Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

ABERRANT BILLING IN SOUTH FLORIDA FOR BENEFICIARIES WITH HIV/AIDS



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OBJECTIVE

- To identify claims patterns associated with HIV/AIDS infusion therapy that may indicate fraudulent or abusive activity in three South Florida counties.
- 2. To assess the effectiveness of past and current efforts to control inappropriate payments to infusion therapy providers in three South Florida counties.

BACKGROUND

In June 2003, the program safeguard contractor alerted the Centers for Medicare & Medicaid Services (CMS) that providers in three South Florida counties (Miami-Dade, Broward, and Palm Beach) were billing aberrantly for infusion therapy services for beneficiaries with HIV/AIDS. Related investigations found that many of the services billed by these aberrant providers were not medically necessary or feasible. In May 2004, CMS issued a National Medicare Fraud Alert describing the "infusion therapy scam." By 2005, the three South Florida counties accounted for 72 percent of submitted charges for beneficiaries with HIV/AIDS nationwide, though only 8 percent of such beneficiaries lived there. Most of these charges were for drugs used in infusion therapy.

CMS is responsible for paying Medicare claims and ensuring the integrity of those payments. The agency uses contractors to execute those responsibilities. CMS and the contractors have a number of tools available to control aberrant billing, including payment suspensions and preenrollment provider site visits.

We used Medicare Part B National Claims History data from 2006 to analyze beneficiary and provider claims patterns in South Florida. In addition, we interviewed staff from CMS and its contractors and reviewed documents related to infusion fraud to assess the efforts to control aberrant billing.

FINDINGS

In the last half of 2006, three South Florida counties accounted for half the total amount, and 79 percent of the amount for drugs, billed nationally for Medicare beneficiaries with HIV/AIDS. Most of the charges originating in these counties were for nonoral drugs; drug

claims represented just 16 percent of the submitted charges in other geographic areas. Aberrant claims patterns differentiated South Florida providers and beneficiaries from those in the rest of the country.

Other metropolitan areas exhibit patterns of billing similar to South Florida but to a lesser extent. CMS and its contractors have identified aberrant billers of infusion therapy outside of South Florida. Our data analysis shows that some metropolitan areas in other geographic regions have patterns of billing for beneficiaries with HIV/AIDS that are somewhat similar to those seen in South Florida.

CMS has had limited success in controlling the aberrant billing practices of South Florida infusion therapy providers. CMS and its contractors have used multiple approaches, but none has proven effective over time. The most common tools include payment suspensions, revocations, and claims-processing edits. CMS has taken limited action to strengthen the enrollment process for new providers.

RECOMMENDATIONS

CMS has had limited success controlling aberrant billing by infusion clinics in South Florida. Therefore, we recommend that CMS:

Mandate site visits for certain providers in high-risk jurisdictions. Site visits are essential in high-risk areas to confirm that providers have physical addresses and report accurate information in their applications.

Afford contractors more time to review new applications from certain providers in high-risk jurisdictions. Contractor standards require that 80 percent of new applications be processed within 60 days of receipt. CMS should set alternative standards in high-risk jurisdictions for certain provider types and/or geographic areas that are vulnerable to fraud.

Modify the Statement of Work for the jurisdiction that includes South Florida to require enhanced activities to fight fraud and abuse. CMS intends to release the Statement of Work for the Medicare Administrative Contractor for Jurisdiction 9, which includes Florida, Puerto Rico, and the U.S. Virgin Islands, later this year. The agency should require and fund the new contractor to conduct enhanced provider enrollment, data analysis, and claims-editing activities in the portion of this area identified as high-risk.

Require extensive review of all reassignments in high-risk areas to confirm that they are legitimate. To minimize the chances that a legitimate provider is associated with a fraudulent one, CMS should take steps to ensure that all reassignments in high-risk areas are legitimate and fund more extensive review of all new and existing reassignments in South Florida as well as other high-risk areas.

Strengthen revocations to prevent further fraud and abuse. CMS should consider shortening the 30-day notice period for revocations. In addition, CMS should require prepayment review on all claims from providers that have effective or pending revocations.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally concurred with our recommendations and stated that our analysis will be useful to its continued efforts to prevent fraudulent payments for infusion therapy. CMS noted that our recommendations to mandate site visits and afford contractors more time to review new applications in high-risk jurisdictions have been incorporated into a new demonstration project.

CMS stated that our recommendations demonstrate that CMS's current actions are working. CMS also stated that the decline in Medicare payments in Florida from 2004 to 2006, despite increased amounts billed, demonstrates the effectiveness of corrective actions. However, we find that the continued aberrant billing and payment patterns documented in our report demonstrate the need for improved provider enrollment controls to prevent the entry of unqualified providers into the Medicare program. CMS acknowledged the need for improvement in the provider enrollment process and described recent actions it has taken to strengthen this process.

CMS's positive response to our recommendations, including its initiation of the new demonstration project, indicates that the agency is now moving toward strategies that should more effectively protect the integrity of Medicare payments in South Florida.

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OBJECTIVES

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BACKGROUND

Medicare Spending for Beneficiaries With HIV/AIDS

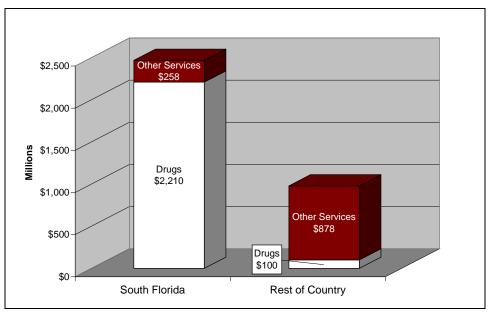
Based on our analysis, Medicare paid approximately \$1 billion in 2005 for services for beneficiaries with a diagnosis of HIV or AIDS. Claims for nonoral drugs¹ accounted for \$610 million of this amount, while claims for other services, primarily evaluation and management services, accounted for the remainder. Together, two codes generated about one-third of the reimbursement for drugs: J9310 (Rituximab, 100 milligrams) and J2353 (Ocreotide, depot form, 1 milligram). Medicare paid approximately \$100 million for each of these codes in 2005.

In 2005, about 8 percent of Medicare beneficiaries with HIV/AIDS lived in three South Florida counties (Miami-Dade, Broward, and Palm Beach), but 72 percent of submitted charges for beneficiaries with HIV/AIDS appeared on claims originating there. Providers in the three counties submitted bills totaling \$2.5 billion to Medicare (of which Medicare paid \$653 million) on behalf of beneficiaries with HIV/AIDS—more than twice the \$978 million submitted (\$311 million paid) by providers in all other areas of the country combined.

As shown in Figure 1, most of the claims in South Florida were for nonoral drugs. South Florida providers submitted bills totaling more than \$2.2 billion (\$568 million paid) for nonoral drugs for beneficiaries with HIV/AIDS in 2005, about 22 times the \$100 million submitted (\$42 million paid) for such claims in the rest of the country.

¹ As identified in the "Current Procedural Terminology" (2006 edition) or "Healthcare Common Procedure Coding System" (2006 edition).

FIGURE 1 Submitted charges for beneficiaries with HIV/AIDS, by location



Source: Office of Inspector General analysis of a 1-percent sample of 2005 Medicare Part B National Claims History data, 2007.

Infusion Therapy for HIV/AIDS Patients

The National Institutes of Health defines AIDS as "a disease of the body's immune system caused by the human immunodeficiency virus (HIV). AIDS is characterized by the death of CD4 cells (an important part of the body's immune system), which leaves the body vulnerable to life-threatening conditions, such as infections and cancers." According to the Kaiser Family Foundation, approximately 438,000 individuals in the United States and its territories were living with AIDS at the end of 2005. Medicare claims data show that about 99,300 beneficiaries had at least one claim that referenced a diagnosis of HIV/AIDS in 2005.4

² "Glossary of HIV/AIDS-Related Terms," 5th ed., October 2005. Available online at http://aidsinfo.nih.gov/contentfiles/GlossaryHIV-relatedTerms FifthEdition en.pdf. Accessed June 6, 2007.

 $^{^3}$ The Henry J. Kaiser Family Foundation, "Estimated Number of Persons Living with AIDS, All Ages, at the End of 2005." Available online at http://www.statehealthfacts.org/cgi-bin/healthfacts.cgi?action=compare&category=HIV%2fAIDS&subcategory=Persons+Living+with+AIDS&topic=Persons+Living+with+AIDS+All+Ages. Accessed March 14, 2007.

 $^{^4}$ Office of Inspector General analysis of a 1-percent sample of 2005 Medicare National Part B Claims History data.

Although no cure for AIDS exists, many treatments currently are available. At some point in their treatment, persons with AIDS may require intravenous infusion therapy: the gradual administration of a drug or other solution into the body through a vein. For AIDS patients, infusion therapy is most commonly used to provide antibiotics, antiviral or antifungal medications (such as those paid for by Medicare under Part B), parenteral (nonoral) nutrition, hydration, and electrolyte repletion. Patients usually receive infusion therapy in a hospital, but outpatient therapy—at a clinic or at home—is appropriate for some patients.

Medicare Administration and Oversight in South Florida

The Centers for Medicare & Medicaid Services (CMS) is responsible for paying Medicare claims and ensuring the integrity of those payments. Contractors of different types perform these functions for CMS in defined geographic areas. Medicare carriers process Part B physician claims and also handle provider enrollment, customer service, and education and training. Program safeguard contractors (PSCs) conduct data analysis and other activities to help reduce fraud, waste, and abuse. First Coast Service Options (FCSO) is the Medicare carrier for Florida (and Connecticut). Electronic Data Systems Corporation (EDS) became the PSC for Florida in March 2005 after taking over the contract from TriCenturion.

CMS's Office of Financial Management (OFM) has the overall responsibility for ensuring the fiscal integrity of all CMS programs. As such, OFM manages contractors' program integrity efforts through its Program Integrity Group. The CMS Regional Offices, including the Atlanta Regional Office that covers Florida, also play a role in protecting Medicare from fraud, waste, and abuse. Also, because of concerns about Medicare fraud in South Florida, CMS established the Miami Satellite Division in 1995. The Satellite Division reports to OFM; is responsible for community outreach regarding fraud, waste, and abuse; and provides support to law enforcement agencies in the area.

Other Government agencies also have a role in protecting Medicare in South Florida. The Office of Inspector General (OIG) investigates cases of health care fraud and levies civil monetary penalties where appropriate and can exclude problem providers from Medicare. Often in coordination with OIG, the Department of Justice also investigates and

prosecutes health care fraud. Florida's Agency for Health Care Administration licenses clinics and enforces statutes related to the provision of health care.

Fraud Involving HIV/AIDS Patients in South Florida

In June 2003, TriCenturion reported to CMS that it had identified a scheme in which providers in South Florida, mainly in Miami, billed for infusion therapy services that were "not medically necessary or feasible" for beneficiaries with HIV/AIDS.⁵ The PSC found that "[p]roactive data analysis revealed that infusion therapy providers could quickly move from start-up to a high billing provider," and "claims are being paid because these egregious providers are circumventing the system edits by submitting claims using allowable diagnosis codes and not the diagnosis found in the medical records." On June 27, 2003, staff from TriCenturion and CMS's Miami satellite office conducted the first of 20 onsite visits to aberrantly billing infusion therapy providers to review records. None of the services reviewed met Medicare payment requirements, and payments to the provider were suspended. Investigations of the remaining 19 providers also resulted in payment suspensions.⁷

CMS issued a National Medicare Fraud Alert to its contractors, regional offices, and other government agencies on May 19, 2004, characterizing the South Florida situation as the "infusion therapy scam." According to this alert, medical record review and investigative findings identified the following characteristics of the scam, among others:

- services that are poorly documented or undocumented;
- documentation that indicates that patients received "vitamin therapy," not infusion of the expensive drugs billed;
- multiple providers billing for the patients on the same date or on alternating dates;
- providers submitting bills for days when the clinic is closed for business;

 $^{^5}$ TriCenturion, LLC, "June 2003 Monthly Status Report" and "Infusion Project Progress Report." September 9, 2004.

⁶ Ibid.

⁷ Ibid.

- providers under prepay medical review circumventing the review by obtaining new provider numbers; and
- providers under payment suspension opening new clinics with new provider numbers.

Federal and State authorities have investigated and prosecuted several cases involving infusion providers. The Chief Financial Officer of Florida cited a scam in which a Tampa man used offers of \$100 cash and \$50 grocery cards to recruit patients to seek treatment at a local clinic as 1 of the top 10 fraud cases in the State for 2005–2006.8 State and Federal law enforcement investigations have revealed similar schemes in which "runners" recruit patients with offers of cash to go to particular infusion clinics for treatment. The clinic then bills for expensive drug infusion treatments for these patients that they do not receive. Investigations by CMS's contractors and OIG revealed that perpetrators of infusion fraud schemes sometimes appropriate the identities of legitimate providers to submit claims to Medicare.

Provider Enrollment and Sanction Authority

Federal regulations and CMS policy define the process for enrolling providers in Medicare and enumerate the rights and responsibilities of participating providers. Pursuant to 42 CFR § 424.510(d)(1), prospective providers must submit completed application forms and supporting documentation to CMS to obtain billing privileges. This form solicits identifying information about the applicant, any adverse legal history (such as felony convictions for financial crimes or the

⁸ Florida Department of Financial Services, "Annual Top 10 Fraud List," June 20, 2006. Available online at http://www.fldfs.com/PressOffice/ViewConsumerAlert.asp?ID=2360. Accessed January 16, 2007.

⁹ The United States Attorney's Office, Southern District of Florida, "Miami Clinic Owner Convicted of Health Care Fraud Involving HIV Infusion Treatments," September 29, 2006. Available online at http://www.usdoj.gov/usao/fls/PressReleases/060929-01.html. Accessed October 25, 2006. The United States Attorney's Office, Southern District of Florida, "Jury Convicts Two in HIV-Clinic Fraud," October 2, 2006. Available online at http://miami.fbi.gov/dojpressrel/pressrel06/mm20061002.htm. Accessed October 25, 2006. Office of the Attorney General of Florida, "Miami Men Arrested for \$1.4 Million Medicare Fraud Through Bogus HIV Clinic," September 6, 2006. Available online at http://myfloridalegal.com/newsrel.nsf/newsreleases/E4CDEA6773BA9E3A852571E1006C66
DE. Accessed October 25, 2006. "Meeting Minutes: Medical Fraud Committee, Florida Board of Medicine, September 26, 2005." Available online at http://www.doh.state.fl.us/mga/medical/min 09-26-05Fraud.pdf. Accessed June 6, 2007.

revocation of a Medicare billing number), the provider's practice location, names of individuals having ownership or managing control of the business, and the billing agent for the provider, if one exists. Clinics with multiple practice locations must identify each location on the application. By signing and submitting the application form, the applicant agrees to follow all Medicare laws, regulations, and program instructions. The CMS "Program Integrity Manual," Chapter 10, Section 2.1, stipulates that carriers must process 80 percent of new applications within 60 days, 90 percent within 120 days, and 99 percent within 180 days of receipt. Pursuant to 42 CFR § 424.80(b)(2), providers may reassign their billing privileges to certain other entities, such as clinics with which they have contractual relationships; providers request reassignment by submitting reassignment applications to CMS. In Florida, the carrier issues a separate billing number for each reassignment or clinic practice location.

Preenrollment site visits can help protect the Medicare program from fraud and abuse. Regulations at 42 CFR § 424.510(d)(8) permit CMS to perform onsite inspections to verify that the information on the enrollment applications is correct and to determine whether the applicants comply with enrollment requirements; onsite visits are required for independent diagnostic testing facilities (IDTFs), Indian Health Service facilities that supply durable medical equipment under Part B, and community mental health centers. 10 CMS stated in an April 25, 2003, proposed rule that in 1998 and 1999, it had funded 320 site visits to various types of new and existing providers that carriers had identified as potentially problematic. 11 About one-third of the providers visited had their applications denied or provider numbers revoked or were referred to contractor fraud units. CMS cited this effort in the proposed rule and stated, "[w]e believe that site visits are an important component of provider enrollment." In August 2005, CMS staff from the Miami and Los Angeles Satellite Divisions reported that contractors in their jurisdictions had terminated the billing privileges of 87 of 180 providers based on recent site visits. They estimated that the

¹⁰ CMS, "Program Integrity Manual," Chapter 10, sections 4.19.6, 11.9.2, and 12.1.1(B).

¹¹ "Medicare Program: Requirements for Establishing and Maintaining Medicare Billing Privileges." 68 FR 22064, 22065 (proposed April 25, 2003).

FIGURE 2
Empty office found
on a 2005 site visit.
If not for the visit,
this provider's
application would
have been approved.



Source: "NHIC CA Provider Enrollment On-Site Verification Program," 2007.

California visits had saved at least \$9 for each \$1 spent. 12 From September through December 2005, the California carrier, National Heritage Insurance Corporation (NHIC), conducted targeted preenrollment site visits of 95 non-IDTF providers; only 28 of the applications were approved.¹³ As shown in Figure 2, some of the visits revealed completely empty offices. The carrier further noted that ". . . these applications would have been approved and the provider could have submitted false claims had it not been for the site visits."

Providers must comply with all Medicare laws and regulations as a condition of their continued enrollment; several authorities exist to remove noncompliant providers from the program if necessary. The Social Security Act specifies circumstances under which the Secretary of the Department of Health and Human Services (HHS) must exclude certain entities from Medicare and others under which the Secretary may, at his or her discretion, exclude entities. ¹⁴ In addition, 42 CFR § 424.535 gives five reasons CMS may revoke the billing privileges of a provider: (1) noncompliance with enrollment requirements, (2) exclusion from Federal programs, (3) certain felony convictions, (4) submitting false or misleading information on an enrollment application, or (5) determination of the onsite review that

 $^{^{12}}$ "Special Rules for Special Places," a position paper submitted by staff from CMS's Miami Satellite Division and Los Angeles Satellite and Regional Offices for Regions 2, 4, and 9 to the CMS central office in August 2005.

¹³ NHIC, "NHIC CA Provider Enrollment On-Site Verification Program," 2007.

 $^{^{14}}$ Social Security Act \S 1128. The Secretary of HHS has delegated the exclusion authority to OIG.

the provider is not operational or does not satisfy enrollment requirements. Providers must be given prior notice of exclusions or revocations and have the right to appeal. Providers may also submit plans of corrective action to avert pending revocations.

In addition to the authority to revoke providers' billing privileges, Federal regulations also define CMS's authority to suspend Medicare payments to providers. Pursuant to 42 CFR § 405.371, CMS may suspend approved payments if it suspects that it has overpaid a provider or that a provider has engaged in fraud or willful misrepresentation of claims. Generally, CMS must inform the provider of the intent to suspend payments, explain the reasons for the action, and allow the provider to submit a rebuttal statement contesting the decision to suspend payments.¹⁵ In cases of suspected fraud or misrepresentation, or if it is likely to harm Medicare Trust Funds, CMS need not provide prior notice. 16 In these cases, the provider may submit a rebuttal statement once the suspension is in effect.¹⁷ Providers may not appeal further if CMS upholds the suspension after considering a rebuttal. 18 Suspensions last for an initial period of 180 days, which CMS may extend by another 180 days at the request of the carrier or a law enforcement agency.¹⁹

Previous Studies

In a 2006 report, the Government Accountability Office (GAO) assessed CMS's allocation of Medicare Integrity Program (MIP) funds between fiscal years 1997 and 2005 and concluded that "the agency's funding approach is not geared to target MIP resources to the activities with the greatest impact on the program and to ensure that the contractors have funding commensurate with their relative workloads and risk of making improper payments." GAO also noted that "one PSC received about 4 cents for conducting benefit integrity work for each \$100 in paid claims . . . in a jurisdiction that included Florida, which is at high risk

¹⁵ 42 CFR § 405.372 (b)(1).

 $^{^{16}}$ 42 CFR $\$ 405.372 (a)(3) .

¹⁷ 42 CFR § 405.372 (b)(2).

 $^{^{18}}$ 42 CFR \S 405.375 (c).

¹⁹ 42 CFR § 405.372 (d).

²⁰ GAO, "Medicare Integrity Program: Agency Approach for Allocating Funds Should Be Revised," September 2006, p. 21.

for fraudulent billing. In contrast, PSCs received the same level of funding to conduct benefit integrity work in states at lower risk for fraudulent billing, including Iowa, Montana, Pennsylvania, and Wyoming."

In March 2007, OIG published the results of 1,581 unannounced site visits to durable medical equipment suppliers in South Florida in a report entitled "South Florida Suppliers' Compliance With Medicare Standards" (OEI-03-07-00150). We found that 31 percent of the suppliers visited "did not maintain a physical facility or were not open and staffed during business hours." We recommended that CMS strengthen the enrollment process for durable medical equipment suppliers. CMS concurred with most of our recommendations and stated that it will take several steps to improve provider enrollment, including conducting more unannounced site visits and more rigorous background checks of applicants.

METHODOLOGY

Claims Patterns Analysis

To analyze beneficiary and provider claims patterns, we first defined the population from which to construct profiles as, respectively, beneficiaries with at least one claim referencing a diagnosis of HIV/AIDS (ICD-9 code 042) during a specified time period and providers that submitted at least one claim with an HIV/AIDS diagnosis during the same time period. During preliminary data analysis, we determined that the dollar amounts submitted and reimbursed for beneficiaries with HIV/AIDS in the three South Florida counties, especially for drugs, were significantly less in the second half of 2006 than in the first. Therefore, to concentrate on more current billing patterns, we defined our time period to be claims received in the third or fourth quarters of 2006 (July through December). We also learned from OIG investigators and from CMS contractors that although CMS adjusts claims data based on monies due from calculated overpayments, participants in infusion fraud rarely actually pay back any of the overpayment amounts. Because we wanted to assess how much money CMS paid to providers, we limited our data set to the original actions that CMS took on the claims.

To create the profiles, we first obtained from CMS the Medicare Part B National Claims History data files containing all claims received in the third and fourth quarters of 2006. We then identified all beneficiaries and providers appearing on at least one claim referencing an HIV/AIDS diagnosis as either the principal diagnosis on the claim or the line item diagnosis for a particular service. Next, we matched these lists of beneficiaries and providers back to the data sets containing all Part B claims from the third and fourth quarters of 2006. Thus, we created two analysis data sets of claims received in the third or fourth quarter of 2006. The first contained all claims received for beneficiaries with at least one claim referencing HIV/AIDS in that period, and the second contained all claims received from providers that submitted at least one claim referencing HIV/AIDS during that period. We then used the SAS statistical software package to analyze the data.

Our analysis often compares the three South Florida counties to other areas of the country. We defined a claim as originating from South Florida if the provider's ZIP Code (as it appeared on the claim) was in Miami-Dade, Broward, or Palm Beach Counties in Florida. We defined a beneficiary as a South Florida beneficiary if more than half of the beneficiary's claims originated from South Florida and a provider as a South Florida provider if more than half of the provider's claims originated there.

In addition to analyzing data from 2006, we examined historical trends from 2001 through 2005 using 1-percent samples of the Medicare Part B National Claims History data. Since the 1-percent samples are compiled by the date of service rather than the date of receipt, we used a slightly different process to create our analysis sets. First, we identified all beneficiaries and providers in a given year with at least one claim referencing a diagnosis of HIV/AIDS. Then, we identified all claims submitted for those beneficiaries or by those providers. We then summarized the combined claims data from the 5 years by the month in which the claim was received and by geographic location (the three South Florida counties, the rest of Florida, or the rest of the country).

²¹ The data were taken from CMS weekly claims-processing cycles, so the dates do not correspond exactly to the starting and ending dates of the third and fourth quarters of 2006. Also, the data did not have the receipt date variable available, only the processing date. The claims in our set spanned processing dates from June 29 to December 28, 2006.

Assessment of Controls

We interviewed staff from CMS and its contractors in South Florida (FCSO and EDS) about infusion fraud and actions taken to address it. We also obtained documents from CMS and its contractors pertaining to infusion fraud, including monthly reports the PSCs submitted to CMS from January 2003 through November 2006. FCSO provided data on provider number revocations, and CMS, FCSO, and EDS provided data on overpayments. We also interviewed staff and obtained documents from CMS's Part B carrier in California to learn about antifraud efforts in another vulnerable area, Southern California. We did not independently verify the information obtained from these interviews and documents. We reviewed applicable laws, regulations, and policies, as well as CMS provider enrollment applications and related materials.

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.

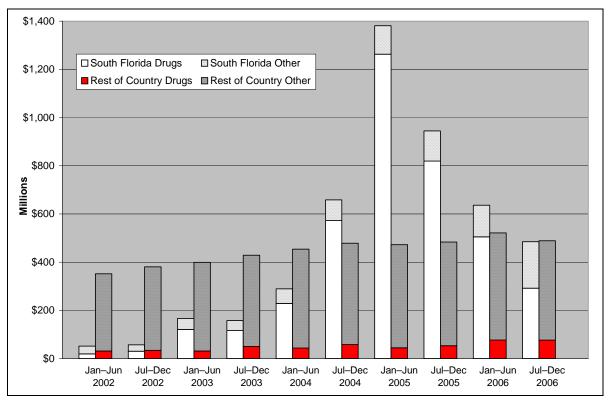


In the last half of 2006, three South Florida counties accounted for half the total amount, and 79 percent of the amount for drugs, billed nationally for Medicare beneficiaries with HIV/AIDS

Our analysis shows that Medicare received bills totaling \$976 million, of which it paid \$240 million, for services claimed for beneficiaries with HIV/AIDS in the last half of

2006. Although in the second half of 2006 about 10 percent of Medicare beneficiaries with HIV/AIDS lived there, claims originating in Miami-Dade, Broward, and Palm Beach Counties constituted 50 percent of the submitted charges and 37 percent of the paid amount. Nearly 61 percent of the total charges originating in the three South Florida counties were for nonoral drugs; nonoral drug claims represented just 16 percent of the submitted charges in other geographic areas. Overall, the three counties accounted for 79 percent of the amount submitted to Medicare nationally for drug claims involving HIV/AIDS patients. Furthermore, as shown in Figure 3, the South Florida proportion was

FIGURE 3
The amount submitted for beneficiaries with HIV/AIDS in South Florida exceeded the amount submitted for beneficiaries in the rest of the country for 2 years



Source: OIG analysis of 1-percent samples of 2001 through 2005 Medicare Part B National Claims History data and 2006 Medicare Part B National Claims History data, 2007.

even higher in previous periods. According to CMS staff who oversee the area, neither CMS nor its contractors have identified any clinical explanation for the high level of billing in South Florida.

Aberrant claims patterns differentiate providers in South Florida from those in the rest of the country

As displayed in Table 1, Medicare Part B claims data show that the claims patterns of providers that billed for HIV/AIDS services in the three South Florida counties in the last half of 2006 differed significantly from those of providers in the rest of Florida or in other States.²² For example, although the overall mean amount submitted to Medicare per provider was comparable in all locations, the mean amount submitted per provider specifically for beneficiaries with HIV/AIDS in the three counties was about 16 times higher than in the rest of Florida and 39 times higher than in all other States. Even greater disparities existed among drug claims: the mean submitted per provider in the three counties for such claims was about 64 times higher than in the rest of Florida and about 518 times higher than the mean in all other States. High billing for beneficiaries with HIV/AIDS was relatively widespread in the three counties—about 5.9 percent of South Florida providers that billed for HIV/AIDS patients submitted more than \$1 million each for those patients in the last half of 2006 compared to less than 0.5 percent in the rest of Florida or in all other States. Sixteen of the top twenty billers of services for beneficiaries with

Table 1: Significant differences exist between South Florida providers and others				
Provider attribute	South Florida	Rest of Florida	Rest of country	
Mean amount submitted	\$711,753	\$614,679	\$414,922	
Mean amount submitted for beneficiaries with HIV/AIDS	\$267,653	\$16,343	\$6,878	
Mean amount submitted for drug codes for beneficiaries with HIV/AIDS	\$197,453	\$3,070	\$381	
Percentage of submitted charges for beneficiaries with HIV/AIDS	38%	2.7%	1.7%	
Percentage of submitted charges for beneficiaries with HIV/AIDS that are for drug codes	74%	19%	6%	
Mean number of beneficiaries with HIV/AIDS	42	17	10	

Source: OIG analysis of claims received in the third or fourth quarter 2006 in the Medicare Part B National Claims History data, 2007.

 $^{^{22}}$ In this finding, the term "provider" refers to any entity that submitted at least one Medicare Part B claim in the last half of 2006 that referenced an HIV/AIDS diagnosis.

HIV/AIDS were located in South Florida, and all of the top 40 billers for drugs for these patients were located there.

In addition to mean billed amounts, two elements of the claims patterns of providers in the three South Florida counties were notable. First, 38 percent of the total charges South Florida providers submitted to Medicare in the last half of 2006 were for AIDS patients; beneficiaries with HIV/AIDS accounted for less than 3 percent of providers' submitted charges in the rest of Florida or in all other States. Second, 74 percent of the charges South Florida providers submitted for beneficiaries with HIV/AIDS were for drugs, compared with 19 percent in the rest of Florida and 6 percent in all other States. Furthermore, of the 78 South Florida providers that billed more than \$1 million for beneficiaries with HIV/AIDS, 58 (74 percent) submitted more than half of their charges for drugs for these patients. Only two of the five providers that billed \$1 million or more for beneficiaries with HIV/AIDS in the rest of Florida and none of the 23 in other States shared this billing pattern.

More reimbursement, especially for drugs, is claimed for beneficiaries with HIV/AIDS in South Florida than for those in the rest of the country

As with providers, the claims patterns of beneficiaries with HIV/AIDS in South Florida differed greatly from those of beneficiaries in other regions in the last half of 2006. For example, average submitted charges per beneficiary with HIV/AIDS in South Florida were about nine times those in the rest of Florida or in all other States. The greatest differences were for drugs—South Florida beneficiaries were listed on drug claims more often, and for higher amounts, than those elsewhere. The average beneficiary in South Florida also was listed on claims for a greater number of unique drug codes and on claims from

Table 2: South Florida beneficiaries with HIV/AIDS are associated with more and larger claims				
Beneficiary attribute	South Florida	Rest of Florida	Rest of country	
Mean amount submitted	\$57,482	\$6,532	\$6,333	
Percentage of beneficiaries with at least one drug claim	66%	12%	10%	
Mean amount submitted for drug claims (all beneficiaries)	\$34,412	\$904	\$1,024	
Mean amount submitted for drug claims (beneficiaries with at least one drug claim)	\$52,505	\$7,463	\$9,778	
Mean number of different drugs for which the beneficiary had claims (beneficiaries with at least one drug claim)	5.2	2.0	1.8	
Mean number of providers that submitted a claim per beneficiary (all beneficiaries)	16	8.5	8.1	

Source: OIG analysis of claims received in the third or fourth quarter 2006 in the Medicare Part B National Claims History data, 2007.

more providers than those in other areas. Table 2 displays some of the attributes that differentiated South Florida beneficiaries from others.

Other metropolitan areas exhibit patterns of aberrant billing similar to South Florida but to a lesser extent

CMS satellite division staff and contractors in South Florida reported concerns that as more controls are instituted in that region, the aberrant

billing patterns observed there may spread to other geographic areas. In October 2004, the PSC identified some aberrantly billing providers outside of South Florida and, in response, requested that existing drug code edits be extended to two Gulf Coast counties.²³ FCSO carried out this request on January 4, 2005.²⁴ In 2005, the Miami Satellite Division's analysis showed that the patterns were spreading into northern and western areas of the State and also to venues outside Florida.²⁵ In late March 2007, CMS issued a National Medicare Fraud Alert because several providers in the greater Detroit metropolitan area billed for infusion therapy in the aberrant manner characteristic of South Florida providers. The alert stated that many of the individuals associated with these providers had recently moved from Florida and Puerto Rico.

Our data analysis suggests that although the aberrant billing patterns are not widespread outside of South Florida, some other metropolitan areas share some characteristics with the three counties. We identified four attributes that characterize Medicare claims patterns for beneficiaries with HIV/AIDS in South Florida: (1) the percentage of the total amount submitted for beneficiaries with HIV/AIDS that is for drugs, (2) the mean amount submitted per provider for beneficiaries with HIV/AIDS, (3) the percentage of beneficiaries with HIV/AIDS who have at least one drug claim, and (4) the mean amount submitted for drugs per beneficiary with at least one drug claim. Table 3 shows the six other geographic areas where at least two of these characteristics

²³ TriCenturion, LLC, "October 2004 Monthly Status Report."

²⁴ TriCenturion, LLC, "January 2005 Monthly Status Report."

 $^{^{25}}$ "Special Rules for Special Places," a position paper submitted by staff from CMS's Miami Satellite Division and Los Angeles Satellite and Regional Offices for Regions 2, 4, and 9 to the CMS central office in August 2005.

were at least twice the national level (excluding South Florida) and the total amount submitted for beneficiaries with HIV/AIDS was at least 1 million.

Table 3: Other areas share some of the claims characteristics of South Florida						
Geographic area	Amount submitted for beneficiaries with HIV/AIDS (millions)	Percentage of submitted amount for drugs	Mean submitted per provider for beneficiaries with HIV/AIDS	Percentage of beneficiaries with at least one drug claim	Mean amount submitted for drugs per beneficiary with at least one drug claim	
All U.S. except South Florida	\$489	16%	\$7,482	11%	\$9,520	
South Florida	\$487	61%	\$267,653	66%	\$52,505	
Riverside-San Bernardino- Ontario, CA	\$14.3	73%	\$6,202	28%	\$4,223	
Nashville-Davidson- Murfreesboro, TN	\$5.9	60%	\$7,852	30%	\$13,023	
Providence-New Bedford-Fall River, RI-MA	\$5.3	70%	\$2,744	5%	\$158,899	
Nonmetropolitan Florida	\$4.7	62%	\$34,209	27%	\$15,229	
Kansas City, MO-KS	\$4.8	50%	\$7,347	12%	\$29,605	
Indianapolis, IN	\$2.9	43%	\$3,912	11%	\$53,817	

Source: OIG analysis of claims received in the third or fourth quarter 2006 in the Medicare Part B National Claims History data, 2007.

CMS has had limited success in controlling the aberrant billing practices of South Florida infusion therapy providers

CMS and its contractors have used multiple approaches in South Florida to try to control aberrant billing for

beneficiaries with HIV/AIDS, but based on our data analysis and review of CMS materials, none has yet proven effective in eliminating it. Recent efforts show promise, but their long-term effectiveness is unknown. The most common tools used include payment suspensions, prepayment review, provider number revocations, claims-processing edits, and onsite investigations of existing providers.

Administrative actions on billing numbers have significant limitations <u>Payment suspensions</u>. Suspending payments gives CMS an immediate and long-lasting way to prevent Medicare from paying suspected false infusion claims from a particular provider number. Once approved, suspensions take effect immediately, thereby stopping payments to

²⁶ See Appendix A for complete details on how we constructed Table 3.

suspected fraudulent providers. Because suspensions last a minimum of 180 days, and longer if extended, the payments remain stopped while the PSC and/or law enforcement investigates the provider. For these reasons, EDS's benefit integrity staff described payment suspensions as the strongest tool available to them to deal with suspected fraudulent providers.

Despite these strengths, administrative requirements limit the usefulness of suspensions in South Florida. All suspensions must be approved by CMS, so although their effect is immediate, the approval process can delay implementation, according to contractor personnel. Also, although aberrant billers often control multiple provider numbers, investigations have also found that they sometimes use other providers' identities to submit claims. Hence, CMS will suspend provider numbers only when there is evidence of an overpayment or fraudulent activity involving those particular numbers, rather than all provider numbers associated with the aberrant biller. While this practice minimizes the chance of inadvertently suspending the billing number of a provider that is not involved in the aberrant billing, it also means that aberrant billers with multiple numbers can continue billing Medicare using unsuspended numbers. Lastly, because having a current payment suspension is not one of the reasons for which CMS may deny an enrollment application, a suspended provider that submits a new application that meets all requirements must be approved.²⁷

To address the last issue, in June 2006 CMS's Program Integrity and Medicare Contractor Management groups instructed FCSO to set aside applications for new provider numbers from providers with active payment suspensions until the suspensions are resolved.²⁸ However, CMS also stated that this set-aside applied only if the new applicant had the same business structure as the suspended provider. Hence, corporate providers could bypass the restriction by changing any element of their board structure. CMS staff told us that the agency verbally advised FCSO in late April 2007 that unless a suspended provider reapplies with a new tax identification number, any new application that lists, in any capacity, individuals that had ownership or

 $^{^{27}}$ 42 CFR \S 424.510.

²⁸ CMS, Joint Signature Memorandum, JSM-TDL-06505, June 23, 2006.

management interest in the suspended provider also should be set aside.

<u>Prepayment review.</u> If the PSC identifies a provider it suspects is submitting false claims, but the amount billed is not high enough or the level of evidence is not sufficient to justify a suspension, it often places the provider on prepayment review. This means that the PSC requests and reviews documentation to support all claims submitted by the provider before payment is made. Although prepayment review has fewer administrative requirements than payment suspension and has proven effective with individual providers, it has limitations. For example, although contractor personnel say most infusion therapy providers under prepayment review do not respond to documentation requests, there is potentially a significant administrative burden if many providers do respond. Also, prepayment medical review affects only future claims; unlike a suspension, it cannot stop payment on already-approved claims. Furthermore, similar to a suspension, the prepayment review requirement is applied only to provider numbers on which the aberrant activity was observed.

Revocations. Revoking a billing number prevents a provider from submitting claims with that number, but administrative requirements limit the ability of revocations to control aberrant billing for infusion therapy. As such, PSC staff told us that they issue revocations as part of their normal investigative procedures, but do not use them as a primary tool. One limitation is that, like suspensions and prepayment reviews, revocations are applied only to particular provider numbers, not to the individual or corporation associated with the problem. CMS staff gave an example of one South Florida provider that had 29 separate provider numbers; although 19 were revoked, the provider can still bill with the remaining numbers. Even if all of a provider's billing numbers are revoked, the provider can regain the ability to bill Medicare. Pursuant to 42 CFR § 424.535, providers that have their billing privileges revoked may reapply by submitting new applications. CMS and contractor staff told us that as long as the provider meets all requirements, they must approve the new application. Our data analysis shows that CMS paid about \$470,000 in 2006 to two South Florida providers that appear to have obtained new provider numbers after revocations.

Requirements related to the effective dates of revocation also limit their value in controlling aberrant billing. Providers must be notified 30 days

prior to the effective date of the revocation, allowing extra time to submit additional claims.²⁹ Also, revoked providers can continue to bill for service dates prior to the effective date of the revocation.³⁰ Hence, "... a fraudulent provider with a revocation date of September 1, 2005 can continue to bill for dates of service going back to March 1, 2004. It also means that the same provider has until March 1, 2006, to bill for services rendered on August 31, 2005."³¹ Although this is cited as vulnerability by several CMS and contractor staff, we did not find any payments made to infusion therapy providers in 2006 on claims received between the date of their revocation letters and the effective dates of the revocations.

Claims-processing edits have been effective in the short term but have not had a lasting effect

<u>Service-level edits</u>. According to monthly reports from the PSC to CMS, starting in March 2004, CMS began approving edits on specific drug codes that were targets of abuse in the three counties in South Florida. The first such edit was a prepayment edit implemented on March 3, 2004. The PSC reported that in its first month of operation, nearly 5,000 claims triggered this edit. Providers responded to the documentation requests for only about 26 percent of these claims, and more than 99 percent of reviewed services were denied. A "medically unbelievable edit," which screens claims for services that are not clinically feasible, for this code was added on April 30, 2004, and also resulted in numerous payment denials. Later edits also have resulted in numerous denials.

Although edits have reduced payments for particular codes, the tendency of aberrant billers to switch to new codes has undermined the edits' overall effectiveness. The PSC noted in a 2005 strategy document submitted to CMS that "[a]s pre pay barriers have been erected, fraudulent providers have scurried in mass [sic] to other codes. Currently there are a number of new J codes which have been billed for

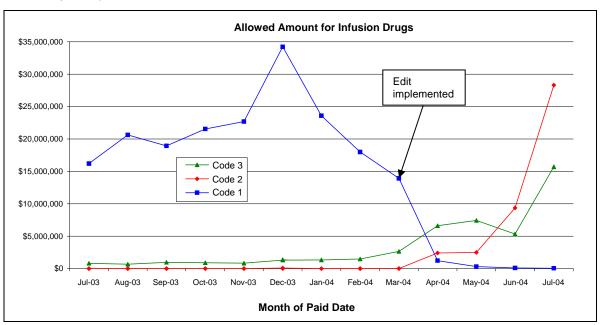
²⁹ 42 CFR § 424.535(f).

³⁰ 42 CFR § 424.535(b).

 $^{^{31}}$ "Special Rules for Special Places," a position paper submitted by staff from CMS's Miami Satellite Division and Los Angeles Satellite and Regional Offices for Regions 2, 4, and 9 to the CMS central office in August 2005.

over \$5 million in March 2005 by known aberrant providers."³² Although the PSC used claims data analysis to detect new codes likely to be abused, this process was too slow to respond adequately; the August 2004 PSC report to CMS noted that "the time span for us to identify a new code, draft an edit and have it implemented by [the carrier] allows weeks to go by while millions of dollars are paid out before the edits control the behavior."³³ Figure 4, which appeared in a September 2004 report from the PSC to CMS, shows South Florida providers' quick response to the first prepayment edit that was implemented, a pattern that generally continued with later edits.

FIGURE 4
South Florida providers responded quickly to the first prepayment edit implemented (Note that the allowed amount in other Florida counties for these codes remained nearly constant over the same period.)



Source: TriCenturion LLC, "Infusion Therapy Project Report, September 9, 2004," 2004. Modified to delete lines showing activity outside of South Florida, to add explanatory text, and to redact the codes involved. Note that the data underlying this chart are not limited to billings for beneficiaries with HIV/AIDS and include Miami-Dade and Broward Counties only.

 $^{^{32}}$ EDS, "Comprehensive Plan by EDS To Stop Infusion Fraud in South Florida," submitted to CMS in early 2005.

³³ TriCenturion, LLC, "August 2004 Monthly Status Report."

According to reports by TriCenturion, investigations conducted in 2004 confirmed providers' swift reactions to claims level edits and their intent to defraud Medicare. In the summer of 2004, TriCenturion identified the 25 top aberrantly billing providers, including those that had switched codes after edits were implemented, and targeted them for site visits. The purpose of the visits was to apprise the providers of their aberrant billing activity and to determine possible reasons for the activity. Some providers claimed ignorance of their billing activity, but others "admitted that they had switched not due to medical necessity but due to Medicare not paying for the other code." 34

As CMS contractors implemented new edits for drug codes, South Florida providers shifted their billing to other services. A new claims edit implemented in July 2006 appears to have limited the overall amount reimbursed for services claimed on behalf of beneficiaries with HIV/AIDS; based on our analysis, reimbursement for these beneficiaries

Table 4: Increase in payments for none	Irug services claimed for beneficiaries with HIV/AIDS
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Ounter	HCPCS	Payment	Payment	Percent
Service	code	1 st half 2006	2 nd half 2006	change
Injection procedure for sacroiliac joint, arthrography, and/or anesthetic/steroid	27096	\$6,324	\$580,111	9,073%
Transluminal balloon angioplasty, percutaneous; renal/visceral artery	35471	\$0	\$196,671	-
Endovenous ablation therapy of incompetent vein, extremity	36475	\$4,167	\$894,496	21,368%
Injection, anesthetic agent and/or steroid, facet joint or facet joint nerve; lumbar or sacral, single level	64475	\$275,566	\$3,182,247	1,055%
Injection, anesthetic agent and/or steroid, facet joint or facet joint nerve; lumbar or sacral, additional level	64476	\$209,789	\$2,623,809	1,151%
Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, single level	64479	\$1,252	\$103,024	8,126%
Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, single level	64622	\$17,477	\$105,026	501%
Destruction by neurolytic agent, paravertebral facet joint nerve; lumbar or sacral, additional level	64623	\$17,195	\$528,337	2,973%
Ultrasonic guidance for needle placement	76942	\$9,688	\$536,636	5,439%
Combined right/retrograde left heart catheterization, for congenital cardiac anomalies	93531	\$0	\$121,023	-

Source: OIG analysis of 2006 Medicare Part B National Claims History data, 2007.

Note: Although some of these codes also had significant growth in areas outside of South Florida, the growth rate in South Florida for each of these codes was at least three times that in the rest of the country.

 $^{^{34}}$ Ibid. and TriCenturion, LLC, "November 2004 Monthly Status Report."

decreased by about 42 percent and reimbursement for drugs by 73 percent from the first half of 2006 to the second half. Meanwhile, payments for services other than drugs increased 54 percent in the second half of 2006 compared to the first, growing from \$37 million to \$57 million. Ten service codes had particularly significant growth, as shown in Table 4; South Florida payment on behalf of beneficiaries with HIV/AIDS for each of these codes was greater than that for the rest of the country combined in the latter half of 2006.

<u>Beneficiary-level edits</u>. In addition to claims-based edits, Medicare has employed beneficiary-based edits to combat fraud in South Florida. In June 2004, the PSC began another antifraud effort called the High Volume Claim Beneficiary Project. This automated edit denied all claims except for certain services, such as emergency services, beyond a certain dollar threshold for a group of 500 beneficiaries. However, most beneficiaries involved in aberrant billing for infusion therapy were not affected because beneficiaries with HIV/AIDS diagnoses were excluded.

CMS later approved a separate project specifically targeted toward infusion beneficiaries called the High Volume Infusion Beneficiary Project (HVIBP). The HVIBP was implemented on January 3, 2005, and immediately resulted in many denials—the PSC claimed savings of \$31 million in the edit's first month of operation. Our analysis of Medicare claims data shows that overall reimbursement for South Florida beneficiaries with HIV/AIDS fell from about \$51 million in December 2004 to \$39 million in January 2005, and the mean reimbursement per beneficiary with HIV/AIDS was cut significantly, from \$8,000 to \$5,000. As with the claims based edits, these effects were temporary; by April 2005, total reimbursement for beneficiaries with HIV/AIDS topped \$150 million in South Florida, and the mean reimbursement per beneficiary surpassed \$18,000.

Onsite investigations of existing providers are effective in uncovering fraudulent activity but are relatively infrequent

According to their monthly reports to CMS, the PSCs have intermittently used onsite visits to investigate suspicious infusion providers in South Florida. Between June and December 2003, the PSC visited 20 providers it had identified as aberrant billers of infusion therapy services. Payments to all 20 were suspended, and 5 were

referred to law enforcement.³⁵ Other targeted site visit efforts in October 2004 and September 2005 produced similar results. Apart from these larger efforts, PSC site visits to infusion providers generally have been limited to one or two a month, according to the PSC reports. By way of reference, our analysis indicated that about 1,300 South Florida providers billed at least one claim in the last half of 2006 that listed an HIV/AIDS diagnosis.

CMS has taken limited action to strengthen the enrollment process for new infusion therapy providers

Although CMS recognized in 2003 that ". . . in many cases site visits are the only method we have to ensure that providers and suppliers actually exist and meet the requirements to participate in [Medicare] . . . , "36 it did not act on numerous contractor suggestions to implement preenrollment site visits for South Florida infusion therapy providers until mid-2006. In September 2004, TriCenturion submitted an "Infusion Project Progress Report" to CMS. The report stated that "the continued fraud and abuse in South Florida requires more drastic action to stop the abuse being perpetrated against the Medicare Trust Fund" and recommended that CMS contract for inspections of "all new clinics in South Florida prior to issuing a provider number." The "Infusion Stopgap Plan" that EDS submitted to CMS in May 2005 also described an enhanced provider enrollment process that included onsite visits. In September 2005, EDS submitted a concept paper outlining the duties and responsibilities of a Special Investigative Team that would conduct in-depth investigations, including preenrollment site visits.³⁷ In May 2006, FCSO submitted a paper to CMS entitled "Medicare Fraud and CERT (Comprehensive Error Rate Testing Program) Scores: The Same Challenge in Fraud-Infected Areas?" In it, FCSO proposed establishing a pilot project to strengthen its prepayment activities, including enhanced provider enrollment. According to FCSO, it identified

³⁵ TriCenturion, LLC, "Infusion Project Progress Report," September 9, 2004.

³⁶ "Medicare Program: Requirements for Establishing and Maintaining Medicare Billing Privileges." 68 FR 22065–22066 (proposed April 25, 2003).

³⁷ EDS, "September 2005 Monthly Status Report."

unspent funds in its contract to finance the estimated \$1 million, 18-month initiative.³⁸

CMS approved the FCSO pilot project starting on July 12, 2006; it is scheduled to end on January 11, 2008.³⁹ As part of the enhanced provider enrollment activity under the pilot, FCSO now conducts site visits of all new clinic applicants in South Florida. These site visits are performed by one individual working under contract to FCSO, who sends a letter to each provider ahead of time announcing the date of the visit and requesting the presence of medical personnel. According to FCSO, each site visit costs \$75; the total budget for the site visits, including resources to review and process the findings, is \$300,000. Although FCSO had projected that it would conduct 30 to 50 site visits of new applicants per month, only 59 had been conducted by December 2006 because fewer clinics applied for billing privileges than had been anticipated. FCSO plans to conduct unannounced visits later in 2007 because it suspects that some fraudulent providers put on false fronts during an announced visit. FCSO also anticipates expanding the pilot to include site visits of existing Medicare providers.

³⁸ For reference, according to FCSO, its total budget (including activities in both Connecticut and Florida) for fiscal year 2007 is approximately \$76 million.

³⁹ FCSO, "Statement of Work, First Coast Service Options, South Florida Pilot Project."



CMS has had limited success in controlling aberrant billing by infusion clinics in South Florida. The aberrant billing patterns discussed in this report raise concerns about the integrity of the Medicare program. Controls implemented to date have had limited effect. Therefore, we recommend that CMS:

Mandate Site Visits for Certain Providers in High-Risk Jurisdictions

Medicare currently requires site visits before carriers issue provider numbers to independent diagnostic testing facilities. The carrier in Southern California expanded these visits to other providers to great effect at little additional cost, but only for a limited time. (See page 7.) Because the normal provider enrollment process is a desk review of paperwork, both announced and unannounced site visits are essential in high-risk areas to confirm that providers have physical addresses and report accurate information in their applications. CMS could fund these site visits out of carriers' program management budgets, which already support current provider enrollment activities.

Afford Contractors More Time To Review New Applications From Certain Providers in High-Risk Jurisdictions

Contractor standards require that 80 percent of new applications be processed within 60 days of receipt. In South Florida, this rule may hinder FCSO's ability to ensure that only legitimate providers obtain billing privileges. CMS should set alternative standards in high-risk jurisdictions for certain provider types and/or geographic areas vulnerable to fraud. CMS also should allow contractors to exempt applications from providers that have had recent revocations or payment suspensions from the timeliness standard, even if the corporate structures of the providers have changed or providers apply under new tax identification numbers.

Modify the Statement of Work for the Jurisdiction That Includes South Florida To Require Enhanced Activities To Fight Fraud and Abuse

CMS intends to release the Statement of Work for the Medicare Administrative Contractor for Jurisdiction 9, which includes Florida, Puerto Rico, and the U.S. Virgin Islands, later this year. The agency should require and fund the new contractor to conduct enhanced provider enrollment, data analysis, and claims-editing activities in the portion of this area identified as high-risk.

Require Extensive Review of All Reassignments in High-Risk Areas To Confirm That They Are Legitimate

OIG investigators and CMS contractor personnel told us that fraudulent infusion clinics in South Florida sometimes appropriate the identities of legitimate providers to obtain billing privileges. For this reason, CMS and the contractors said that they are reluctant to use sanctions such as revocations and suspensions on all of the provider numbers associated with a particular clinic when it revokes or suspends one, which potentially leaves Medicare open to further abuse. To minimize the chances of a legitimate provider being associated with a fraudulent one, CMS should take steps to ensure that all reassignments in high-risk areas are legitimate. The FCSO pilot project partially addresses this by funding the carrier to conduct a more extensive review when it receives a sixth reassignment application for a particular provider. For example, contractors are directed to send the physician a letter to verify the reassignment and to deactivate the provider identification number and deny the application if the physician does not respond. CMS should extend this policy by funding carriers to conduct this level of review for all new and existing reassignments that meet the criteria specified in the pilot, both in South Florida and in other high-risk geographic areas.

Strengthen Revocations To Prevent Further Fraud and Abuse

Currently, because providers may use revoked numbers to continue to submit potentially fraudulent claims for service dates prior to the effective date of the action, revocations do not adequately protect Medicare funds. Similarly, in cases when fraudulent activity is evident, the requirement to provide 30 days' notice prior to the effective date of the revocation may expose Medicare to additional potentially fraudulent claims. CMS should consider shortening the notice period for revocations. In addition, CMS should require prepayment review on all claims from providers that have effective or pending revocations. CMS also should develop a strategy for minimizing the risk to Medicare from providers with multiple billing numbers, perhaps automatically placing all numbers associated with a revoked number on prepayment review pending further investigation.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS generally concurred with our recommendations. CMS stated that our analysis will be useful to its continued efforts to prevent fraudulent payments for infusion therapy and that the agency will be contacting OIG for details about additional metropolitan areas exhibiting aberrant billing patterns. CMS also stated that our recommendations to mandate site visits and afford contractors more time to review new applications in high-risk jurisdictions have been incorporated into a new demonstration project.

CMS stated that our recommendations demonstrate that CMS's current actions are working. CMS also stated that the decline in Medicare payments in Florida from 2004 to 2006, despite increased amounts billed, demonstrates the effectiveness of corrective actions. However, we found that in the last half of 2006, approximately 10 percent of beneficiaries with HIV/AIDS lived in the three South Florida counties, but claims originating in those counties constituted 50 percent of submitted charges and 37 percent of the Medicare paid amount. The continued aberrant billing and payment patterns documented in our report demonstrate the need for improved provider enrollment controls to prevent the entry of unqualified providers into the Medicare program. CMS acknowledged the need for improvement in the provider enrollment process and described recent actions it has taken to strengthen this process.

In response to our recommendation to modify the Statement of Work for the jurisdiction including South Florida to require enhanced activities to fight fraud and abuse, CMS concurred and stated that it has added language to the Statement of Work to indicate that Florida is a high-risk area and special actions are needed to deal with fraud. We recommend that CMS require and fund enhanced provider enrollment, data analysis, and claims-editing activities in this area.

In response to our recommendation that CMS review all reassignments in high-risk areas, CMS concurred and stated that Medicare contractors are currently required to review such reassignments. We have revised our recommendation to clarify that CMS should conduct a more extensive review sufficient to confirm the legitimacy of such reassignments. For example, CMS could require contractors to send the physician a letter to verify the reassignment and to deactivate the provider identification number and deny the application if the physician does not respond. This level of review is required and funded by the FCSO pilot project only when the contractor receives a sixth reassignment application for a particular provider. We recommend that CMS extend this policy by funding carriers to conduct this level of review for all new and existing reassignments that meet the criteria

specified in the pilot, both in South Florida and in other high-risk geographic areas.

CMS also concurred with our recommendation to strengthen revocations. CMS states that it will consider enhancements to this section of the regulations.⁴⁰

While we recognize that traditional CMS program integrity actions form an integral part of any antifraud strategy, they have proven insufficient to control aberrant billing in South Florida. Our report shows that while claims edits depress infusion claims activity for a time, providers respond by changing billing patterns; this pattern of action and response produces payment denials but few long-term savings to Medicare as providers circumvent the controls. Payment suspensions, revocations, and investigations eliminate particular problem providers or provider numbers from the program, but have limited scope. Additional efforts are needed to prevent unscrupulous individuals from becoming Medicare providers.

CMS's positive response to our recommendations, including its initiation of the new demonstration project, indicates that the agency is now moving toward strategies that should more effectively protect the integrity of Medicare payments in South Florida.

The full text of CMS's comments is available in Appendix B.

 $^{^{40}}$ We note a technical correction—CMS's comments cited 42 CFR 434.535; the regulations listing the reasons a Medicare contractor may use to revoke billing privileges are found at 42 CFR 424.535.



DETAILED METHODOLOGY FOR TABLE 3

To produce Table 3, we first determined the Metropolitan Statistical Area (MSA) in which each service was claimed to have been provided. To do so, we matched the Medicare Part B National Claims History data to the Office of Management and Budget's MSA data by the provider's ZIP Code. If a ZIP Code did not match any MSA, we considered the claim to originate from a nonmetropolitan area of the State in which the ZIP Code was located. Next, we summarized the claims data by beneficiary, adding up the number of claims from each MSA in which the beneficiary had a service. If any MSA was the source of more than 50 percent of a beneficiary's claims, we considered the beneficiary as belonging to that MSA. If not, we considered the beneficiary as belonging to no MSA. We used the same process to determine to which MSA, if any, each provider belonged. We then matched the beneficiary and provider MSA data back to the claims data so that each claim record contained three geographic indicators: the MSA from which the claim originated, the MSA to which the beneficiary belonged, and the MSA to which the provider belonged.

Next we calculated the four characteristics we had identified as representative of aberrant billing in South Florida for each MSA. We calculated the percentage of the submitted amount that was for drugs by dividing the amount submitted for drugs in each MSA by the total amount submitted in that MSA. We calculated the mean submitted per provider for beneficiaries with HIV/AIDS for each MSA by dividing the total submitted for beneficiaries with HIV/AIDS by providers with at least one claim referencing an HIV/AIDS diagnosis belonging to that MSA by the number of such providers. We found the percentage of beneficiaries with at least one drug claim in each MSA by dividing the number of beneficiaries belonging to the MSA that had at least one drug claim by the total number of beneficiaries belonging to that MSA. Lastly, we calculated the mean amount submitted for drugs among beneficiaries with at least one drug claim in each MSA by dividing the total amount submitted for drugs for beneficiaries belonging to each MSA by the number of beneficiaries belonging to the MSA that had at least one drug claim. We calculated the same values for the entire nation excluding South Florida using the same methodology. We included all MSAs (or nonmetropolitan areas) that had at least two characteristics that were at least twice the national level in Table 3.





DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Office of the Administrator Washington, DC 20201

DATE:

AUG 2 3 2007

TO:

Daniel R. Levinson

Inspector General

FROM:

Herb B. Kuhn

Acting Deputy Administrator

SUBJECT:

Office of Inspector General (OIG) Draft Report: "Aberrant Billing in South

Florida for Beneficiaries with HIV/AIDS" (OEI-09-07-00030)

Thank you for the opportunity to comment on this Office of Inspector General (OIG) draft report. OIG performed this study to assess the effectiveness of the Centers for Medicare & Medicaid Services' (CMS) efforts to prevent inappropriate payments for infusion therapy in south Florida. Medicare infusion fraud involves for-profit clinics and doctors recruiting patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) and paying kickbacks to these patients so that they will come to their clinics and receive unnecessary or non-rendered services that are billed at clinically unlikely frequencies and dosages. Infusion providers manipulate claims by shifting codes, billing maximum numbers of units, splitting claims to evade edit parameters, obtaining multiple personal identification numbers, opening and closing clinics, and sometimes by operating out of "phantom clinics," which bill for services but never open a practice location, treat patients, purchase drug inventories, or operate like legitimate providers. As quickly as they are identified and Medicare payments are suspended, they shut down and reopen (or claim to reopen, in the case of phantom clinics) at another location under a different corporate name.

The CMS has recognized that infusion therapy is a significant area of Medicare fraud. We have been aggressively working on this issue since 2004, which is evident in the success of the activities undertaken by our contractors, Electronic Data Systems (EDS) and First Coast Service Options (FCSO), to combat infusion fraud. We have already addressed many of the issues discussed in this report, and we are glad to see that OIG shares CMS' concerns about preventing fraud in this area of the Medicare program. Since the majority of the OIG recommendations are for CMS to continue activities already underway, we believe this demonstrates that CMS' current actions are working. In fact, many of the providers with aberrant billing activity identified by CMS' oversight actions were referred to law enforcement and are now facing prosecution as a result of the South Florida Strike Force effort led by the Department of Justice in conjunction with OIG.

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The results of OIG's data analysis will be useful in CMS' continued efforts to prevent fraudulent payments for infusion therapy. The methodology and claims pattern analysis have not only illustrated south Florida's acknowledged aberrancy, but have also identified additional metropolitan areas exhibiting patterns of aberrant billing to a similar but lesser extent. We will be contacting your staff for additional details in order to investigate this situation further.

The OIG's finding that in the last half of 2006, three south Florida counties accounted for half of the total amount billed nationally for Medicare beneficiaries with HIV/AIDS and 79 percent of the amount of drugs billed nationally for these HIV/AIDS patients underscores the enormity of the problem.

Following are the Medicare billed and paid amounts for J Codes related to HIV/AIDS in Florida, demonstrating the increasing effectiveness of CMS/FCSO/EDS corrective actions:

- Of \$1.5 billion billed in Florida in calendar year (CY) 2004, Medicare paid approximately \$1 billion (66.6 percent);
- Of \$3.18 billion billed in Florida in CY 2005, Medicare paid \$916.2 million (28.7 percent); and
- Of \$3.30 billion billed in Florida in CY 2006, Medicare paid \$890 million (26.9 percent).

Although billing in Florida increased from \$1.5 billion to over \$3.3 billion, Medicare payment in Florida *dropped* from \$1 billion to \$890 million during the same timeframe as a direct result of CMS' containment efforts. During the period from 2005-2006, for every dollar the Medicare program spent on program integrity activities related to HIV/AIDS infusion therapy, the combined return on investment was \$195 to \$1 based on combined payment denials in excess of \$1.8 billion. This highlights what has been successful in south Florida, which should be continued there and replicated elsewhere.

The CMS acknowledges the points raised by OIG regarding the need for improvements in the provider enrollment process, some of which require regulatory change. In fact, CMS has undertaken several aggressive recent actions with respect to provider enrollment that address many of OIG's recommendations in this draft report. We would note that in our recently announced durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) and home health demonstration projects in California and Florida, and California and Texas respectively, which were approved prior to OIG's draft report, CMS has prominently featured the report's provider enrollment recommendations (conduct site visits for certain providers in high-risk areas, set alternative standards for application review in high-risk jurisdictions, and review all reassignments in high-risk areas). In addition, CMS has recently announced a 2-year infusion demonstration project in Florida, which includes all of the provider enrollment recommendations offered by OIG.

The CMS has published two proposed regulations that address many of OIG's concerns. The proposed rules are CMS-6006-P, "Surety Bond Requirement for Suppliers of Durable Medical

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Equipment, Prosthetics, Orthotics, and Supplies" and CMS-6003-P2, "Appeals of CMS or Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges." In addition, CMS has proposed manual instruction changes regarding the designation of high-risk areas and enhanced program integrity activities (data analysis, site visits, and medical review editing in addition to provider enrollment).

We have already built this high-risk concept into our contracting strategy to specifically address the need for additional program integrity resources and activities.

OIG Recommendation

The CMS should mandate site visits for certain providers in high-risk jurisdictions.

CMS Response

We concur with OIG regarding the need for enhanced site visits in high-risk areas of the country. As stated above, CMS has recently announced a demonstration project in south Florida focusing on infusion therapy. Under this demonstration, currently-enrolled infusion therapy clinics located in the targeted area will be required to submit a new CMS-855 application and will undergo a mandatory site visit.

OIG Recommendation

The CMS should afford contractors more time to review new applications from certain providers in high-risk jurisdictions.

CMS Response

We concur. Currently, processing timeframes can be adjusted as needed if additional review is necessary. Under the aforementioned demonstrations, Medicare contractors will have more time to review incoming CMS-855 applications than is currently allowed.

OIG Recommendation

The CMS should modify the Statement of Work (SOW) for the jurisdiction that includes south Florida to require enhanced activities to fight fraud and abuse.

CMS Response

Language has been added to the Florida MAC (J9) SOW indicating that Florida is a high-risk area for fraud and special actions are needed to deal with the fraud. In the PIM 100-08 Chapters 4 and 10 have language instructing contractors on how to handle areas identified as high risk.

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OIG Recommendation

The CMS should review all reassignments in high-risk areas to confirm that they are legitimate.

CMS Response

We concur, though we note that Medicare contractors are currently required to review such reassignments prior to their approval.

OIG Recommendation

The CMS should strengthen revocations to prevent further fraud and abuse.

CMS Response

We concur. 42 CFR 434.535 lists the reasons that a Medicare contractor may use to revoke a provider's or supplier's billing privileges. CMS is currently considering enhancements to this section of our regulations.

The CMS thanks the OIG for reviewing this issue and providing information that will be useful in developing additional policies to control the escalation of inappropriate Medicare payments for infusion therapy services.



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