer to this period.

After the budesonide edit took effect, 39 of 41 high-dollar South Florida suppliers either completely stopped or reduced billing for the drug

Thirteen high-dollar suppliers stopped billing after the edit. Nearly 30 percent (119 of 414) of the South Florida suppliers that had billed Medicare for budesonide in the 6 months before the edit completely stopped billing for budesonide in the 6 months after the edit. Most of these suppliers had billed only small amounts before the edit. However, 13 high-dollar suppliers that submitted \$12 million in budesonide claims to Medicare in the 6 months before the edit stopped billing completely.³⁸ If the nearly 12,000 claims submitted by the 13 high-dollar suppliers during the prior 6 months were accurate, this would mean that these suppliers stopped providing budesonide to all 3,628 beneficiaries that had received the drug before the edit.

In the 6-month period before the edit took effect, 2 of the 13 suppliers were indicted for alleged Medicare fraud. These suppliers were believed to be billing for services not rendered. In each case, the physicians did not know and did not prescribe the medications for the beneficiary listed on the claim.³⁹

Twenty-six high-dollar suppliers significantly reduced billing after the edit.

Seventy-one percent of South Florida suppliers (295 of 414) that billed for budesonide in the 6 months before the edit continued to bill for the drug in the 6 months after the edit. Slightly more than half of these had decreases in their amounts billed. The decreases were greatest among suppliers that were the top billing suppliers in the 6 months before the edit. All but 2 of 28 high-dollar suppliers that continued billing for budesonide had billing decreases, some significant, in the 6 months after the edit.⁴⁰ For example, one supplier billed over \$800,000 in the 6 months before the edit, but less than \$1,000 in the 6 months after the edit. Combined, the 28 high-dollar suppliers billed \$13 million less in the 6 months after the edit (53-percent decrease).

³⁸ High-dollar suppliers were identified as suppliers that billed more than \$500,000 each for budesonide in the 6 months before the edit. Forty-one South Florida suppliers met this criterion.

³⁹ We referred the 11 remaining suppliers to OI for further investigation. See Appendix C for the criteria we used when referring all suppliers identified as potentially fraudulent in this report, and for further information from OI about the status of these referrals.

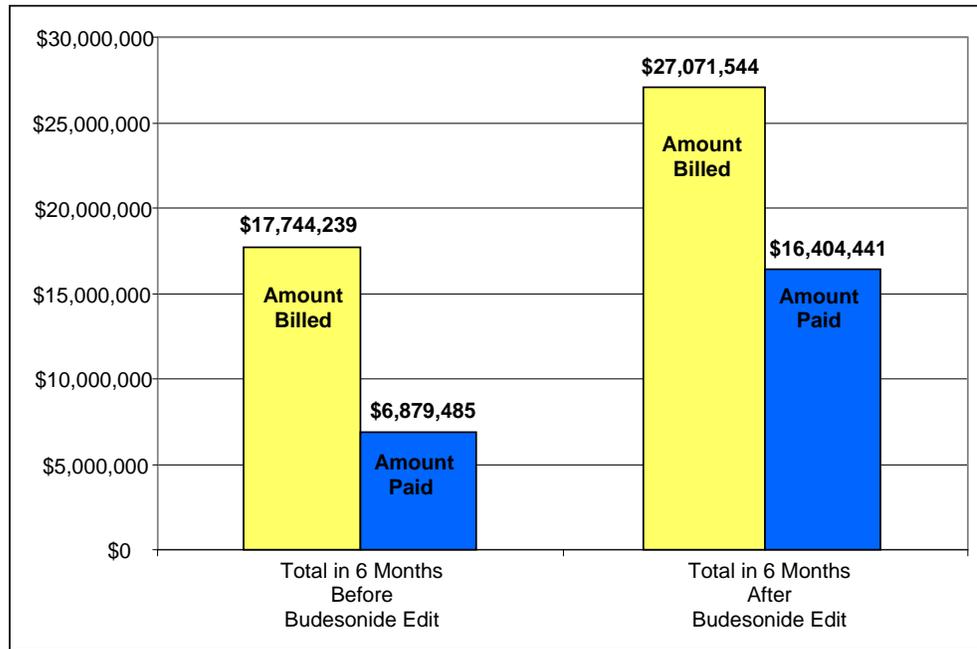
⁴⁰ We referred the 26 high-dollar suppliers with decreases in budesonide billings in the 6 months after the edit to OI for further investigation. See Appendix C for the criteria we used when referring all suppliers identified as potentially fraudulent in this report, and for further information from OI about the status of these referrals.

Medicare payments for arformoterol to South Florida suppliers more than doubled after a utilization edit for budesonide was implemented

Although a utilization edit reduced Medicare payments for budesonide in the 6 months following its implementation,

South Florida suppliers instead began billing in substantial amounts for the similarly expensive brand-name inhalation drug arformoterol (which was not subject to an edit).⁴¹ In the 6 months after the budesonide edit took effect, arformoterol billings by South Florida suppliers increased by 53 percent and Medicare payments for the drug to South Florida suppliers rose 138 percent compared to 6 months prior (see Figure 2).⁴²

Figure 2: Before and After the Budesonide Edit—Amount Billed and Paid to South Florida Suppliers for Arformoterol



Source: OIG analysis of 2008 and 2009 DME claims data, 2010.

⁴¹ Although both drugs treat lung diseases, large shifts from budesonide to arformoterol would not be expected. These drugs are not interchangeable in terms of approved use or classification.

⁴² Six months refers to the 180 days before the edit was implemented on September 19, 2008, and the 180 days after the edit was implemented. In the remainder of this finding, comparisons before the edit to after the edit refer to this period.

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In 2008, South Florida suppliers accounted for 44 percent of the total amount billed to Medicare for arformoterol (\$33 million of the \$75 million billed nationally). Furthermore, Medicare was billed more for beneficiaries in South Florida than for beneficiaries in the rest of Florida and the 18 next-highest-billing States combined. In 2009, South Florida suppliers accounted for 40 percent of arformoterol billings to Medicare (\$39 million of the \$97 million billed nationally).

In 2008, Medicare paid over \$14 million to South Florida suppliers for arformoterol; 45 percent of these payments were for services provided in the last quarter of 2008 (i.e., the quarter after the budesonide edit was implemented). Medicare payments for arformoterol increased in 2009. In fact, within the first 4 months of that year, Medicare payments to South Florida suppliers had already exceeded the 2008 total. By the end of 2009, Medicare payments to South Florida suppliers for arformoterol were more than double payments in the previous year.

One hundred sixty-nine suppliers increased or began billing for arformoterol after the edit. Nearly half of the South Florida suppliers that submitted arformoterol claims in the 6 months before the budesonide edit had billing increases in the 6 months after the edit (85 of 177 suppliers).⁴³ These 85 suppliers billed an average of nearly 5 times more for a total billing increase of \$13 million (\$3 million billed before the edit; \$16 million billed after).⁴⁴ Overall, 67 of the 85 South Florida suppliers billed amounts that were at least double the amounts billed before the budesonide edit. In an extreme case, a supplier billed nearly 3,000 times more for arformoterol than the amount billed before the edit. In total, Medicare payments to these 85 suppliers increased by \$8 million (341 percent increase).

In addition, in the 6 months after the edit, 84 South Florida suppliers began billing for arformoterol. For example, one supplier never billed for arformoterol in the 6 months before the edit, but billed \$1.6 million

⁴³ Among the 177 South Florida suppliers that billed for arformoterol before the edit, 53 suppliers did not bill for the drug in the 6 months after the edit and 39 suppliers billed the same amounts or had billing decreases.

⁴⁴ Thirteen of these suppliers billed more than \$500,000 each in the 6 months after the edit. We referred these 13 suppliers to OI for further investigation. See Appendix C for the criteria we used when referring all suppliers identified as potentially fraudulent in this report, and for further information from OI about the status of these referrals.

for the drug in the 6 months after the edit (Medicare paid 90 percent).⁴⁵ In total, these 84 suppliers billed Medicare \$5 million for arformoterol after the edit and were paid \$4 million.

South Florida suppliers submitted two-thirds of their arformoterol billings for 2008 to Medicare after the budesonide edit was put in place in September 2008

In the month after the budesonide edit was implemented (i.e., October 2008), South Florida suppliers billed Medicare for a quarter of the \$33 million submitted for arformoterol in 2008. This was more than double the amount South Florida suppliers billed in any other month before the edit (and significantly more than the total amount billed in any month for suppliers in the rest of the country). In total, 66 percent of arformoterol billings for 2008 services were submitted by South Florida suppliers after the edit was implemented. See Appendix D for a monthly breakdown of when South Florida suppliers submitted arformoterol claims.

In 2008, the top-billing South Florida supplier submitted \$8.4 million to Medicare for arformoterol. Based on claims data, the drug was supposedly provided to beneficiaries throughout the year, starting on January 31. However, this supplier submitted all but 1 of its more than 2,300 arformoterol claims beginning 2 days after the September 2008 edit was implemented. In other words, after claims for budesonide were subject to an edit, this supplier began submitting a large volume of claims for arformoterol that had supposedly been provided during the previous 8 months.

After the September 2008 budesonide edit, decreases to Medicare expenditures for budesonide were offset by increases in expenditures for arformoterol

Although the edit reduced Medicare expenditures for budesonide, because South Florida suppliers increased billing for arformoterol, Medicare actually paid more per month for both drugs combined soon after the edit took effect. For example, Medicare paid \$6.5 million for both drugs in August 2008 (\$1.7 million for arformoterol and \$4.8 million for budesonide). However, Medicare paid \$7 million for both drugs in March 2009 (\$4 million for arformoterol and \$3 million for

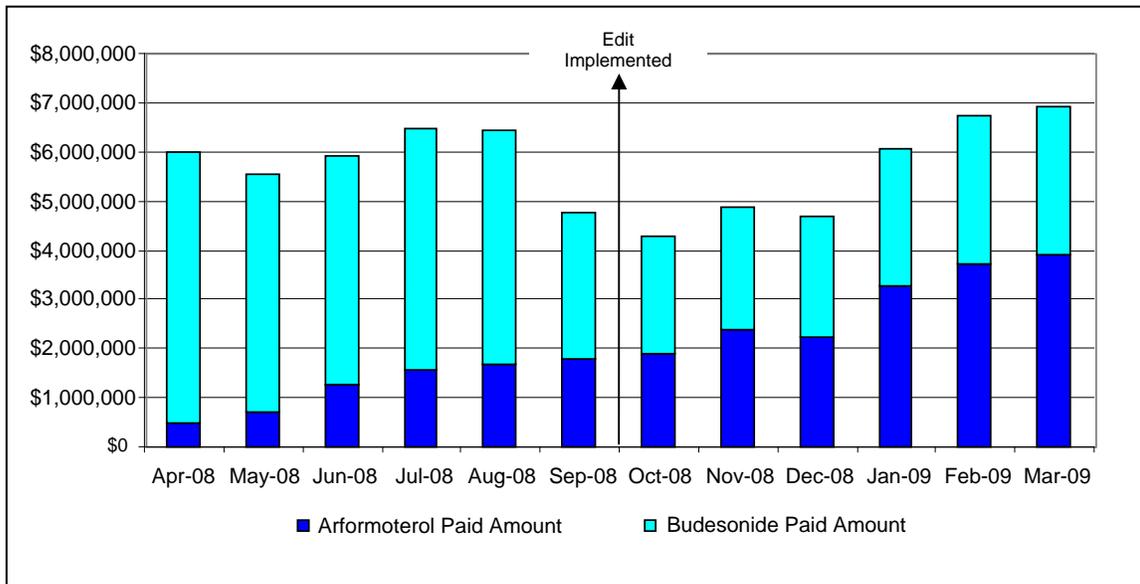
⁴⁵ We referred this supplier and an additional high-dollar supplier that began billing for arformoterol after the edit to OI for further investigation. See Appendix C for the criteria we used when referring all suppliers identified as potentially fraudulent in this report, and for further information from OI about the status of these referrals.

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budesonide). See Figure 3 for a monthly breakdown of combined Medicare payments for budesonide and arformoterol.

For example, budesonide billings for one Miami-Dade supplier decreased by more than 50 percent after the edit (\$654,000 billed in the 6 months before the edit; \$306,000 billed in the 6 months after the edit). Medicare denied the majority of the budesonide claims submitted by this supplier both before and after the edit. However, this supplier’s billing for arformoterol increased from just \$300 before the edit to \$856,000 after the edit. Even though Medicare had been denying the majority of this supplier’s budesonide claims, Medicare paid for 55 percent of the amount submitted for arformoterol after the edit, or \$474,000.

Figure 3: Medicare Payments to South Florida Suppliers for Budesonide and Arformoterol in the 6 Months Before and After the Budesonide Edit



Source: OIG analysis of the 2008 and 2009 DME claims data, 2010.

We estimate that in 2008 and the first half of 2009, Medicare paid South Florida suppliers for up to 10 times more units of arformoterol than were distributed for sale in the area

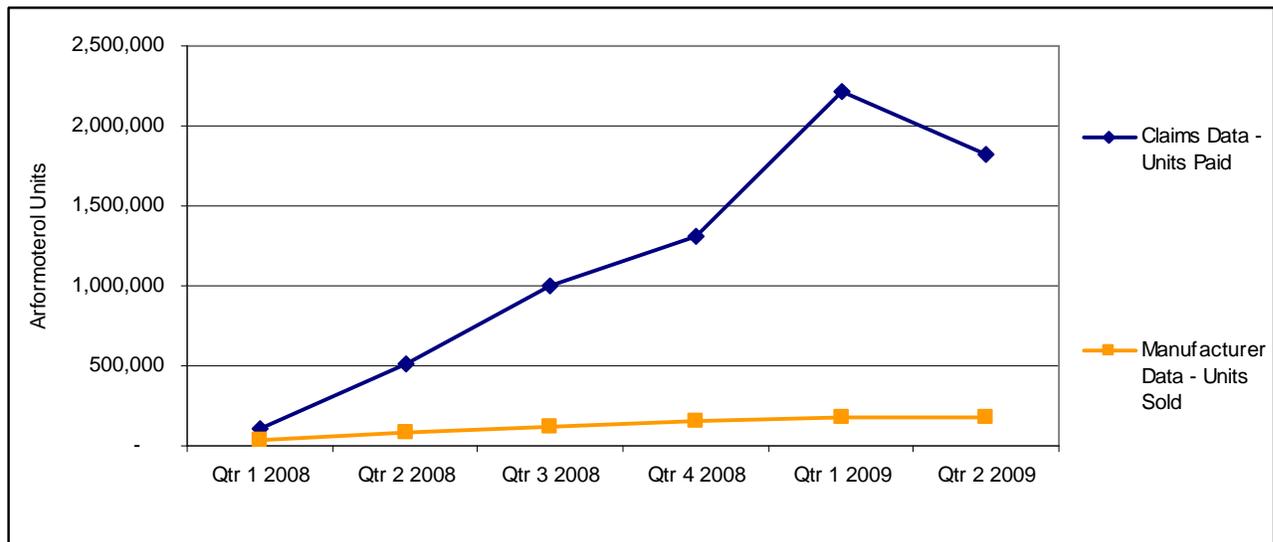
Although Medicare paid South Florida suppliers \$34 million for arformoterol between January 2008 and June 2009, it does not appear

that these suppliers purchased enough of the drug to justify these payments. During this time, Medicare paid for 7 million units of arformoterol, whereas the manufacturer and the 3 largest wholesalers sold only 750,000 units to suppliers in the area (approximately

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3 percent of total Sepracor sales of the drug). As a result, Medicare paid South Florida suppliers for nearly 10 times more units of arformoterol (6.2 million units) than the drug’s manufacturer and the 3 largest wholesalers sold to South Florida suppliers. See Figure 4 for a quarterly comparison of the number of units sold by the manufacturer and the three largest wholesalers to the number of units paid for by Medicare.

Figure 4: Comparison of Manufacturer’s Units Sold to Claims Data in South Florida (2008 and first half of 2009)



Source: OIG analysis of the 2008 and 2009 DME claims data and manufacturer data, 2010.

Even when factoring in the 25 percent to 30 percent of missing sales data, it is highly unlikely that South Florida suppliers purchased this quantity of the drug. According to our analysis of CMS’s ASP data, other wholesalers would have sold approximately 6.6 million units of arformoterol for all Medicare and non-Medicare arformoterol use in the entire country. To account for the amount paid by Medicare, South Florida suppliers would have needed to purchase nearly all of those 6.6 million units (94 percent) and provided them to Medicare beneficiaries only. Aside from the rampant fraud in South Florida, as well as the aberrant billing patterns for the drug, the fact that only 3 percent of the manufacturer’s and the three largest wholesalers’ sales went to South Florida suppliers makes this possibility seem highly unlikely. In addition, this addresses only the number of units paid and not the amount South Florida suppliers billed to Medicare.

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Records from a February 2009 NSC site visit provide evidence that South Florida suppliers are billing and receiving payments for inhalation drugs that were not actually purchased and provided to Medicare beneficiaries. Staff from NSC visited a Miami-Dade supplier that had billed Medicare \$600,000 and was paid \$33,000 for arformoterol in 2008 and the first half of 2009. During the site visit, NSC staff noted a limited inventory of DME items, including nebulizers and inhalation drugs. In addition, this supplier could not fulfill NSC's request to provide invoices or credit agreements showing that it actually purchased the inhalation drugs and DME items. It was recommended that this supplier's billing privileges be revoked.

Based on data from the manufacturer and the 3 largest wholesalers, South Florida suppliers billed Medicare for up to 17 times more than the amount that was distributed for sale in the region

Had all South Florida sales reported by Sepracor and the three largest wholesalers gone to beneficiaries, the program would have spent \$3.7 million on arformoterol in the area in 2008 and the first half of 2009. Instead, South Florida suppliers billed Medicare for \$62 million, or 17 times more than the amount the manufacturer and the 3 largest wholesalers could have sold in the region. Medicare actually paid \$34 million to South Florida suppliers for arformoterol.

Furthermore, South Florida suppliers billed Medicare for such an exceedingly large volume of arformoterol that this amount could not be accounted for in the 25 percent to 30 percent of sales by other wholesalers. Based on our analysis of CMS's ASP data, had every unit sold by an entity other than the manufacturer and the three largest wholesalers been purchased by a South Florida supplier for Medicare beneficiaries, Medicare would have spent \$36 million in this region. Therefore, the \$62 million billed by South Florida suppliers far exceeds total possible sales by the manufacturer, the three largest wholesalers, and any other wholesaler that could have provided arformoterol.

The majority of Miami-Dade County suppliers never purchased arformoterol from the drug's manufacturer or the three largest wholesalers in 2008 and the first half of 2009

Among South Florida suppliers, the majority billing for arformoterol in 2008 and the first half of 2009 were located in Miami-Dade County (79 percent). Sixty-five percent of Miami-Dade County suppliers that billed Medicare for arformoterol between January 2008 and June 2009

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did not purchase a unit of the drug from the drug's manufacturer or the three largest wholesalers during this period.⁴⁶ These suppliers billed Medicare for \$44 million, of which Medicare paid \$23 million (these figures represent 71 percent of total billings and 68 percent of total payments to Miami-Dade County suppliers).

Arformoterol's manufacturer and 3 largest wholesalers sold the drug to only 5 of the 20 Miami-Dade suppliers with the most arformoterol billings in South Florida. This means that 15 of these top-billing suppliers would have had to purchase arformoterol from another source. The 15 suppliers billed Medicare for \$29 million in 2008 and the first half of 2009; Medicare paid \$13 million of this.⁴⁷ Medicare paid these 15 suppliers for 2.6 million units of arformoterol that could not be accounted for in the sales data of the manufacturer and the 3 largest wholesalers. Because these suppliers were among the biggest providers of arformoterol in the country, they most likely would have had purchasing contracts with the drug's manufacturer or the largest wholesalers to obtain purchasing discounts.

Even the suppliers that did buy arformoterol from the manufacturer or the three largest wholesalers did not purchase enough to account for their high level of billings. For the five suppliers with sales data, Medicare paid an average of nine times more units than what was actually sold by the manufacturer and the three largest wholesalers.

⁴⁶ Again, these suppliers may have purchased arformoterol from another source. However, given the substantial purchasing and distribution of the drug from certain suppliers, these suppliers would have most likely purchased the drug directly from the manufacturer or one of the three largest wholesalers.

⁴⁷ Among the 15 suppliers, we referred to OI the 13 suppliers that billed Medicare over \$1 million for arformoterol during 2008 and the first half of 2009. See Appendix C for the criteria we used when referring all suppliers identified as potentially fraudulent in this report, and for further information from OI about the status of these referrals.



South Florida is known for its susceptibility to Medicare fraud, particularly by DME suppliers. Fraudulent billings jeopardize the financial integrity of Medicare and may endanger a beneficiary's well-being when drugs are overprescribed. Recent efforts, such as the HEAT initiative, have focused on reducing Medicare fraud, waste, and abuse in areas such as South Florida.

A previous OIG report identified potential fraud related to billings for budesonide by South Florida suppliers. In September 2008, a CMS contractor implemented an automated edit to detect and deny claims that exceed the maximum milligrams that a physician can safely prescribe to a beneficiary for budesonide. Our findings indicate that this edit did in fact decrease budesonide billings by and Medicare payments to South Florida DME suppliers. However, South Florida suppliers instead began billing for another brand-name inhalation drug, arformoterol. The substantial difference between the sales data provided by arformoterol's manufacturer and the claims data for South Florida suppliers suggest that these suppliers were billing for drugs that may not have been actually purchased. Therefore, we recommend that CMS:

Require DME contractors to implement utilization edits in high-fraud areas as soon as Medicare begins paying for a brand-name drug

The substantial drop in beneficiary utilization of budesonide after the edit brings into question the validity of many of the budesonide claims submitted by South Florida suppliers prior to the edit. The fact that such a large number of suppliers stopped providing this drug further illustrates this point.

Even though the edit resulted in lowering budesonide payments, Medicare could not realize the savings because South Florida suppliers instead began to bill for a new high-dollar, brand-name inhalation drug. Within a few months after the edit, Medicare decreases in expenditures for budesonide were offset by increases in expenditures for arformoterol. Medicare should require DME MACs and PSCs (or their successor, the ZPICs) to implement payment edits as soon as the drug is issued a payment code, particularly in areas known for Medicare fraud, such as South Florida. Medicare had been paying for budesonide for at least

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3 years and the LCD's coverage guideline had been in place for over 1 year before the edit was implemented. As of March 2010, contractors had yet to place an edit (despite an LCD that has utilization guidelines) on arformoterol claims, and CMS should enforce its implementation as soon as possible. In the case of arformoterol and budesonide, implementing an edit as soon as the drug was issued a payment code could have saved the program hundreds of millions of dollars

Monitor utilization changes among brand-name inhalation drugs

CMS and its contractors should vigilantly monitor utilization changes to detect instances in which utilization of a drug is disproportionate to utilization in the rest of the country and/or suppliers exhibit billing spikes for a new drug or a drug for which it had never previously billed. This is especially important following implementation of a utilization edit, such as that for budesonide. Because of payment restrictions for budesonide, many South Florida suppliers sought a new drug to bill for in its place and did so in extraordinary amounts. Sales data for arformoterol indicate that many South Florida suppliers were most likely billing for drugs that were never even provided to the beneficiaries. If CMS and its contractors had detected aberrations in arformoterol billings, South Florida suppliers with questionable billings could have been investigated and potentially had their billing privileges revoked.

Strengthen initial claim review processes to focus on prevention of improper payments

Medicare generally has 30 days to pay a supplier for the claim and is able to review only approximately 3 percent of all Medicare claims prior to payment. DME suppliers have a much longer time to bill Medicare and can submit claims up to a year after the services are provided. Because the majority of the claims billed by South Florida suppliers for arformoterol were submitted soon after the budesonide edit, CMS would have received an influx of claims for this drug in a short timespan. If these claims had been reviewed, the time constraints to pay the claim would most likely have made a thorough review difficult. However, increasing the number of arformoterol claims reviewed would probably have resulted in more denials, thereby significantly reducing payments. For that reason, to strengthen the initial claim review process, we recommend:

- working with Congress (if necessary) to increase the time Medicare has to review claims in areas known for fraudulent activities, such as South Florida; and

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- performing prepayment reviews on suppliers in high-fraud areas that submit the majority of their claims well after the dates of service.

Perform site visits and request documentation from South Florida suppliers to support budesonide and arformoterol billings

As discussed in the findings, we have provided a list to OI of high-dollar suppliers we believed warranted investigation for criminal wrongdoing. After consulting with OI, we also forwarded information on certain of these suppliers to CMS. See Appendix C for a summary of the criteria used to identify these suppliers. CMS should perform unannounced site visits to the problematic high-dollar suppliers we refer to the agency. These visits would determine whether these suppliers are stocked with the drugs; have appropriate storage facilities for the drugs; have stored the drugs properly (e.g., refrigeration for arformoterol); and meet Medicare supplier standards. CMS should also request that the suppliers provide documentation to justify the amounts billed for budesonide and arformoterol. Documentation should include items such as purchasing receipts, invoices, credit agreements, and proof of delivery to the beneficiary. Where appropriate, CMS should take steps to revoke billing privileges for any suppliers with fraudulent claims.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all four of our recommendations (one of the concurrences included a caveat). CMS also described a number of steps that the agency has taken to resolve problematic billings for brand-name inhalation drugs by DME suppliers in South Florida and in certain other areas of the country. Effective July 16, 2010, a CMS contractor implemented three new edits covering multiple States (including Florida) for budesonide; arformoterol; and a third inhalation drug, formoterol. To prevent suppliers from switching to related products to evade these new edits, this contractor is also developing utilization edits for an additional nine inhalation drugs. CMS also described its efforts to closely track shifts in utilization from budesonide to arformoterol and formoterol under its DME Stop Gap Initiative, as well as supplier-specific measures under the ZPICs.

In response to our first recommendation about utilization edits, CMS generally concurred, but included the caveat that the requirements listed in the Medicare manual be met first. CMS stated that before implementing automated prepayment edits for brand-name inhalation

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drugs, a “clear policy,” such as developing and issuing an LCD, would need to be finalized so that unintended adverse consequences would be avoided. OIG acknowledges the importance of CMS’s requirements and agrees with the agency about the need to avoid adverse consequences. However, in the case of budesonide and arformoterol, utilization guidelines were listed in the LCD years before the edits took effect. Once utilization guidelines for brand-name inhalation drugs are established and listed in an LCD, CMS should ensure that edits to enforce them are put in place, particularly in high-fraud areas.

CMS agreed with our recommendation to monitor utilization changes among brand-name inhalation drugs, as well as with our recommendation to strengthen initial claim review processes. The agency stated that to strengthen these processes, it would recommend to DME PSCs and ZPICs that the identification of late-billing suppliers be used as an additional risk indicator for initiating prepayment reviews and that it would request the Pricing and Data Analysis Contractor to add this parameter to its DME Stop Gap Supplier Reporting Templates. CMS also stated that it would forward our suggestion that the agency work with Congress to increase the time Medicare has to review claims to its Office of Legislation. Finally, CMS concurred with our recommendation to review specific problematic suppliers and provided details regarding its planned actions.

We did not make any changes to the report based on CMS’s comments. For the full text of CMS’s comments, see Appendix E.

Medicare Process for Enrolling Durable Medical Equipment Suppliers

Before a durable medical equipment (DME) supplier may bill Medicare, it must obtain a National Provider Identifier (NPI), which is a unique identifier for health care providers that is assigned by the National Plan and Provider Enumeration System. Recently, the Centers for Medicare & Medicaid Services (CMS) added two additional requirements that suppliers must meet to obtain Medicare billing privileges. First, as of May 2009, DME suppliers seeking to enroll or change their ownership must also submit a \$50,000 surety bond for each NPI with Medicare billing privileges (suppliers enrolled prior to this date were required to submit the surety bond by October 2, 2009). Second, all DME suppliers must meet quality standards and submit evidence of accreditation as of October 1, 2009.^{48, 49}

After meeting these requirements, the DME applicant must submit a completed application form (Form CMS-855S) and supporting documents to CMS. By signing and submitting the application form, the applicant agrees to follow all Medicare laws, regulations, and program instructions. The applicant must also meet certain Medicare supplier standards.⁵⁰

CMS contracts with the National Supplier Clearinghouse (NSC) to manage the enrollment of suppliers. To ensure that an applicant is meeting the Medicare supplier standards, NSC must conduct an unannounced site visit while the application is being processed. Generally, if the supplier is not in compliance, NSC will deny the application. Suppliers are required to reenroll in Medicare every 3 years to continue receiving payment.⁵¹ The reenrollment process requires a resubmission of the CMS-855S application form and the required documentation. NSC will conduct an unannounced reenrollment site visit to ensure that the supplier continues to meet Medicare standards.

⁴⁸ Medicare Improvements for Patients and Providers Act of 2008, P.L. 110-275 § 154(b)(1) (July 15, 2008). Certain professionals and persons did not have to meet this deadline. Pharmacies supplying DME did not have to meet the accreditation requirements until December 31, 2009.

⁴⁹ The new health care reform statute recently enhanced CMS’s authority related to supplier enrollment by implementing measures to improve the oversight and screening of suppliers. For example, as part of these changes, enrolling suppliers will now be required to have a compliance program and disclose certain affiliations with excluded entities. Patient Protection and Affordable Care Act of 2010, P.L. 111-148 § 6401 (Mar. 23, 2010).

⁵⁰ 42 CFR § 424.57(c).

⁵¹ 42 CFR § 424.57(e).

Related Office of Inspector General Work

Unannounced site visits. In March 2007, the Office of Inspector General (OIG) issued a report entitled *South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits* (OEI-03-07-00150). In that study, OIG made 1,581 unannounced site visits in late 2006 to durable medical equipment (DME) suppliers in South Florida. We found that 491 suppliers (31 percent) visited did not maintain a physical facility or were not open and staffed during business hours. At the time that we conducted the visits, these 491 suppliers had billed Medicare for almost \$237 million in 2006. We referred these suppliers to the Centers for Medicare & Medicaid Services (CMS) so that the agency could consider revocation. We recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare supplier standards. CMS stated that it would take several steps to strengthen supplier standards and revoked the billing privileges for the 491 suppliers OIG referred.

OIG issued a followup report in October 2008 entitled *South Florida Durable Medical Equipment Suppliers: Results of Appeals* (OEI-03-07-00540), that determined the number of revoked suppliers identified in the aforementioned study that appealed their revocations and were reinstated into the Medicare program. Nearly half of the 491 revoked South Florida suppliers appealed their revocations and received hearings; among these, 91 percent were reinstated by the hearing officers based on a variety of evidence. After being reinstated, two-thirds of these suppliers had their billing privileges revoked again or inactivated. We recommended that CMS strengthen the supplier appeal process by developing criteria for reinstatements. In response, CMS stated that it had been taking aggressive steps to prevent Medicare fraud and agreed that reinstatement guidelines should be developed.

Aberrant billing patterns. In September 2007, OIG issued a report entitled *Aberrant Billing in South Florida for Beneficiaries With HIV/AIDS* (OEI-09-07-00030). This study analyzed claim patterns associated with HIV/AIDS infusion therapy providers in South Florida and the oversight mechanisms CMS had in place to control inappropriate payments to these providers. In the last half of 2006, South Florida accounted for 79 percent of the amount of drug products billed nationally for Medicare beneficiaries with HIV/AIDS, even though

only about 10 percent of Medicare beneficiaries with HIV/AIDS lived there. Based on our review of CMS materials and claims data, we found that CMS and its contractors had used multiple approaches in South Florida to control aberrant billing for beneficiaries with HIV/AIDS, but none had proven effective as of the time we conducted our review. We recommended that CMS implement a number of controls that could reduce aberrant billing by infusion clinics. CMS generally concurred with our recommendations.

The April 2009 OIG report entitled *Aberrant Claim Patterns for Inhalation Drugs in South Florida* (OEI-03-08-00290), found that South Florida accounted for 17 percent of Medicare spending on inhalation drugs in 2007, even though only 2 percent of all Medicare beneficiaries lived there. In particular, per-beneficiary spending on budesonide was much greater in South Florida than in the rest of the country (\$4,429 per beneficiary compared to \$1,567 per beneficiary in the rest of the country). We also found that 75 percent of South Florida beneficiaries who received budesonide had Medicare-reimbursed budesonide claims that exceeded the utilization guidelines for this drug, compared to 14 percent in the rest of the country. We recommended that CMS ensure that all Program Safeguard Contractors are enforcing the guidelines (especially for budesonide), eliminate Medicare's vulnerability to potentially fraudulent claims, and review the cases in which the supplier appears to be fraudulently billing Medicare. CMS concurred with all of our recommendations and described its recent efforts to address the issues cited in our report, including the implementation of an automated edit for budesonide in September 2008.

Medicare Fraud Strike Force and the Health Care Fraud Prevention and Enforcement Action Team

On March 1, 2007, a strike force of Federal, State, and local investigators began operating in South Florida to detect, prosecute, and prevent Medicare fraud by area DME suppliers. The Strike Force's efforts have resulted in more than \$220 million in court-ordered restitutions to the Medicare program in cases involving 159 defendants charged with criminal health care fraud offenses. In March 2008, a second phase of the strike force began operating in Los Angeles.

In May 2009, the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative was launched to renew efforts to reduce Medicare fraud. This initiative is a collaboration of officials from the Department of Health & Human Services and the Department of

Justice that builds upon existing programs that combat fraud and identifies new methods to prevent fraud. HEAT is intended to increase Medicare compliance training for providers, improve data sharing between CMS and law enforcement, and strengthen program integrity monitoring. The HEAT initiative also strengthened and expanded the Medicare Strike Force to Detroit, Houston, Brooklyn, Tampa, and Baton Rouge.

Criteria Used To Identify and Refer Potentially Fraudulent South Florida Durable Medical Equipment Suppliers

In total, we identified 49 high-dollar durable medical equipment suppliers in South Florida as especially problematic and worthy of further review.⁵² Suppliers were identified using the three criteria below. Because suppliers may meet more than 1 of the criteria, the number of suppliers listed does not add up to the 49 unique suppliers we believed warranted investigation.

Our criteria used to identify the potentially fraudulent suppliers include:

- billing over \$500,000 for budesonide before the utilization edit was implemented, but then having a significant drop or completely stopping billing in the 6 months after the edit (37 suppliers);
- beginning to bill or significantly increasing billing for arformoterol in the 6 months after the edit and billing for over \$500,000 during this period (15 suppliers); and
- billing over \$1 million in 2008 and the first half of 2009 for arformoterol, but not purchasing a unit of the drug from the manufacturer or the 3 largest wholesalers (13 suppliers).

We have referred these 49 suppliers to OI. Of the 49, OI and the Federal Bureau of Investigation had more than half under investigation. Some of the providers have already had prosecutorial actions taken against them. After consulting with OI, we have forwarded information for certain of the 49 suppliers, as deemed appropriate, to the Centers for Medicare & Medicaid Services for possible revocation.

⁵² We initially identified 51 suppliers as being especially problematic; however, at the time of our data analysis, 2 of those suppliers had already been indicted for alleged Medicare fraud and we therefore did not refer them to the Office of Investigations (OI).

▶ A P P E N D I X ~ D

Table D-1: Monthly Claims Submitted by South Florida Suppliers for Arformoterol Services Provided in 2008

Month Claim Was Submitted	Amount Submitted per Month	Monthly Percentage of Total Submitted	Cumulative Amount Submitted	Cumulative Percentage
Jan-08	\$4,687	0%	\$4,687	0%
Feb-08	\$127,056	0%	\$131,743	0%
Mar-08	\$261,453	1%	\$393,196	1%
Apr-08	\$469,923	1%	\$863,119	3%
May-08	\$786,074	2%	\$1,649,193	5%
Jun-08	\$1,786,228	5%	\$3,435,421	10%
Jul-08	\$3,769,246	11%	\$7,204,667	22%
Aug-08	\$1,572,232	5%	\$8,776,900	27%
Sep-08	\$2,540,261	8%	\$11,317,161	34%
<i>Budesonide edit implemented at the end of the September</i>				
Oct-08	\$8,161,763	25%	\$19,478,924	59%
Nov-08	\$4,580,203	14%	\$24,059,127	73%
Dec-08	\$6,187,195	19%	\$30,246,323	92%
Jan-09	\$2,124,999	6%	\$32,371,322	98%
Feb-09	\$361,259	1%	\$32,732,581	99%
Mar-09	\$323,095	1%	\$33,055,676	100%

Source: Office of Inspector General analysis of the 2008 claims data, 2010.

Note: Amounts submitted per month are based on the dates that the suppliers actually submitted the claims for processing.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 12 2010

TO: Daniel R. Levinson
Inspector General

FROM: Donald M. Berwick, M.D. /S/
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Questionable Billing for Brand-Name Inhalation Drugs in South Florida" (OEI-03-09-00530)

Thank you for the opportunity to review and comment on the subject OIG draft report. The Centers for Medicare & Medicaid Services (CMS) has been aware of a problem with billings for brand-name inhalation drugs by durable medical equipment (DME) suppliers in South Florida, and in certain other areas of the country. Therefore, CMS has already taken a number of steps to address this problem.

Although, as OIG reports, edits were not in place for arformeterol as of March 2010, Clinically Unlikely Edits (CUEs) have since been placed by CMS' Zone 7 Zone Program Integrity Contractor (ZPIC), SafeGuard Services (SGS), on arformeterol. CUEs have also been developed and placed on an additional inhalation drug, formeterol.

In addition, although the budesonide edit savings for the South Florida tri-county area for the period September 9, 2008, through March 31, 2010, exceeded \$9 million, SGS modified the edit to expand its scope and geographic location to increase its effectiveness. Specifically, SGS has tightened the utilization parameters for the budesonide edit and has expanded the geographic area from the original three South Florida counties. On July 16, 2010, these three new edits for budesonide, arformeterol, and formeterol were input into the system by SGS.

In order to maximize the impact of these edits and in recognition of the fact that billing shifts within and beyond high-fraud areas, at the request of the Zone 7 ZPIC, these three edits have been placed jurisdiction-wide for Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction C. Following are the 14 states and 2 territories, by ZPIC jurisdiction, in which these edits are in effect:

- ZPIC Zone 4, Health Integrity: Texas, Oklahoma, Colorado, and New Mexico;
- ZPIC Zone 5, AdvanceMed: West Virginia, Virginia, North Carolina, Georgia, Alabama, Mississippi, Tennessee, Arkansas, and Louisiana;
- ZPIC Zone 7, SGS: Florida, Puerto Rico, and the U.S. Virgin Islands.

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Included in the 14 states are 3 DME Stop Gap states (Texas, Florida, and North Carolina) and 4 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Strike Force Cities (Houston, TX; Miami, FL; Tampa, FL; and Baton Rouge, LA).

The CMS and the Pricing and Data Analysis Contractor (PDAC) are closely tracking this activity as part of the Medicare 7-State DME Stop Gap Initiative. In addition, in order to preclude the possibility that suppliers will try to evade these edits by switching to other related procedure codes, SGS has conducted extensive data analysis and coordinated with the MAC Medical Director and staff and is in the process of developing utilization edits (CUEs) for an additional nine inhalation drugs.

Under CMS' DME Stop Gap Initiative, SGS, the Zone 7 ZPIC, has been closely tracking shifts in utilization from budesonide to arformoterol and formeterol. SGS is monitoring the suppliers associated with questionable billings for additional scrutiny. SGS has identified and is specifically reporting on the top 10 suppliers (based on total reimbursement for particular drugs) in 2007, 2008, 2009, and 2010 in the 3-county South Florida area (Miami-Dade, Broward, and Palm Beach Counties) as well as statewide for Florida and by county and island-wide in Puerto Rico. Since each supplier is tracked for the full 4-year period and as new suppliers emerge, previously reported suppliers continue to be tracked, shifts in billing over time are quickly identified for appropriate action. These reports currently exist for budesonide (J7626). As data for the newer edits are developed, these trending reports will be replicated for arformoterol (J7605) and formeterol (J7606).

The OIG study identified potential fraud related to billings of brand-name inhalation drugs by South Florida DME suppliers. During this study, OIG:

- Identified changes in billing among South Florida DME suppliers for budesonide and arformoterol after payment controls were put in place to detect and deny excessive budesonide claims.
- Determined whether the amount of arformoterol billed by South Florida DME suppliers and paid under Medicare Part B exceeded the amount of the drug distributed for sale in the area between January 2008 and June 2009.

The CMS appreciates the effort that went into this report, and our specific comments on the OIG recommendations follow.

OIG Recommendation

The OIG recommends that CMS require DME contractors to implement utilization edits in high-fraud areas as soon as Medicare begins paying for a brand-name drug.

CMS Response

The CMS generally concurs with OIG's recommendation with the following caveats. CMS Medicare manual instructions require that, before contractors can implement automated

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prepayment edits, a “clear policy,” such as a Local Coverage Determination (LCD), must be developed and issued in draft to allow for public comments prior to finalizing the LCD. This is particularly important in the case of inhalation drugs, because any LCDs, such as CUEs, that are designed to auto-deny services exceeding units of service parameters must reflect accurate information on dosages and diagnoses and labeling information to avoid unintended adverse consequences. CMS will ensure that the Medical Directors at the DME MACs are aware of OIG’s recommendation and remind them to consider development of an LCD when a new brand-name inhalation drug is issued a payment code.

OIG Recommendation

The OIG recommends that CMS monitor utilization changes among brand-name inhalation drugs.

CMS Response

The CMS agrees with OIG’s recommendation and has already been “vigilantly monitoring utilization changes to detect instances in which utilization of a drug is disproportionate to utilization in the rest of the country and suppliers exhibit spikes for a new drug or a drug for which it had never previously billed.”

OIG Recommendation

The OIG recommends that CMS strengthen initial claim review processes to focus on prevention of improper payments.

CMS Response

The CMS agrees with OIG’s recommendation to identify “suppliers in high-fraud areas that submit the majority of their claims well after the date of service;” however, decisions on whether to perform “prepayment reviews” are contingent on additional factors beyond the date of claim submission.

In addition to recommending identification of late-billing suppliers to DME Program Safeguard Contractors (PSCs) and ZPICs as an additional risk indicator, CMS will request the PDAC to add this parameter to its current cadre of DME Stop Gap Supplier Reporting Templates. Once developed, CMS will advertise the availability of this information via weekly DME Stop Gap conference calls and at PDAC quarterly meetings with the DME PSCs/ZPICs, PDAC, National Supplier Clearinghouse (NSC), DME MACs and Medical Directors and CMS and OIG staff.

The CMS will forward OIG’s recommendation to the Office of Legislation regarding “working with Congress (if necessary) to increase the time Medicare has to review claims in areas known for fraudulent activities, such as South Florida.” In the interim, in order to maximize the time in which they can review high-risk providers’ claims, several PSCs and ZPICs have access to information on claims in process through their MACs and DME MACs.

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OIG Recommendation

The OIG recommends that CMS perform site visits and request documentation from South Florida suppliers to support budesonide and arformoterol billings.

CMS Response

The CMS concurs with OIG’s recommendation. OIG has indicated that it will provide CMS with a list of high-dollar South Florida suppliers identified as “especially problematic and worthy of further review” for which CMS should perform unannounced site visits, determine if they are stocked with the drug, have appropriate storage facilities for the drug, and have stored the drug properly (e.g., refrigeration for arformeterol), request documentation (i.e., purchasing receipts, invoices, credit agreements, and proof of delivery), and take steps to revoke billing privileges for any suppliers with fraudulent claims.

Upon receipt of OIG’s supplier list, CMS will:

- Determine current enrollment status of those suppliers since numerous NSC site visits have taken place in South Florida since the date OIG’s list was generated.
- Determine if the list has been vetted with local law enforcement and Strike Forces.
- Identify if any of these suppliers have been the subject of DME Stop Gap interviews and/or site visits of suppliers, ordering physicians, or beneficiaries and/or the subject of prepayment edits.
- Request the NSC to conduct unannounced site visits to the remaining suppliers and, if results of the site visits show failure to meet Medicare supplier standards, the NSC will take steps to revoke billing privileges. The NSC will refer any non-provider enrollment-related issues to the ZPIC for appropriate action.

The CMS will share the above-referenced OIG report and the data with the Recovery Audit Contractors (RACs) and encourage the RACs to request documentation supporting the billing of budesonide and aformoterol for all claims in their universe.

Again, we appreciate the opportunity to comment on this draft report and look forward to working with OIG on this and other issues.



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

This report was prepared under the direction of Robert A. Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and David E. Tawes, Director of the Medicare and Medicaid Prescription Drug Unit.

Stephanie Yeager served as the team leader for this study. Central office staff who contributed include Natasha Franklin and Scott Manley.

Office of Inspector General

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