

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**ABERRANT CLAIM PATTERNS
FOR INHALATION DRUGS IN
SOUTH FLORIDA**



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OBJECTIVES

1. To compare Medicare utilization and spending for inhalation drugs among beneficiaries in South Florida to utilization and spending among beneficiaries in the rest of the country.
2. To compare Medicare supplier billings for inhalation drugs in South Florida to Medicare supplier billings in the rest of the country.
3. To compare beneficiary utilization of inhalation drugs (in South Florida and the rest of the country) to utilization guidelines set by the Medicare program.
4. To examine relationships between inhalation drug suppliers, prescribing physicians, and Medicare beneficiaries in South Florida.

BACKGROUND

Medicare Part B covers inhalation drugs when they are used in conjunction with durable medical equipment (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 for DME claims. CMS also contracts with Program Safeguard Contractors (PSC) to administer benefit integrity functions and conduct medical review.

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 inhalation drugs (L5007), originally effective on April 1, 1997, and revised on July 1, 2007, establishes coverage limitations such as the maximum milligrams per month that may reasonably be billed for a beneficiary.

We used the Medicare National Claims History file to identify all inhalation drug claims in 2007. We compared the average number of paid claims and the dollar amount paid for inhalation drug claims for

beneficiaries in South Florida (Miami-Dade, Broward, and Palm Beach Counties) to beneficiaries in the rest of the country. We compared the average amount submitted and paid per supplier for beneficiaries in South Florida to the average amount submitted and paid per supplier for beneficiaries in the rest of the country. We also compared the average Medicare spending per beneficiary for inhalation drugs in South Florida and the rest of the country to the amounts associated with the maximum milligrams listed in the LCD. Finally, we determined the percentage of paid South Florida inhalation drug claims in 2007 for which the beneficiary did not have any Medicare Part B service claims (e.g., a Medicare-billed office visit) occurring in 2005, 2006, or 2007 with the physician who reportedly prescribed the drug.

FINDINGS

Although only 2 percent of Medicare beneficiaries live in South Florida, this area accounted for 17 percent of Medicare spending on inhalation drugs in 2007. Medicare paid almost \$143 million for inhalation drugs in Miami-Dade County alone—an amount 20 times greater than the amount paid in Cook County, Illinois, the county (outside South Florida) with the next highest total payments. However, according to Medicare enrollment data, Cook County is home to almost twice as many Medicare beneficiaries as Miami-Dade County.

In 2007, Medicare’s average per-beneficiary spending on inhalation drugs was five times higher in South Florida than in the rest of the country. Among beneficiaries with paid inhalation drug claims, Medicare spent approximately \$4,400 per South Florida beneficiary on inhalation drugs, compared to just \$815 per beneficiary on inhalation drugs in the rest of the country.

For individual inhalation drugs, Medicare per-beneficiary spending on brand name products (budesonide and levalbuterol) was much greater in South Florida than in the rest of the country, while spending on generic products (albuterol and ipratropium bromide) was similar to the rest of the country. Among beneficiaries with paid budesonide claims in 2007, the average Medicare spending on the drug in South Florida was \$4,429 per beneficiary compared to \$1,567 per beneficiary in the rest of the country. In the first half of 2007 (before a coding change took effect on July 1), Medicare’s spending on levalbuterol per beneficiary in South Florida was \$2,312 as compared to \$1,035 per beneficiary in the rest of the country. In 2007, 56 percent of South Florida beneficiaries who

received inhalation drugs had claims paid for budesonide, compared to 14 percent of beneficiaries in the rest of the country.

Supplier billing patterns for inhalation drugs differed substantially between South Florida and the rest of the country. Beneficiaries in South Florida were more likely to have multiple suppliers. Thirty-one percent of South Florida beneficiaries had more than one supplier providing inhalation drugs during 2007, as compared to 12 percent of beneficiaries in the rest of the country. Beneficiaries with claims for budesonide were particularly likely to have more than one supplier of the drug. In 2007, an average of 27 percent of beneficiaries with budesonide claims in South Florida had multiple suppliers in the first half of the year, as compared to 9 percent of beneficiaries in the rest of the country.

Overall, suppliers billed Medicare an average of \$1,176 in inhalation drug claims for each of their South Florida beneficiaries in 2007; on average, they were paid \$585 for each beneficiary that year. In the rest of the country, suppliers billed Medicare an average of \$661 per beneficiary for inhalation drugs in 2007 and were paid \$307.

Medicare paid for inhalation drug claims that did not comply with LCD guidelines. The average Medicare payment for a 90-day supply of budesonide in South Florida was more than double the payment amount for the maximum milligrams listed in the LCD. Seventy-five percent of South Florida beneficiaries who received budesonide had Medicare-reimbursed budesonide claims that exceeded the utilization guidelines, compared to 14 percent in the rest of the country. Although the average payment for the other inhalation drugs fell within the guidelines set by the LCD, several individual South Florida beneficiaries still exceeded the maximum payment amount for a 90-day supply of the other drugs.

For 62 percent of inhalation drug claims in South Florida, the beneficiary did not have a Part B service visit during the last 3 years with the physician who reportedly prescribed the drug. According to Medicare data, for 62 percent of South Florida inhalation drug claims, the beneficiaries on these claims did not have a Medicare-billed office visit or other service in 2005, 2006, or 2007 with the physician who reportedly prescribed the drug. Medicare paid \$114 million (71 percent of total South Florida payments) for these inhalation drug claims in 2007. For 16 percent of suppliers, not a single South Florida beneficiary

to whom they provided inhalation drugs had a billed claim with the physician listed on the claim form.

Certain ordering physicians in South Florida were associated with a large volume of inhalation drug claims. In 2007, 10 South Florida physicians were each listed as the ordering physician on more than \$3.3 million in submitted inhalation drug claims. Each of the 10 physicians reportedly ordered inhalation drugs for an average of 745 South Florida beneficiaries in 2007. These physicians had Medicare-paid office visits in 2005 through 2007 with between 1 percent and 53 percent of the beneficiaries for whom they reportedly ordered inhalation drugs for in 2007. Medicare paid a total of \$28 million for inhalation drugs reportedly ordered by these 10 physicians during the year.

RECOMMENDATIONS

South Florida has been identified by the Office of Inspector General (OIG), CMS, and other agencies as a high-risk area for fraudulent billings to Medicare by DME suppliers. Fraudulent billings jeopardize the financial integrity of Medicare and may endanger Medicare beneficiaries when the drugs are overprescribed.

Our findings demonstrate that even though CMS has made efforts to reduce DME fraud in South Florida, a problem may persist among DME suppliers billing for inhalation drugs. Medicare spent substantially more on inhalation drugs per beneficiary in South Florida during 2007 than it did among beneficiaries in the rest of the country. The greatest spending discrepancies occurred among the brand name drugs budesonide and levalbuterol. In particular, spending and utilization for budesonide were much higher not only in comparison to averages in the rest of the country but also in relation to coverage guidelines. Furthermore, many of the South Florida beneficiaries did not have a Medicare service claim during the last 3 years with the physician who reportedly prescribed the inhalation drugs. Therefore, we recommend that CMS:

Ensure That All PSCs, Particularly the PSC Covering Florida, Are Enforcing the Guidelines for Maximum Milligrams per Month for All Inhalation Drugs, Especially Budesonide.

Eliminate Medicare's Vulnerability to Potentially Fraudulent or Excessive Claims for Beneficiaries Prescribed Inhalation Drugs in South Florida.

Review Cases in Which the DME Supplier Appears To Be Fraudulently Billing Medicare for Inhalation Drugs and Take Appropriate Action Based on the Review’s Results.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all three of our recommendations. CMS stated that through its Program Integrity Miami field office and the DME Stop Gap Plan, it has already identified and begun to address many of the same issues cited in our report. In addition, CMS noted that OIG’s findings reinforce the validity of the agency’s efforts.

In response to our recommendations, CMS stated that, as of September 2008, the DME PSC for South Florida and the DME MAC had implemented a “medically unlikely” edit for budesonide. According to CMS, there was an immediate and significant 50-percent decrease in both allowed and billed amounts for the drug in Miami-Dade and Broward counties. In addition, CMS described the efforts by its Miami and Los Angeles field offices to identify suppliers whose beneficiaries had no clinical relationship with the physicians listed on DME claims, and revoke the Medicare billing numbers for suppliers not meeting supplier standards. Finally, CMS expressed its commitment to continually reviewing and refining the process to improve the Medicare program and will review any additional information provided by OIG. We did not make any changes to the final report based on CMS’s comments.

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OBJECTIVES

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2. To compare Medicare supplier billings for inhalation drugs in South Florida to Medicare supplier billings in the rest of the country.
3. To compare beneficiary utilization of inhalation drugs (in South Florida and the rest of the country) to utilization guidelines set by the Medicare program.
4. To examine relationships between inhalation drug suppliers, prescribing physicians, and Medicare beneficiaries in South Florida.

BACKGROUND

Medicare Part B Coverage of Inhalation Drugs

Although Medicare Part D covers most outpatient prescription drugs, the Centers for Medicare & Medicaid Services (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: drugs furnished incident to a physician's service, drugs explicitly covered by statute, and drugs administered through durable medical equipment (DME).¹

Inhalation drugs administered via a nebulizer, a class of DME drug, are provided to Medicare beneficiaries by DME suppliers. Physicians typically prescribe these drugs to treat and prevent symptoms associated with lung diseases, such as asthma and chronic obstructive pulmonary disorder. Long term use is usually required because inhalation drugs are often used to treat incurable and lifelong diseases. In 2007, four products (albuterol, levalbuterol, budesonide, and ipratropium bromide) accounted for 72 percent of the \$946 million Medicare spent on inhalation drugs nationally and 95 percent of the \$160 million spent in South Florida.

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

CMS contracts with four geographically defined DME Medicare Administrative Contractors (MAC) to process and pay for DME claims, including those for inhalation drugs.² For an inhalation drug claim to be eligible for Medicare reimbursement, the DME supplier must have a signed prescription from the treating physician and the physician's identification number must be listed on the submitted claim form. 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 contracts with Program Safeguard Contractors (PSC)³ to perform benefit integrity and medical review functions for each of the four DME MAC jurisdictions.⁴ Benefit integrity functions include fraud investigations; data analysis; and prepay and postpay medical reviews of claims involving potential fraud, waste, and abuse. Before March 1, 2008, the PSCs also conducted medical reviews for purposes other than benefit integrity, such as performing comprehensive error rate testing, educating suppliers, and making coverage determinations. However, effective March 1, 2008, CMS transferred the responsibility for these types of medical reviews from the PSCs to the DME MACs.

DME Coverage Determinations

CMS may establish national coverage determinations for DME items (including inhalation drugs) and has typically based those determinations on statutory guidelines found in section 1862(a)(1) of the Social Security Act. National coverage determinations specify whether certain medical items, services, treatment procedures, or technologies are eligible for Medicare payment. The DME MACs and PSCs are required to follow national coverage determinations when they exist.

² The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires CMS to implement competitive procedures to replace DME regional carriers with DME MACs. In 2006, CMS competitively selected four DME MACs and began to transition claims administration activities from DME regional carriers to DME MACs. As of June 1, 2007, the four DME MACs awarded contracts were the National Heritage Insurance Company for Jurisdiction A; AdminaStar Federal, Inc., for Jurisdiction B; CIGNA Government Service, LLC, for Jurisdiction C (Florida is 1 of 15 States and 2 U.S. territories included in Jurisdiction C); and Noridian Administrative Services for Jurisdiction D.

³ Social Security Act § 1893(a), 42 U.S.C. § 1395ddd.

⁴ Each DME MAC is responsible for coordinating with the PSC that conducts program integrity reviews in the DME MAC's jurisdiction. The PSC for Jurisdictions A and B is TriCenturion; the PSC for Jurisdiction C is TrustSolutions, LLC; and the PSC for Jurisdiction D is Electronic Data Systems.

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

Effective March 1, 2008, DME MACs have full responsibility for developing and revising LCDs. Before that date, the PSCs developed the LCDs and submitted them to the DME MACs (or their predecessors, the DME regional carriers) for approval. The DME MACs reviewed the recommended LCDs and determined whether they would be adopted or rejected.

One PSC established an LCD (L5007), effective April 1997, that set guidelines for the maximum milligrams per month that may reasonably be billed for certain inhalation drugs. The LCD states that a claim will be denied if it does not follow these guidelines unless there is documentation in the patient's medical records to support medical necessity. As required by CMS, the LCD is effective nationally, meaning that it applies to inhalation drug claims in all four DME MAC jurisdictions. Numerous revisions have been made to the LCD since its establishment. For example, as part of the July 1, 2007, revision, a maximum milligrams guideline for budesonide was included in the LCD.⁵

The maximum milligrams listed in this LCD are typically much higher than the normally prescribed dose. For example, the LCD lists the maximum milligrams for levalbuterol as up to 232.5 milligrams per month. However, the package insert for levalbuterol states that patients receiving the highest dosage (112.5 milligrams per month) should be monitored closely for adverse side effects (e.g., seizures, tachycardia, cardiac arrest).⁶

⁵ The maximum milligrams per month listed in the LCD for the four inhalation drugs that account for the majority of Medicare inhalation drug payments are: up to 465 milligrams for albuterol, up to 232.5 milligrams for levalbuterol, up to 93 milligrams for ipratropium bromide, and up to 31 milligrams for budesonide (effective July 1, 2007).

⁶ Levalbuterol package insert. Available online at <http://www.xopenex.com>. Accessed on September 2, 2008.

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According to staff at the DME MAC that includes Florida, automated edits have been implemented for most of the inhalation drugs covered by the LCD. These edits detect whether the beneficiary's utilization of an 83-day supply of the drug exceeds the LCD's maximum milligrams parameters for a 3-month period and, if so, suspends payment until the claim can be reviewed manually.⁷ Although budesonide was included in the LCD as of July 1, 2007, as of August 18, 2008, the PSC for Jurisdiction C (the region including Florida) has yet to establish edits that will enable the DME MAC to monitor this drug's utilization.

Medicare Enrollment of DME Suppliers

Before a 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. After obtaining the NPI, the DME applicant must submit a completed application form (Form CMS-855S) and supporting documents to CMS. The forms contain information about the applicant (e.g., adverse legal actions and convictions); the supplier's practice location; the names of organizations or individuals having ownership or managing control of the business; and the billing agent for the supplier, if one exists. By signing and submitting the application forms, the DME applicant agrees to follow all Medicare laws, regulations, and program instructions. Additionally, the DME applicant must meet certain Medicare supplier standards.⁸

CMS contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefit Administrators, 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.

DME suppliers are required to reenroll in the Medicare program every 3 years to continue receiving Medicare payment.⁹ The reenrollment process requires a resubmission of the CMS-855S application form and the required documentation. NSC conducts an unannounced

⁷ The edit is based on an 83-day period (7-day grace period for delivery) because a supplier may bill for up to a 90-day supply of the drug.

⁸ 42 CFR § 424.57(c).

⁹ 42 CFR § 424.57(e).

reenrollment site visit to ensure that the supplier continues to meet Medicare standards.

Medicare DME Fraud in South Florida

On March 1, 2007, a multiagency task force of Federal, State, and local investigators began operating in South Florida to detect, prosecute, and prevent Medicare fraud by area DME suppliers. Medicare beneficiaries and physicians often play a key role in the suppliers' efforts to bill Medicare for unnecessary items. The task force found that one method used to defraud Medicare involved DME suppliers paying physicians for writing fraudulent inhalation drug prescriptions and paying Medicare beneficiaries for accepting the unnecessary medication. In these cases, beneficiaries typically received around \$100 to \$150 per month for use of their Medicare cards. In multiple cases, beneficiaries testified that they did not use, but instead threw away, the inhalation drugs they received.¹⁰ DME suppliers have testified that the medication billed to Medicare was illegally manufactured in shell pharmacies that did not stock real medications and did not have customers.¹¹

However, beneficiaries and physicians are not always aware that the DME suppliers are using their identification numbers for fraudulent activities. Sometimes, DME suppliers fraudulently obtain beneficiary identification information to submit DME claims for Medicare beneficiaries who did not see the ordering physician and never received the item submitted on the claim.¹² DME suppliers have also used a physician's identification number without the physician's consent or

¹⁰ Department of Justice Press Release. "Medicare Fraud Strike Force Convicts Owner of Miami Durable Medical Equipment Company of Defrauding Medicare." Available online at http://www.usdoj.gov/opa/pr/2007/June/07_crm_472.html. Accessed on December 18, 2007. Department of Justice Press Release. "Miami Jury Convicts Physician and Three Business Owners of Medicare Fraud." Available online at <http://miami.fbi.gov/dojpressrel/pressrel08/medfraud030708.htm>. Accessed on April 15, 2008.

¹¹ Ibid. Illegally manufactured drugs included inhalation drugs compounded by untrained individuals without pharmacy licenses. Compounding is the process in which a pharmacist mixes medications such as albuterol and ipratropium bromide in the pharmacy, instead of purchasing the premixed form directly from a manufacturer or wholesaler.

¹² Department of Justice Press Release. "Miami-Dade DME and Clinic Owners Indicted for Using Stolen Patient Information in Multi-million Dollar Medicare Fraud Scheme." Available online at <http://miami.fbi.gov/dojpressrel/pressrel08/mm20080401.htm>. Accessed on October 1, 2008.

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knowledge.¹³ According to CMS staff, a project began in November 2006 to minimize the improper use of physician identification numbers on claims for all DME items. This project identifies potentially compromised physician identification numbers and allows physicians to request that claims for either specific DME items or a category of DME be denied.

Medicare Demonstration Project in South Florida

Section 402(a)(1)(J) of the Social Security Amendments of 1967 permits the Secretary of the Department of Health and Human Services to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by the Social Security Act.¹⁴ Pursuant to this authority, on November 1, 2007, CMS implemented a 2-year demonstration project, targeting the South Florida and Los Angeles metropolitan areas, to improve its ability to detect potentially fraudulent behavior among DME suppliers at both the preenrollment and postenrollment stages. This demonstration project consists of three components: (1) suppliers submit a CMS-855S Medicare enrollment application; (2) CMS revokes billing privileges if the supplier meets certain criteria (e.g., if the DME supplier fails to submit a CMS-855S within 30 days); and (3) CMS performs enhanced reviews of DME suppliers that were not revoked based on components one or two.

Related Work

A January 2007 Government Accountability Office (GAO) report examined the PSCs' efforts to prevent and minimize improper DME payments, as well as CMS's oversight of the PSCs' program integrity activities.¹⁵ GAO found that PSCs did not have automated prepayment controls to identify claims associated with atypical billing patterns and claims that were medically improbable. GAO recommended that CMS require PSCs to develop thresholds for unexplained increases in billing and use them to develop automated prepayment controls and to share these with other PSCs. CMS agreed with the report's findings and

¹³ Department of Justice Press Release. "DME Operators Charged in Health Care Fraud and Identity Theft Conspiracy." Available online at <http://www.usdoj.gov/usaof/fls/PressReleases/071205-01.html>. Accessed on October 2, 2008.

¹⁴ 42 U.S.C. § 1395b-1(a)(1)(J).

¹⁵ GAO Report. "Medicare: Improvements Needed to Address Improper Payments for Medical Equipment and Supplies," GAO-07-59 (January 31, 2007).

responded that it had begun further automating its claims payment systems to prevent improper payments.

In March 2007, the Office of Inspector General (OIG) issued the report “South Florida Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits” (OEI-03-07-00150). OIG made 1,581 unannounced site visits in late 2006 to DME suppliers in South Florida. We found that 491 suppliers (31 percent) did not maintain physical facilities or were not open and staffed during business hours. At the time we conducted the visits, these 491 suppliers had billed Medicare for almost \$237 million in 2006. We recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare supplier standards. In response, CMS stated that it would take several steps to strengthen supplier standards.

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 has 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 drugs 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 have used multiple approaches in South Florida to control aberrant billing for beneficiaries with HIV/AIDS, but none has proven effective thus far.

In February 2008, OIG issued a report entitled “Los Angeles County Suppliers’ Compliance With Medicare Standards: Results From Unannounced Visits” (OEI-09-07-00550). OIG conducted unannounced site visits to 905 DME suppliers in the Los Angeles metropolitan area to determine their compliance with certain Medicare standards and to identify atypical billing characteristics. Thirteen percent of the suppliers did not maintain physical facilities or were not open during the time of the site visits. Fourteen percent of suppliers met a Medicare standard but had atypical billing patterns, such as billing for a beneficiary that did not receive other Medicare services (e.g., office visits) from the ordering physician within a 6-month period preceding the DME claim. We recommended that CMS strengthen the DME supplier enrollment process and ensure that these suppliers meet the Medicare standards. In response, CMS stated that it has already

addressed the majority of our recommendations but would consider increasing prepayment reviews of suppliers' claims and may establish more frequent enrollment requirements for suppliers.

METHODOLOGY

Scope and Data Source

We used the Medicare National Claims History File (NCH) to identify all inhalation drug claims in 2007. Using county codes, we separated the claims into two groups: one with beneficiaries in South Florida (defined as Miami-Dade, Broward, and Palm Beach Counties) and one with beneficiaries in the rest of the country. We also used the NCH to identify all claims for Part B physician services provided between January 1, 2005, and December 31, 2007, for South Florida beneficiaries who received inhalation drugs under Medicare.

Data Analysis

Beneficiary comparison. We calculated the average number of paid claims and amounts allowed¹⁶ for all inhalation drugs per beneficiary in South Florida in 2007 and compared these to average values for the rest of the country. We also performed this comparison for the four individual products (albuterol, levalbuterol, ipratropium bromide, and budesonide) that accounted for most (95 percent) of Medicare spending on inhalation drugs in South Florida.¹⁷ Among these four products, budesonide and levalbuterol are brand name products marketed by a single manufacturer; albuterol and ipratropium bromide have generic versions available from numerous manufacturers.

Supplier comparison. We compared the average amount submitted and paid per supplier for beneficiaries in South Florida to the average amount submitted and paid per supplier for beneficiaries in the rest of the country. Additionally, we determined the percentage of

¹⁶ In the remainder of this report, calculations involving the amount allowed (total amount Medicare spent, including the beneficiary copayment) are referred to as either the amount Medicare spent or paid.

¹⁷ The four inhalation drugs under review were actually represented by five Healthcare Common Procedures Coding System (HCPCS) codes on Medicare claims during 2007. In the first half of 2007, albuterol and levalbuterol had separate HCPCS codes. However, in the second half of 2007 these drugs were combined into one new HCPCS code. We focused the analysis involving these two drugs on the first half of 2007, when the drugs had separate HCPCS codes.

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beneficiaries in South Florida and in the rest of the country who had more than one supplier providing inhalation drugs in 2007.

LCD guideline comparison. An LCD (L5007) provides guidelines for the maximum milligrams per month that may reasonably be billed (without additional documentation) for the majority of the inhalation drugs covered by Medicare. We compared actual beneficiary utilization to guidelines in the LCD for the four drug products (albuterol, levalbuterol, ipratropium bromide, and budesonide) included in the beneficiary comparison.

The maximum doses listed in the LCD for albuterol, levalbuterol, and ipratropium bromide were consistent throughout 2007. However, budesonide did not have a maximum milligrams per month listed in the LCD before its July 1, 2007, revision. Therefore, our analysis of this drug (in terms of the LCD) was limited to the second half of 2007. Additionally, the HCPCS codes, and subsequently the Medicare payment amount, for levalbuterol and albuterol were combined as of July 1, 2007 (although the maximum doses for each remained the same). As a result, it was not possible to differentiate between albuterol and levalbuterol billed on claims during the second half of 2007. Because of this, we analyzed albuterol and levalbuterol claims for only the first half of 2007.

Because beneficiaries may receive up to a 90-day supply of a drug, edits for the utilization guidelines were set for an 83-day period (excluding a 7-day grace period for delivery). For each of the four drugs included in the LCD analysis, we calculated the average Medicare payment per beneficiary for an 83-day period. We calculated these amounts for beneficiaries in South Florida and the rest of the country and compared them to the Medicare payment amount that reflected the maximum milligrams listed in the LCD for 3 months (i.e., 90 days). We also calculated the percentage of South Florida beneficiaries exceeding the utilization guidelines within the 83-day period and compared it to the percentage exceeding it in the rest of the country. Please refer to the Appendix for a more detailed description of this analysis.

Relationships among suppliers, physicians, and beneficiaries. For each South Florida beneficiary with a paid inhalation drug claim in 2007, we determined whether or not there was a Medicare Part B service claim (e.g., Medicare-billed office visit) occurring in 2005, 2006, or 2007 with the physician who ordered the inhalation drug. In

addition, for each supplier, we determined the percentage of South Florida beneficiaries with paid inhalation drug claims that did not have Part B service claims in 2005 through 2007 with the ordering physician listed on the inhalation drug claim.

Using the physician's identifier, we selected the 10 prescribing physicians associated with the highest dollar amount of South Florida inhalation drug claims submitted in 2007. We then determined whether there are certain suppliers operating in South Florida that had large volumes of claims with any of the high-dollar physicians.

Limitations

The Health Insurance Portability and Accountability Act of 1996 requires issuance of a unique NPI to each physician, supplier, and other health care provider. CMS began issuing NPIs on May 23, 2005; however, it was not until May 23, 2008, that all submitted claims were required to have an NPI. In the interim, CMS allowed submitted claims to have either the NPI only; the Medicare legacy identifier only (i.e., Unique Physician Identification Number); or a combination of the NPI and Medicare legacy identifier on the claim. For calculations in this report involving Part B service claims, we excluded claims for which only an NPI was present; i.e., we included only claims that listed a legacy identifier. In South Florida, these NPI-only claims accounted for less than 1 percent of the total amount submitted to Medicare and of the total amount Medicare paid for inhalation drugs.

We did not examine medical records to verify whether there was documentation to support claims for a drug that exceeded the maximum milligrams per month listed in the LCD.

Standards

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

► FINDINGS

Although only 2 percent of Medicare beneficiaries live in South Florida, this area accounted for 17 percent of Medicare spending on inhalation drugs in 2007

In 2007, South Florida accounted for 17 percent of the total Medicare reimbursement for inhalation drugs (\$160 million of \$946 million), even though just 2 percent of beneficiaries resided there.¹⁸ Medicare paid almost \$143 million for inhalation drugs in Miami-Dade County alone—an amount 20 times greater than the amount paid in Cook County, Illinois, the county (outside South Florida) with the next highest total payments. However, according to Medicare enrollment data, Cook County is home to almost twice as many Medicare beneficiaries as Miami-Dade County.

In 2007, Medicare’s average per-beneficiary spending on inhalation drugs was five times higher in South Florida than in the rest of the country

Among beneficiaries with paid inhalation drug claims, Medicare spent approximately \$4,400 per South Florida beneficiary on those drugs in 2007. In the rest of the country, Medicare spent \$815 per beneficiary on inhalation drugs that year (see Table 1). For 53 percent of the South Florida beneficiaries, Medicare spending for inhalation drugs was greater than \$2,000 each in 2007. In comparison, just 11 percent of beneficiaries in the rest of the country exceeded that amount. For 10 South Florida beneficiaries, Medicare paid an average of \$44,000 for inhalation drugs in 2007, an amount 54 times higher than the average per-beneficiary payment outside South Florida. These 10 beneficiaries had an average of more than \$72,000 in submitted inhalation drug claims in 2007.

Table 1. Inhalation Drug Claims in 2007 (per beneficiary)

| | South Florida | | Rest of the Country | |
|--|-------------------------------|---------------------|-------------------------------|---------------------|
| | Average Number of Paid Claims | Average Amount Paid | Average Number of Paid Claims | Average Amount Paid |
| Inhalation drug claims for Medicare beneficiaries in 2007* | 10.2 | \$4,377 | 6.5 | \$815 |

* Limited to beneficiaries with paid inhalation drug claims.

Source: OIG analysis of inhalation drug claims in the Medicare NCH file, 2007.

¹⁸ CMS Medicare Enrollment Reports. Available online at <https://www.cms.hhs.gov/MedicareEnrpts/>. Accessed on October 21, 2008. Enrollment data have not been updated since July 1, 2007; therefore, this estimate assumes that Medicare enrollment did not change significantly after July 1, 2007.

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Medicare per-beneficiary spending on brand name inhalation drugs was much greater in South Florida than in the rest of the country; spending on generic inhalation drugs was similar

For the four inhalation drugs that accounted for the majority of spending, Medicare spent substantially more per beneficiary on the brand name products (budesonide and levalbuterol) in South Florida compared to the amount spent in the rest of the country. As Table 2 illustrates, among those who received budesonide in 2007, Medicare’s per-beneficiary spending for the drug was much higher in South Florida (\$4,429 per beneficiary in South Florida compared to \$1,567 per beneficiary in the rest of the country). In addition, in the first half of 2007 (before the HCPCS coding change), Medicare’s per-beneficiary spending on levalbuterol in South Florida was more than double its spending in the rest of the country (\$2,312 per beneficiary in South Florida compared to \$1,035 per beneficiary in the rest of the country). At the same time, per-beneficiary payments for the two generic inhalation drugs (albuterol and ipratropium bromide) were roughly the same or less in South Florida.

Table 2. Paid Inhalation Drug Claims for Individual Drug Products in 2007

| Short Description of Drugs | South Florida | | | Rest of the Country | | |
|---|--|-------------------------------|---------------------|--|-------------------------------|---------------------|
| | Percentage of Beneficiaries Receiving Drug | Average Number of Paid Claims | Average Amount Paid | Percentage of Beneficiaries Receiving Drug | Average Number of Paid Claims | Average Amount Paid |
| Budesonide inhalation solution (unit dose), up to 0.5 mg | 56 | 6.6 | \$4,429 | 14 | 5.1 | \$1,567 |
| Levalbuterol inhalation solution (unit dose), 0.5 mg* | 71 | 4.1 | \$2,312 | 19 | 2.7 | \$1,035 |
| Albuterol inhalation solution (unit dose), 1 mg* | 17 | 2.1 | \$37 | 40 | 2.7 | \$50 |
| Ipratropium bromide inhalation solution (unit dose), 1 mg | 29 | 3.3 | \$46 | 23 | 3.8 | \$43 |

* The amounts listed for albuterol and levalbuterol are for the first half of 2007, when they had separate HCPCS codes.

Calculations for individual drugs are based only on the beneficiaries who were provided those drugs. Therefore, the figures listed in this table do not add up to the figures listed for all inhalation drugs per beneficiary in Table 1.

Source: OIG analysis of inhalation drug claims in the Medicare NCH file, 2007.

Furthermore, not only did Medicare spend more per beneficiary on brand name drugs in South Florida, but also substantially more South Florida beneficiaries had claims for brand name drugs. In 2007, 56 percent of South Florida beneficiaries who received inhalation drugs had Medicare-paid claims for budesonide, compared to 14 percent of beneficiaries who received inhalation drugs in the rest of the country. Before the HCPCS coding change, 71 percent of these South Florida beneficiaries had paid claims for levalbuterol, versus just 19 percent of these beneficiaries elsewhere.

As a result, Medicare’s total expenditures for budesonide and levalbuterol were disproportionately higher in South Florida. Medicare spent \$306 million for budesonide in 2007; 30 percent (\$91 million) of this was attributed to budesonide payments in South Florida. Similarly, Medicare spent \$205 million on levalbuterol in the first half of 2007 (before the HCPCS coding change), with South Florida accounting for 25 percent (\$51 million) of that total.

Because Medicare payment amounts were substantially higher for budesonide and levalbuterol (before the HCPCS coding change) than the two generic drugs, suppliers may have had a greater incentive to overbill for the brand name products.¹⁹ Budesonide had the highest reimbursement amount among the products we reviewed.

Supplier billing patterns for inhalation drugs differed substantially between South Florida and the rest of the country

Consistent with the substantial differences in inhalation drug utilization and expenditures between beneficiaries in South

Florida and those in the rest of the country, the suppliers that provided drugs in South Florida exhibited different billing patterns as well. Not only did suppliers bill more per beneficiary for inhalation drugs in South Florida when compared to amounts billed in the rest of the country, but also in many cases, multiple suppliers billed for inhalation drugs provided to the same beneficiary.

¹⁹ In 2007, the average Medicare payment amount for one vial of budesonide was \$4.67; levalbuterol was \$3.66; albuterol was \$0.18; and ipratropium bromide was \$0.10. After Medicare combined the payment amounts for levalbuterol and albuterol, one vial of either drug was reimbursed at \$1.18.

Beneficiaries in South Florida were more likely to have multiple suppliers

Thirty-one percent of South Florida beneficiaries had more than one supplier providing inhalation drugs during 2007. Thirty-five percent of the multiple-supplier beneficiaries received drugs from three or more suppliers, often for the same drug in the same month. For example, one beneficiary received levalbuterol and budesonide from 12 different suppliers in 2007, with as many as 6 suppliers each providing both drugs in a single month. In comparison, only 12 percent of beneficiaries in the rest of the country had claims submitted from more than one supplier, with almost all of these (91 percent) receiving drugs from just two.

Beneficiaries with claims for budesonide were particularly likely to have more than one supplier of the drug. In the first half of 2007, an average of 27 percent of beneficiaries with budesonide claims in South Florida had multiple suppliers providing budesonide compared to 9 percent of beneficiaries in the rest of the country (budesonide’s average payment amount per vial was \$4.67 in 2007). In contrast, in the first half of 2007, 4 percent of South Florida beneficiaries and 7 percent of beneficiaries in the rest of the country had more than one supplier of albuterol (albuterol’s average payment amount was \$0.18 per vial).

Inhalation drug suppliers billed more for beneficiaries in South Florida than in the rest of the country

Overall, suppliers billed Medicare an average of \$1,176 in inhalation drug claims for each of their South Florida beneficiaries in 2007; on average, they were paid \$585 for each beneficiary that year. In the rest of the country, suppliers billed Medicare an average of \$661 per beneficiary for inhalation drugs in 2007 and were paid \$307. One supplier in South Florida was paid an average of \$14,000 per beneficiary for inhalation drugs in 2007—an amount 46 times the average for the rest of the country.

Medicare paid for inhalation drug claims that did not comply with LCD guidelines

Effective July 1, 2007, utilization guidelines for budesonide were included on

LCD L5007. However, as of September 2008, the PSC covering Florida had not implemented edits to deny budesonide claims in

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excess of the LCD amount.²⁰ As Table 3 shows, the average Medicare payment for a 90-day supply²¹ of budesonide in South Florida (\$1,874 per beneficiary) was more than double the payment amount for the maximum milligrams listed in the LCD (\$888 per beneficiary) during the second half of 2007; in the rest of the country, the average payment for budesonide was lower than the LCD guideline (\$746 per beneficiary). Seventy-five percent of South Florida beneficiaries who received budesonide had paid claims that exceeded the utilization guidelines, compared to 14 percent of beneficiaries in the rest of the country. In the case of one South Florida beneficiary, Medicare paid for a 90-day supply of budesonide that was 15 times greater than the maximum listed in the LCD (and was provided by four different suppliers during the period).

Table 3. Ninety-Day Supply of Drugs Covered Under the LCD (per beneficiary)

| Short Description of Drug | Maximum Payment Amount in LCD for 90-Day Drug Supply | South Florida | | Rest of the Country | |
|---|--|-----------------|---|---------------------|---|
| | | Average Payment | Percentage of Beneficiaries Exceeding LCD | Average Payment | Percentage of Beneficiaries Exceeding LCD |
| Budesonide inhalation solution (unit dose), up to 0.5 mg | \$888 | \$1,874 | 74.5% | \$746 | 14.3% |
| Levalbuterol inhalation solution (unit dose), 0.5 mg | \$2,041 | \$1,619 | 24.0% | \$736 | 0.7% |
| Albuterol inhalation solution (unit dose), 1 mg | \$102 | \$30 | 0.3% | \$35 | 0.6% |
| Ipratropium bromide inhalation solution (unit dose), 1 mg | \$53 | \$33 | 19.7% | \$24 | 3.4% |

The average payment amounts listed are for only an 83-day period in 2007. Not all beneficiaries receiving each drug had a claim during the sampled time. Therefore, these monthly averages will not add up to the average spending per drug for the entire year.

Source: OIG analysis of inhalation drug claims in the Medicare NCH file, 2007.

Although the average payment for the other inhalation drugs fell below the guidelines set by the LCD, several individual South Florida beneficiaries still exceeded the maximum payment amount for a 90-day supply of those drugs. For example, nearly a quarter of South Florida beneficiaries exceeded the maximum amount for levalbuterol,

²⁰ We discussed the implementation of the budesonide edit only with staff from Jurisdiction C (the region including Florida) on August 18, 2008. We did not determine whether other PSCs had this edit in place.

²¹ As discussed in the methodology and appendix, this 90-day supply was actually calculated based on claims from an 83-day period to allow for a 7-day delivery window.

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and 20 percent exceeded it for ipratropium bromide. In contrast, only 1 percent and 3 percent of beneficiaries in the rest of the country exceeded the limits for these drugs, respectively. For the remaining drug (albuterol), less than 1 percent of the beneficiaries in South Florida and in the rest of the country exceeded the limits.

For 62 percent of inhalation drug claims in South Florida, the beneficiary did not have a Part B service visit during the last 3 years with the physician who reportedly prescribed the drug

According to Medicare data, for 62 percent of South Florida inhalation drug claims, the beneficiaries on these claims did not have a Medicare-billed office

visit or other service in the past 3 years with the physician who reportedly prescribed the drug. Medicare paid \$114 million (71 percent of total South Florida payments) for these inhalation drug claims in 2007. For example, one beneficiary had almost \$45,000 in Medicare-paid claims for inhalation drugs in 2007 even though the beneficiary did not have a single billed service visit with any of the six physicians who reportedly prescribed the drugs.

For 16 percent of suppliers, not a single South Florida beneficiary to whom they provided inhalation drugs had a billed service with the physician listed on the claim form

In other words, every one of these suppliers' inhalation drug claims listed a beneficiary that did not have a Medicare-paid office visit or other service in 2005, 2006, or 2007 with the physician who reportedly prescribed the drugs. For an additional 27 percent of suppliers, more than half of their inhalation drug claims were for beneficiaries who had no Part B service claims with the physician listed on the claim.

Furthermore, among the 10 suppliers with the highest dollar amount of inhalation drug reimbursement in 2007, between 66 percent and 97 percent of claims were for beneficiaries without any associated Part B services. These 10 suppliers accounted for almost a quarter of the total amount billed to Medicare for inhalation drugs in South Florida.

Certain ordering physicians in South Florida were associated with a large volume of inhalation drug claims

In 2007, 10 South Florida physicians were each listed as the ordering physician on more than \$3.3 million in submitted

inhalation drug claims, or an average of \$12,000 per day. In comparison, only one of the nearly 200,000 physicians ordering inhalation drugs for beneficiaries in the rest of the country had claims submitted totaling more than this amount.

Among the 10 South Florida physicians, all but one had significant increases in the total amount billed with their identifiers as compared to the amount billed in the previous year. For example, one physician was listed as the ordering physician on \$4.7 million in submitted inhalation drug claims in 2007, a 56-fold increase from the \$84,000 submitted for inhalation drugs claims billed with that identifier in 2006.

Each of the 10 physicians reportedly ordered inhalation drugs for an average of 745 South Florida beneficiaries in 2007. These physicians had Medicare-paid office visits or other Part B-related services in 2005 through 2007 with between 1 percent and 53 percent of the beneficiaries for whom they reportedly ordered inhalation drugs in 2007.

Medicare paid a total of \$28 million for inhalation drugs reportedly ordered by these 10 physicians during the year. Based on claims data, 148 different suppliers provided inhalation drugs to the South Florida beneficiaries associated with these physicians. However, 33 suppliers accounted for the majority (79 percent) of the amount paid by Medicare.



South Florida has been identified by OIG, CMS, and other agencies as a high-risk area for fraudulent billings to Medicare by DME suppliers. Fraudulent billings jeopardize the financial integrity of Medicare and may endanger Medicare beneficiaries when the drugs are overprescribed.

Our findings demonstrate that even though CMS has made efforts to reduce DME fraud in South Florida, a problem may persist among DME suppliers billing for inhalation drugs. Medicare spent substantially more on inhalation drugs per beneficiary in South Florida during 2007 than on beneficiaries in the rest of the country. The greatest spending discrepancies occurred among the brand name drugs budesonide and levalbuterol. In particular, spending and utilization for budesonide were much higher not only in comparison to averages in the rest of the country but also in relation to coverage guidelines. Furthermore, many of the South Florida beneficiaries did not have a Medicare service claim during the last 3 years with the physician who reportedly prescribed the inhalation drugs. Therefore, we recommend that CMS:

Ensure That All PSCs, Particularly the PSC Covering Florida, Are Enforcing the Guidelines for Maximum Milligrams per Month for All Inhalation Drugs, Especially Budesonide

LCD L5007 states that claims exceeding the maximum milligrams per month for certain inhalation drugs should be denied as not medically necessary unless there is documentation to justify larger amounts. However, 75 percent of Medicare beneficiaries in South Florida exceeded the utilization guideline for budesonide. Although we did not determine whether documents supporting this use were provided to the PSCs, it seems improbable that three-quarters of the South Florida beneficiaries would require a higher dose of budesonide. In comparison, only 14 percent of beneficiaries in the rest of the country had claims for budesonide exceeding the utilization guideline.

Furthermore, although the average monthly reimbursement for other inhalation drugs fell below the guidelines set by the LCD, several individual South Florida beneficiaries still exceeded the maximum milligrams per month. For example, almost a quarter of South Florida beneficiaries exceeded the LCD guidelines for levalbuterol.

Based on our conversations with DME MAC staff from the jurisdiction that includes Florida, claim edits have been put in place to detect when beneficiaries exceed the maximum milligrams per month for most

inhalation drugs covered by the LCD. However, as of August 18, 2008, there are currently no such edits for budesonide, even though the utilization guideline has been in effect for over a year. Adding an edit to detect overutilization of budesonide and ensuring that payments for other inhalation drugs comply with LCD utilization guidelines will help minimize payments for unnecessary medications.

Eliminate Medicare’s Vulnerability to Potentially Fraudulent or Excessive Claims for Beneficiaries Prescribed Inhalation Drugs in South Florida

Medicare spending per beneficiary on inhalation drugs, especially budesonide, was much greater in South Florida than in the rest of the country. The increased spending in this region, along with that fact that the beneficiaries listed on more than 60 percent of South Florida inhalation drug claims did not have a Medicare-billed office visit during the last 3 years with the physician who reportedly prescribed the drug, suggests improper billing for inhalation drugs by DME suppliers operating in South Florida. One method CMS could use to better detect aberrancies and further reduce Medicare’s vulnerability is working with the DME MACs and PSCs to establish additional claims edits.

Review Cases in Which the DME Supplier Appears To Be Fraudulently Billing Medicare for Inhalation Drugs and Take Appropriate Action Based on the Review’s Results

DME suppliers billed almost twice as much for inhalation drugs provided to beneficiaries in South Florida compared to beneficiaries in the rest of the country. In addition, multiple suppliers often submitted claims for the same drug for the same beneficiary in a single month. Because South Florida has been a notoriously high-risk area for supplier DME fraud, CMS should take action to ensure that claims submitted by these suppliers, particularly the top-billing DME suppliers, are legitimate. We will provide CMS with information on the suppliers and physicians associated with a large quantity of questionable inhalation drug claims for its review. Where appropriate, CMS should take steps to revoke the Medicare billing numbers of suppliers with fraudulent claims. Additionally, we will refer to our Office of Investigations information on the DME suppliers with aberrant billing patterns.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with all three of our recommendations. CMS stated that through its Program Integrity Miami field office and the DME Stop Gap Plan, it has already identified and begun to address many of the same issues cited in our report. In addition, CMS noted that OIG's findings reinforce the validity of the agency's efforts.

In response to our recommendations, CMS stated that, as of September 2008, the DME PSC for South Florida and the DME MAC had implemented a "medically unlikely" edit for budesonide. According to CMS, there was an immediate and significant 50-percent decrease in both allowed and billed amounts for the drug in Miami-Dade and Broward counties. In addition, CMS described the efforts by its Miami and Los Angeles field offices to identify physicians who ordered high volumes of DME items, including inhalation drugs, for beneficiaries with no clinical relationship to the physician. Following the interviews with these physicians, the field office revoked billing privileges of suppliers not meeting supplier standards and established granular prepay edits at the beneficiary, supplier, physician, and procedure code level to deny payment to suppliers for DME never ordered by these physicians. Finally, CMS expressed its commitment to continually reviewing and refining the process to improve the Medicare program and will review any additional information provided by OIG.

We did not make any changes to the final report based on CMS's comments. For the full text of CMS's comments, see Appendix B. We have provided CMS with information on the suppliers and physicians that we identified as having potentially fraudulent activities in this report.

Calculation for Local Coverage Determination Guideline Comparison

A local coverage determination (LCD L5007) provides guidelines for the maximum milligrams per month that may reasonably be billed (without additional documentation) for the majority of the inhalation drugs covered by Medicare. Because beneficiaries may receive up to a 90-day supply of a drug, edits for the utilization guideline are set for an 83-day period (excluding a 7-day grace period for delivery). Because of this, we used an 83-day period for our LCD comparison analysis.


For albuterol, levalbuterol, and ipratropium bromide, we identified each beneficiary's initial drug claim in the first quarter of 2007 and selected the claims submitted in the 83 days following. Because budesonide did not have an LCD guideline until July 1, 2007, we selected the initial claim in the third quarter of 2007. For each selected beneficiary's 83-day period, we calculated the total Medicare payment amount for each drug.

Because we selected beneficiaries with their initial claim in the first or third quarter, not all beneficiaries prescribed that drug were included in the analysis. For example, 25 percent of beneficiaries taking levalbuterol in 2007 did not have a claim in the first quarter and therefore were not included in this drug's analysis.

Additionally, we determined the average Medicare payment amount that would be reflective of the maximum milligrams listed in the LCD for 3 months. Because beneficiaries could have their 83-day period extend into the following quarter (e.g., a beneficiary could have had the initial claim on the last day of the first quarter, meaning the majority of the 83 days falls into the second quarter), we calculated the average maximum amount per month based on the first and second quarter for albuterol, levalbuterol, and ipratropium bromide, and based on the third and fourth quarter for budesonide. We calculated the average based on two quarters because Medicare payment amounts for each drug may fluctuate from quarter to quarter. To make it representative of the 83-day period, we multiplied the average maximum amount per month by three (approximately 90 days).

Using the beneficiary's total Medicare payment amount in the 83 days, we determined the percentage of beneficiaries who exceeded the payment amount associated with the maximum milligrams listed in the LCD for 3 months. We also calculated the average Medicare payment amount per each drug for South Florida beneficiaries and compared it to the average amount for beneficiaries in the rest of the country. We then compared both amounts to the 90-day maximum amount in the LCD guidelines.

Agency Comments



DEPARTMENT OF HEALTH & HUMAN SERVICES

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GENERAL

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: MAR 23 2009

TO: Daniel R. Levinson
Inspector General

FROM: Charlene Frizzera *Charlene Frizzera*
Acting Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Aberrant Claim Patterns for Inhalation Drugs in South Florida" (OEI-03-08-00290)

Thank you for the opportunity to comment on the OIG's draft report on Aberrant Claim Patterns for Inhalation Drugs in South Florida (OEI-03-08-00290). CMS is extremely concerned about inappropriate Durable Medical Equipment (DME) billing. On October 6, 2008, CMS announced a DME Seven State Stop Gap Plan to address high-fraud risk issues involving Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers, ordering physicians, beneficiaries, and items and equipment. Our DME Stop Gap plan focuses on seven high risk States. Through the ongoing efforts of our Program Integrity Miami Field Office (FO) and our DME Stop Gap Plan, CMS has already identified and begun to address many of the same issues that the OIG is citing in this draft report. Since both of our agencies are focused on improving fraud detection and prevention, the similarity in some of the OIG's findings reinforce the validity of our DME Stop Gap efforts.

OIG Recommendation
Ensure that all Program Safeguard Contractors (PSCs), particularly the PSC covering Florida, are enforcing the guidelines for maximum milligrams per month for all inhalation drugs, especially budesonide.

CMS Response
We concur with this recommendation. In September 2008, the DME PSC for South Florida recommended, and the DME Medicare Administrative Contractor (MAC) implemented, a "medically unlikely" edit for budesonide. The DME MAC is in the process of reviewing its experience with the edit to determine whether the edit tolerances can be tightened. After the September, 2008 implementation of the edit, there was an immediate and significant 50 percent decrease in both allowed and billed amounts for budesonide in Miami-Dade and Broward counties in October, 2008. Because of the impact and effectiveness of the edit, we expect this decrease to continue. CMS will continue to emphasize to the MACs that local coverage determination (LCD) development, effective medical review, and education related to inhalation drugs is important.

Page 2- Daniel R. Levinson

OIG Recommendation

Eliminate Medicare's vulnerability to potentially fraudulent or excessive claims for beneficiaries prescribed inhalation drugs in South Florida.

CMS Response

We concur with this recommendation. In an effort to address potentially fraudulent claims for inhalation drugs, the CMS' Los Angeles and Miami FOs identified physicians who ordered high volumes of DME items and equipment, including inhalation drugs, where beneficiaries have no clinical relationship with those physicians. Following interviews with these physicians, the FOs revoked billing privileges of suppliers not meeting supplier standards and established granular prepay edits at the beneficiary, supplier, physician and procedure code level to deny payment to suppliers for DME never ordered by these physicians. CMS' DME Stop Gap Plan builds on the current Miami and Los Angeles FO model and will expand its scope to include other high risk States. In Florida alone, approximately 60 percent of the top 100 ordering physicians are the subject of administrative actions by CMS or its contractors or are the subject of law enforcement investigations.

OIG Recommendation

Review cases in which the DME Supplier appears to be fraudulently billing Medicare for inhalation drugs and take appropriate action based on the review's results.

CMS Response

We concur with this recommendation. The DME PSC and the DME MAC for Florida have been analyzing data and closely monitoring the utilization of inhalation drugs, including budesonide. Prior to the implementation of the September 2008 budesonide edit, the DME PSC and the DME MAC in Florida were denying claims involving inhalation solutions for compounded ingredients not approved by the FDA. This work contributed to the development of the September 2008 edit for budesonide.

The CMS will review any additional information provided by OIG to determine the extent to which corrective actions have already been taken and to determine if any other actions are needed.

The CMS is committed to continually reviewing and refining our processes to improve the Medicare program, and we thank the OIG for its efforts on this report. We look forward to receiving the requested identifying information on the suppliers and ordering physicians cited in your draft report. We also look forward to continuing to work with the OIG to identify and prevent fraud, waste, and abuse in the Medicare program.



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 lead analyst for this study. Other regional and central office staff who contributed include Scott Manley and Dave Graf.