

Good afternoon, Chairman Pallone, Ranking Member Deal, and distinguished members of the Subcommittee. I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections at the Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you today to discuss our work related to Medicare integrity and efficiency.

My testimony today will briefly describe the Office of Inspector General's (OIG) mission and role in protecting and promoting the integrity, efficiency, and effectiveness of the Medicare program. In addition, I will provide a general overview of our approach and work related to Medicare oversight touching on our efforts to assess the appropriateness of payments and prices, as well as addressing access and quality-of-care issues for beneficiaries. I will also discuss our recent work related to durable medical equipment as a specific illustration of some of the program vulnerabilities we have identified and our recommendations to strengthen Medicare enrollment safeguards. As part of that discussion, my testimony will provide details on our recent work in three South Florida counties, in which we determined that 45 percent of suppliers did not meet one or more of five Medicare enrollment requirements we reviewed.

Role and Responsibility of the HHS OIG

Our office was created in 1976 as the first statutory OIG in the Federal Government. Two years later, the Inspector General Act of 1978 (IG Act), modeled after the law creating the HHS OIG, established OIGs at other Cabinet-level departments of the Federal Government, as well as at some independent Government agencies. Congress created OIGs to be independent and objective units within Federal departments and agencies for the purposes of: (1) conducting audits and investigations of programs and operations; (2) coordinating and recommending policies to promote economy, efficiency, and effectiveness in the administration of programs; (3) preventing and detecting fraud and abuse; and (4) keeping the Department Secretary or Agency Administrator and Congress informed about the necessity for corrective action.

To achieve these important objectives, our office reviews programs to identify systemic vulnerabilities and makes recommendations to improve their efficiency and effectiveness; investigates specific instances of potential fraud or abuse and takes appropriate enforcement actions; audits specific payments, providers, and programs to identify and recommend recovery of overpayments; and promotes voluntary compliance by issuing guidance to the health care industry.

While we recognize that the majority of providers and suppliers are trustworthy and honest and strive to submit accurate and appropriate claims for payment, provider efforts alone are not sufficient to ensure the integrity of the program. OIG's oversight plays a key role in protecting program resources and the health and welfare of beneficiaries.

OIG's effectiveness in protecting the integrity of Medicare relies heavily on our partnerships with other law enforcement organizations. We work with the Department of Justice's Civil, Criminal, and Civil Rights Divisions, the U.S. Attorneys Offices, the Federal Bureau of Investigation, other Offices of Inspector General, and State and local law enforcement officials to investigate allegations of fraud cases and curb abusive behavior. We also frequently collaborate with the Centers for Medicare & Medicaid Services (CMS) to address mutual issues of concern.

Our staff expertise, national presence, organizational structure, ongoing identification of high risk areas, and collaboration with law enforcement partners enable OIG to leverage our resources to achieve maximum return for the dollars invested in our office. For the 3-year period from fiscal years (FY) 2004 through 2006, on average we reported savings of \$13 for every dollar invested in our office.

OIG Priority Setting, Reporting, and Followup

Each year, OIG publishes a work plan, which outlines our activities for the upcoming fiscal year. Although resource constraints preclude us from reviewing all 300-plus programs of the Department annually, OIG engages in a comprehensive work-planning process to identify the most important and timely issues and to direct our resources accordingly. Additionally, as part of the Department's mandated Performance and Accountability Report, each year our office identifies, based upon OIG's body of work, the most significant management and performance challenges facing the Department. And, consistent with the requirements of the IG Act, OIG reports to Congress semiannually on OIG's audit, evaluation, and enforcement accomplishments during the prior 6-month reporting period.

Finally, OIG reports on all recommendations based on findings from OIG audits and evaluations that have not been fully implemented by the Department. To present one comprehensive listing of these recommendations, OIG is in the process of combining two documents that we have historically issued — the "Red Book" and "Orange Book" — into one publication that will be titled "Compendium of Unimplemented Office of Inspector General Recommendations." This document will serve as a useful tool for Congress, the Administration, and the Department in their respective efforts to identify ways to maximize the effectiveness of programs and services and to improve the efficiency of departmental programs. OIG expects to release this compendium in May 2007.

OIG Identification of Program Inefficiencies and Vulnerabilities

The Medicare program has grown dramatically since its inception in 1965 and currently provides health care insurance for more than 43 million persons. More than 1 billion fee-for-service claims are processed annually, and Medicare is the largest purchaser of managed care services in the country. Total Medicare expenditures have grown from \$206 billion in FY 1996 to over \$382 billion in FY 2006.

With increasing dollars at stake and a growing beneficiary population, the importance and the challenges of safeguarding this program are greater than ever. Fraud, waste and abuse schemes have become increasingly complex and constantly change in response to the latest oversight efforts by Congress, CMS, our office, and our law enforcement partners. With Medicare's expansive network of health care activities comes a tremendous responsibility to protect the program's integrity, promote efficiency in operation, and ensure effectiveness.

OIG is committed to identifying program weaknesses and vulnerabilities to help prevent fraud, waste, and abuse, promote economies and efficiencies, and to improve quality of care. Our work is aimed at identifying and recommending methods to minimize inappropriate payments, identifying ways to close loopholes that allow unscrupulous providers to defraud the program, and examining payment and pricing methods to ensure that Medicare, its beneficiaries, and taxpayers realize good value for program expenditures. Further, we routinely monitor quality controls and oversight to ensure that beneficiaries have access to and receive quality health care. To illustrate the variety of approaches we use in our oversight of the Medicare program, I have highlighted some of our significant work below.

Ensuring Appropriate Payments

In 1996, OIG estimated that over \$23 billion (about 14 percent of expenditures) in improper payments had been made by the Medicare fee-for-service program. CMS, which is now responsible for determining the error rate, estimated that incorrect Medicare fee-for-service payments were reduced to \$10.8 billion (4.4 percent of expenditures) in 2006.

Although the overall Medicare fee-for-service payment error rate has decreased in recent years, the increasing size and scope of the Medicare program continue to place it at high risk for payment errors in terms of both frequency and magnitude. Improper payments and problems in specific parts of the program continue to be identified by OIG audits and evaluations and by CMS's assessment of the Medicare payment error rate. These reviews have revealed payments for unallowable services, improper coding, and other types of improper payments. Improper payments range from reimbursement for services provided but inadequately documented and inadvertent mistakes to outright fraud and abuse.

For example, OIG identified \$1.1 billion in improper payments in 1 year for services billed as consultations, a total of \$676 million in improper payments in a series of

reviews for mental health services provided in various settings, \$402 million in 1 year for inappropriately paid emergency and nonemergency ambulance transports, and \$136 million in a 6-month period for inappropriately paid physical therapy services. Additionally, OIG determined that in 2001, Medicare and its beneficiaries paid an estimated \$96 million for claims that did not meet Medicare's coverage criteria for any type of wheelchair or scooter and also spent an estimated \$82 million in excessive payments for claims that could have been billed using a code for a less expensive mobility device.

To promote access to hospital care for patients with substantial medical needs, CMS makes additional payments called outlier payments. In a recent audit, OIG found that a major hospital chain took advantage of the Medicare outlier payment system by billing for and receiving hundreds of millions of dollars in outlier payments by merely increasing its charges for services. The hospital chain recently reached a \$920 million settlement with the Government to settle allegations concerning the improper outlier payments, and, in addition, to settle allegations that it paid illegal kickbacks to doctors to refer Medicare patients to its hospitals and used improper billing codes to receive payments to which it was not entitled.

Ensuring Appropriate Prices

To further identify potential savings to the Medicare program, OIG has conducted extensive reviews of payment and pricing methodologies, which have determined that Medicare pays too much for certain items and services. For example, in a series of reports, OIG consistently found that Medicare's Part B drug reimbursement methodology led to overpayments and was vulnerable to abuse. In a 2001 review, OIG concluded that Medicare and its beneficiaries could save \$761 million a year by paying for 24 drugs at the prices available to physicians and suppliers. Consistent with the recommendations in our body of work, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included provisions that instituted a new drug reimbursement methodology for Part B. Recognizing the extensive work by OIG on Part B drug reimbursement, Congress also included provisions in the MMA mandating that OIG monitor Part B drug reimbursement and certain market prices for Part B-covered drugs on an ongoing basis.

In another example, OIG issued a report in September 2006 on the cost and servicing of home oxygen equipment. This study built upon earlier work mandated by the MMA that compared Medicare reimbursement for home oxygen equipment to the prices paid by Federal Employees Health Benefits plans. In this review, we found that the program spent \$2.3 billion in 2004 to rent oxygen concentrators, which are stationary equipment, for approximately 1.3 million beneficiaries. The Deficit Reduction Act of 2005 ended indefinite rental for oxygen equipment and established a rental cap of 36 months. Under the new rental cap, which beneficiaries will start to reach in January 2009, our report found that Medicare will allow \$7,215 for a concentrator that costs about \$600 to purchase new. Additionally, beneficiaries will incur \$1,443 in coinsurance over the 36

months. We noted that if such payments were limited to 13 months, Medicare and its beneficiaries would save \$3.2 billion over 5 years.

Ensuring Access and Quality of Care

OIG also conducts reviews to identify whether beneficiaries are able to promptly obtain needed health care services, and monitors oversight activities designed to ensure that beneficiaries receive quality services. In particular, OIG has long been concerned with the quality of care rendered in nursing facilities. Prior OIG work found an increase in the number of deficiencies, and a large number of nursing homes had been cited for substandard care. Recent work has focused on enforcement mechanisms against nursing homes that are out of compliance for designated time periods or have deficiencies that put residents in immediate jeopardy. For example, a recent OIG report found that for the majority of cases requiring mandatory termination of nursing facilities, CMS did not apply the remedy due to both late case referrals by States and CMS staff's reluctance to impose this severe remedy. In another recent review, OIG found that CMS did not investigate some of the most serious nursing home complaints within the required timeframe and that CMS's oversight of nursing home complaint investigations is limited.

We also recently conducted a review of quality-of-care data for End Stage Renal Disease facilities and found that limitations in data may limit quality oversight in these facilities. Another recent report examining the use of restraints and seclusion in hospitals found that CMS and survey agencies did not respond consistently to reported deaths in a timely manner and that CMS does not maintain comprehensive and reliable information about hospital deaths related to restraint and seclusion. We also recently examined beneficiary access to home health and skilled nursing facility care since the implementation of the prospective payment system and found that, while most Medicare beneficiaries have access to care, some with certain medical conditions, such as those needing IV antibiotics and/or expensive drugs and those with complex wound care needs, may experience delays in obtaining necessary care. Additional past work has included assessing the frequency of surveys of nonaccredited hospitals and CMS oversight of the Joint Commission on Accreditation of Healthcare Organizations performance.

Enrollment Vulnerabilities: Durable Medical Equipment Suppliers

Medicare Part B pays for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that are necessary and reasonable for the treatment of a beneficiary's illness or injury. These are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, nebulizers, and other equipment that physicians prescribe for home use. Medical supplies include catheter, ostomy, incontinence, and wound care supplies. Medicare also covers braces and artificial limbs. In FY 2005, Medicare paid over \$10 billion in claims for medical equipment and supplies.

OIG has consistently found that the Medicare DMEPOS benefit is vulnerable to fraud and abuse. Specifically, we have identified problems related to a wide range of items and

equipment, including orthotic body jackets, wound care supplies, incontinence supplies, lymphadema pumps, therapeutic shoes, enteral nutrition supplies, and, as provided in earlier examples, oxygen and power wheelchairs.

To ensure that payments are made correctly and services provided properly, it is essential that only qualified and trustworthy providers and suppliers are enrolled in the Medicare program. Our best strategy is twofold: to work to prevent these abuses from happening in the first place by ensuring that Medicare only does business with legitimate DMEPOS suppliers, and to pursue those unscrupulous providers who have exploited the current system.

Activities of such providers not only cost taxpayers billions of dollars, but also deprive vulnerable beneficiaries of the care and support they need as well as put them at financial risk. When fraud is perpetrated, such as an item being inappropriately billed on behalf of a Medicare beneficiary, the beneficiary is not only responsible for the copayments for unneeded or undelivered medical equipment, but may also face difficulties in obtaining medical equipment in the future if it appears that Medicare has already provided such equipment to that individual.

Fraudulent Activities

OIG has found that fraudulent suppliers continue to enroll and participate in the Medicare program. From 2002 through 2006, OIG excluded from the Medicare and Medicaid programs 121 DMEPOS companies and 457 individuals associated with DMEPOS. OIG has also aggressively investigated individuals and entities that have defrauded Medicare and Medicaid. Between 2002 and 2006, our investigations resulted in 289 successful criminal prosecutions of DMEPOS suppliers. During this same period, there were 76 civil settlements or judgments imposed. Together, these criminal convictions and civil adjudications resulted in more than \$796 million in restitution, fines and penalties.

To help combat DMEPOS fraud, OIG, in conjunction with the U.S. Attorney's Office for the Southern District of Florida, the Federal Bureau of Investigation, and the Department of Justice launched a health care initiative designed to identify suspicious suppliers and review questionable financial activities. Since its inception, the initiative has recovered more than \$10 million from nominee account holders who agreed to turn over the funds in the bank accounts when confronted by law enforcement officials. In most cases, the nominee account holders stated that they had no operational control of the businesses and had only lent their names in return for remuneration.

The DMEPOS fraud schemes we have uncovered generally fall into the following categories: (1) filing claims for equipment that was never delivered; (2) billing for high cost equipment when lower cost equipment was actually provided (upcoding); (3) billing for the component parts of a piece of equipment instead of the entire unit (unbundling); (4) delivering medical equipment to beneficiaries who do not need it; and (5) paying kickbacks to physicians and other sources in return for referring beneficiaries, access to beneficiaries Medicare numbers and/or signing certificates of medical necessity.

For example, an OIG investigation found that as part of a fraud scheme, a psychiatrist and his associates received kickbacks from DMEPOS suppliers for improperly certifying that many of their patients qualified for wheelchairs. The DMEPOS suppliers, in turn, supplied scooters to the beneficiaries but billed for the higher priced motorized wheelchairs or billed for wheelchairs that were never delivered. These fraudulent claims to Medicare were in excess of \$50 million. Another investigation resulted in a DMEPOS company paying \$8.4 million pursuant to its guilty plea to false statements relating to health care matters. Over a period of several years, the DMEPOS supplier billed Medicare and Medicaid for equipment provided to beneficiaries residing in assisted living facilities who did not meet coverage criteria, created false documents to support the false claims, and routinely misled assisted living facility personnel and physicians when marketing and servicing the equipment.

Supplier Enrollment Process

CMS contracts with the National Supplier Clearinghouse (NSC), operated by Palmetto Government Benefits Administrators, to manage the enrollment of suppliers. To enroll in the program and apply for a Medicare billing number, suppliers must comply with 21 Medicare DMEPOS supplier standards. Suppliers must also report to CMS any changes in the information provided in the application, including change of address, within 30 days of the change. DMEPOS suppliers are required to reenroll with NSC every 3 years to maintain their Medicare billing privileges. If a supplier fails to comply with all standards at any time, CMS may revoke these privileges.

Over the past decade, OIG has identified and reported on weaknesses in Medicare's enrollment process for and oversight of DMEPOS suppliers. A 1997 report examined Medicare supplier enrollment practices in 12 large metropolitan areas in 5 States, including Florida. Based on unannounced site visits, we concluded that the enrollment process was unreliable for detecting unethical and improper practices of suppliers and recommended that CMS conduct site visits at the physical locations of DMEPOS supplier applicants. In a 2001 report assessing whether DMEPOS suppliers met the Medicare standards, OIG found that the expansion of the CMS site inspection program improved supplier compliance with Medicare standards. OIG made several recommendations to further improve the compliance rates, such as instituting random, unannounced site visits of DMEPOS businesses at times other than initial enrollment and reenrollment.

Consistent with prior OIG recommendations, the NSC now conducts site visits to verify that DMEPOS supplier applicants or reenrollees comply with the 21 Medicare supplier standards before assigning a Medicare billing number. After the initial site visit, suppliers are generally not visited by NSC inspectors until they are due for reenrollment after 3 years. An unannounced, out-of-cycle visit may occur if NSC becomes aware that a supplier may be in violation of one or more Medicare standards.

South Florida Suppliers' Compliance with Medicare Enrollment Standards

According to NSC supplier enrollment data, Miami-Dade County has the highest concentration of suppliers per Medicare beneficiary of any county in the Nation. Broward and Palm Beach Counties also have high concentrations of suppliers. NSC reported that during the last two quarters of 2005, Florida led the Nation in allegations of supplier noncompliance with Medicare standards. In the first quarter of 2006, the NSC initiated a project to conduct out-of-cycle visits to approximately 500 DMEPOS suppliers in Miami-Dade, Broward, and Palm Beach Counties. As a result of that project, NSC revoked the Medicare billing numbers for 286 of these suppliers. These revocations suggested that DMEPOS suppliers intent on defrauding the Medicare program could take advantage of the predictable site visit cycle by establishing businesses that do not maintain compliance with Medicare standards after NSC conducts the initial or reenrollment site visit.

Working in collaboration with CMS and NSC, OIG conducted unannounced site visits to 1,581 suppliers¹ in Miami-Dade, Broward, and Palm Beach Counties in the fall of 2006 to assess their compliance with selected Medicare supplier standards.² According to data from a CMS contractor, these three counties account for approximately 5 percent of total Medicare DMEPOS payments nationally. We focused on three supplier standards that could be verified quickly through direct observation and desk review and that are directly related to the ease of beneficiary access to DMEPOS services. These three standards include five specific requirements, which state that suppliers must: (1) maintain a physical facility, (2) be accessible during business hours, (3) have a visible sign, (4) post hours of operation, and (5) maintain listed telephone numbers.

During the site visits, OIG found that 31 percent of suppliers (491 of 1,581) did not comply with the first two requirements of maintaining a facility at the business addresses that they provided to Medicare and being open and staffed during business hours.

- Six percent of the suppliers (98 of 1,581) did not maintain physical facilities. In some cases, instead of finding operational facilities, site reviewers found vacant facilities or facilities in which another type of business was operating, including a wedding florist, a rental car company, a real estate office, and an accountant's office.

We also visited one supplier location where there was no sign or any other information on the building, mail was stacked up outside, the door was open and there was no one there. At another supplier location, we found a nearly empty office space with a barely legible name printed on the door. There was a "Pharmacy is Closed" sign posted on the door along with several eviction notices,

¹ We did not visit suppliers associated with large chains, suppliers that were under investigation by OIG, or suppliers that had or were in the process of having their Medicare number revoked by NSC.

² "South Florida Suppliers' Compliance with Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150), March 2007.

including a final eviction notice. In addition, we saw several storefront locations that were empty inside and “For Rent” signs were posted.

- Twenty-five percent of suppliers (393 of 1,581) were not accessible during reasonable business hours. Of these suppliers, 385 were closed during unannounced site visits on a minimum of 2 weekdays during reasonable or posted business hours. For the remaining 8 suppliers, site reviewers found the door unlocked, but no one in the facility. Site reviewers observed some locations housing multiple suppliers that were either not open or not staffed during posted or reasonable business hours. For example, at one building, 15 suppliers were either not open or staffed. On the same street, another building housed nine suppliers that were not open or not staffed. Other locations had two to six suppliers that were not open or staffed.

We identified an additional 14 percent of South Florida suppliers that were open and staffed but failed to meet at least one of the three remaining requirements that OIG reviewed (having posted hours of operation, a visible sign, and a listed telephone number). Two hundred and six of these suppliers did not comply with one of these requirements and 10 suppliers did not comply with 2 or more of these requirements. The remaining 55 percent of suppliers we visited met all of the 5 requirements included in our review.

For the period January through November 2006, Medicare allowed over \$97 million for DMEPOS to the 491 suppliers we identified as not maintaining a physical facility or were not open and staffed. We referred these suppliers to CMS for potential revocation of their Medicare billing numbers.

In a separate report, OIG documented the results of our out-of-cycle site visits to 169 DMEPOS suppliers in 10 States other than Florida. The report, titled “Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements,”³ notes that 10 of the 169 suppliers did not have a physical location and that an additional 6 of the suppliers existed at their stated business address but were closed during posted hours of operation. While this study did not uncover supplier noncompliance in all areas visited, our findings suggest that out-of-cycle visits of targeted DMEPOS suppliers may be warranted in other areas of the country.

Addressing Weaknesses in the Enrollment Process

Given our findings related to noncompliance with supplier standards, it is essential that additional system improvements and preventative practices be adopted to ensure the integrity of the Medicare program and to protect beneficiaries from potentially unscrupulous suppliers. Such changes must be made on a national level so that fraudulent activities are not simply shifted to another geographic area over time.

³ “Medical Equipment Suppliers: Compliance with Medicare Enrollment Requirements” OEI-04-05-00380, March 2007.

Based on the findings of these two recent reports, OIG recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare standards through a number of actions, which include:

- conducting more unannounced site visits and out-of-cycle inspections,
- requiring all DMEPOS suppliers to post a surety bond,
- performing more rigorous background checks of applicants,
- increasing the prepayment review of DMEPOS claims,
- deactivating the Medicare billing numbers of DMEPOS suppliers that have been inactive for a 90-day period,
- implementing an enhanced review of all new enrollment applications by DMEPOS suppliers in South Florida,
- prioritizing processing reenrollment applications for current suppliers over processing new supplier applications,
- assessing the fraud risk of suppliers and target monitoring and enforcement on high-risk suppliers,
- implementing a competitive bidding acquisition program for DMEPOS within high-vulnerability areas,
- requiring suppliers in areas particularly vulnerable to fraud and abuse to reenroll with NSC more frequently than every 3 years, and
- strengthening the Medicare supplier standards by establishing a minimum number of hours of operation required for each supplier and establishing minimum inventory requirements for product and service types provided by a supplier.

In response, CMS described several actions it is taking to implement these recommendations, including: revisiting contract requirements to increase the number of unannounced supplier site visits; drafting a proposed regulation requiring suppliers to post surety bonds; considering targeted background checks of supplier applicants; considering requiring greater claims scrutiny for high fraud risk suppliers; requiring suppliers to become accredited as meeting DMEPOS quality standards; and developing a proposal to revise deactivation requirements for inactive Medicare billing numbers. CMS is also implementing new DMEPOS Accreditation Standards to help ensure that DMEPOS suppliers meet Medicare supplier standards. Once the accreditation process is fully phased in, the NSC will not issue a Medicare billing number to a nonaccredited supplier.

Additionally, CMS has recently issued a final rule to implement the DMEPOS competitive bidding program required by the MMA. It will replace the current fee schedule payment amounts for specified DMEPOS items with payment rates established by the bidding process. In 2008, the competitive bidding program will operate within 10 of the largest Metropolitan Statistical Areas (MSA), including the Miami-Fort Lauderdale-Miami Beach area. Items in the initial phase of this program will include various types of oxygen equipment and wheelchairs, mail-order diabetic supplies, enteral nutrients, hospital beds, negative pressure wound therapy pumps, and walkers. In 2009, the program will be expanded to 70 additional MSAs and after 2009, CMS will expand

the program to additional areas and items. Suppliers must be accredited or have accreditation pending before they can submit bids.

Conclusion

Within the DMEPOS benefit alone, we have identified numerous integrity problems and program inefficiencies. And, in our most recent work, we have also found that the current Medicare supplier enrollment process is inadequate in identifying and preventing unscrupulous suppliers from participating in and billing the Medicare program. We are continuing our examination of enrollment, compliance, and oversight of DMEPOS suppliers, including collaborating with CMS and the Department of Justice on specific efforts in high risk geographic areas. We also have ongoing work to determine the appropriateness of Medicare payments for certain medical equipment and supplies, such as wound care equipment and pricing for wheelchairs.

In addition, OIG will continue our efforts to identify areas in rest of the Medicare program where program dollars are not being utilized efficiently or are vulnerable to fraud and abuse. We also maintain a commitment to ensuring that beneficiaries have access to, and are receiving, high quality care from honest and dedicated providers. We will continue to apply our comprehensive and multifaceted approach to carrying out our mission to protect the integrity of the Medicare program and its beneficiaries.

I greatly appreciate the opportunity to discuss our work to enhance the efficiency and integrity of the Medicare program. I would be happy to answer any questions.