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Good morning, Chairmen Waxman and Pallone, Ranking Members Barton and Shimkus, and distinguished Members of the Subcommittee. I am Daniel Levinson, Inspector General of the U.S. Department of Health & Human Services. I thank you for the opportunity to appear before you today to discuss the Office of Inspector General's (OIG) efforts to combat health care fraud, waste, and abuse, specifically as it relates to medical equipment and supplies.

My testimony today will focus on OIG's body of work and recommendations related to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Over the past three decades, OIG has identified significant levels of fraud and abuse related to this important Medicare benefit. I will describe OIG's strategy for strengthening the integrity of the health care system in the context of the five principles OIG has identified as essential to combating health care fraud. I also will discuss recent improvements to ensure the integrity of the DMEPOS benefit. Finally, I will discuss additional corrective action needed to ensure that necessary DMEPOS are provided to beneficiaries appropriately, efficiently, and without fraud.

OIG's five-principle strategy combats health care fraud, waste, and abuse

Fraud, waste, and abuse in the Medicare and Medicaid programs cost taxpayers billions of dollars each year and put beneficiaries' health and welfare at risk. The impact of these losses and risks is exacerbated by the growing number of people served by these programs and the increased strain on Federal and State budgets. Therefore, it remains critical that oversight of these essential health care programs be strengthened. To combat health care fraud, a comprehensive strategy of prevention, detection, and enforcement is required. To that end, OIG has identified five principles of an effective health care integrity strategy:

1. Enrollment: Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment or reenrollment in the health care programs.
2. Payment: Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.
3. Compliance: Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.
4. Oversight: Vigilantly monitor the programs for evidence of fraud, waste, and abuse.
5. Response: Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.

No Medicare benefit area underscores the importance of these principles more than durable medical equipment and supplies. With respect to the first principle, enrollment, we have found that low barriers to entry and weak oversight and enforcement of enrollment standards make DMEPOS a compelling target for fraudulent suppliers. It is easy to become a DMEPOS supplier, relative to other types of providers, such as physician practices and hospitals, which

require extensive licensure and credentialing. In many geographic areas, DMEPOS suppliers are abundant. Regarding the second principle, payment, OIG reviews have consistently revealed that Medicare reimbursement rates for certain DMEPOS are significantly misaligned with market prices. This makes DMEPOS fraud particularly lucrative, further attracting bad actors to the system. These problems must be addressed to safeguard the Medicare Trust Fund from fraud and abuse.

These vulnerabilities can be offset through efforts to implement the final three principles: compliance, oversight, and response. For OIG's part, we strive to educate and provide assistance to the many legitimate suppliers that seek to comply with Medicare laws and regulations. We conduct oversight reviews of the DMEPOS benefit to identify fraud, waste, and abuse and recommend actions to the Centers for Medicare & Medicaid Services (CMS) to better safeguard the integrity of the program. Finally, in partnership with the Department of Justice (DOJ), we work to ensure that once detected, fraud schemes are shut down and perpetrators are prosecuted.

Medicare provides DMEPOS to more than 11 million beneficiaries, at a cost of more than $10 billion per year

To provide context, I will first offer some background about the Medicare DMEPOS benefit.

Medicare Part B provides for coverage of DMEPOS if the equipment is necessary and reasonable for treatment of an illness or injury or to improve the functioning of a malformed body member. Durable medical equipment (DME) is defined as equipment that serves a medical purpose, can withstand repeated use, is generally not useful in the absence of an illness or injury, and is appropriate for use in the home. DME includes items such as oxygen equipment, wheelchairs, nebulizers, walkers, and other equipment that physicians prescribe for home use. Prosthetic devices are devices needed to replace a body part or function, such as artificial limbs and cardiac pacemakers. Orthotic devices include leg, arm, back, and neck braces that provide rigid or semirigid support to weak or deformed body parts or restrict or eliminate motion in a diseased or injured part of the body. Medicare-reimbursed supplies are items that are used in conjunction with DME, such as drugs used for inhalation therapy, or are items that need to be replaced on a frequent (usually daily) basis, such as surgical dressings.

Medicare pays for DMEPOS through fee schedules. These fee schedules are based on the average amount that suppliers charged on Medicare claims in 1986 for individual DMEPOS items and are adjusted for inflation. Medicare pays 80 percent of the cost of a DMEPOS item up to the fee schedule amount, while the beneficiary is responsible for paying the remaining 20 percent.

Medicare pays for DMEPOS claims on behalf of more than 11 million beneficiaries. In 2009, Medicare payments for DMEPOS exceeded $10 billion and represented approximately 2 percent of all Medicare expenditures for that year.[1] In 2009, nearly 100,000 DMEPOS suppliers were enrolled in Medicare.

[1] See "Improper Medicare FFS Payments Report November 2009," available at http://www.cms.gov/CERT/Downloads/CERT_Report.pdf .

To be eligible for Medicare reimbursement, all DMEPOS suppliers must enroll in the program and must comply with 26 supplier standards. These standards are designed to ensure that suppliers are legitimate. Standards include but are not limited to the following:

- The supplier must maintain a physical facility.
- The facility must be accessible during business hours.
- The facility must have a visible sign.
- The supplier's hours of operation must be posted.
- The supplier must maintain a primary business telephone listed under the name of the business.

The National Supplier Clearinghouse (NSC), under contract with CMS, is responsible for verifying initial and ongoing compliance with the 26 supplier standards and issuing Medicare billing numbers to DMEPOS suppliers. Also, DMEPOS suppliers must be accredited prior to submitting applications and must renew their applications every 3 years. For most suppliers, NSC conducts an unannounced site visit before approving applicants and granting Medicare billing privileges. NSC may also conduct an unannounced reenrollment site visit every 3 years. Site visits may take place at any other time as deemed necessary, but generally site visits are made only when suppliers enroll and reenroll in the Medicare program.

To participate in the Medicare DMEPOS Competitive Bidding Program, DMEPOS suppliers must continue to meet the 26 supplier enrollment standards, which also include being accredited by a CMS-approved accreditation organization, fulfilling all licensing requirements, and obtaining a surety bond.

Enrollment: It has been too easy for fraudulent DMEPOS suppliers to obtain Medicare billing privileges

The enrollment standards that I have described are intended to ensure that only legitimate and qualified businesses are enrolled as Medicare suppliers. Unfortunately, we have found that all too often, unscrupulous suppliers are able to gain entry to the system and defraud Medicare. For example, in southern California, an individual defrauded the Medicare program by establishing various fraudulent DMEPOS companies, primarily by using street gang members to pose as nominee owners of his sham companies. He paid each gang member $5,000 to establish bank accounts and to fill out the Medicare paperwork. The nominee owners submitted claims for reimbursement to Medicare for power wheelchairs and orthotic devices that were not medically necessary or legitimately prescribed by a physician. To date, nine of the gang members and associates have been indicted for charges including health care fraud and providing false statements to Government agencies. The gang members involved in this fraud had previously been convicted of charges ranging from assault on a peace officer to numerous narcotics violations. Thus far in fiscal year 2010, OIG investigations of DMEPOS fraud have resulted in more than 80 convictions with ordered recoveries of more than $90 million.

OIG has identified systemic enrollment vulnerabilities for more than a decade. Since 1997, OIG has issued several reports that have assessed supplier compliance with standards by conducting unannounced site visits. We have consistently found that Medicare enrollment standards and

oversight are not sufficient to prevent noncompliant and sham suppliers from obtaining Medicare provider numbers and billing privileges. Some Medicare-enrolled suppliers fail to maintain even the most basic Medicare standards – for example, maintaining a physical facility, or being open during reasonable business hours.

In 2006, we conducted unannounced site visits to 1,581 DME suppliers in south Florida after learning of allegations of noncompliance with Medicare standards in that geographic area.[2] We found that 31 percent of these DME suppliers did not maintain physical facilities or were not open and staffed during business hours. Another 14 percent of suppliers were open and staffed but did not meet additional requirements we reviewed. We recommended several steps that CMS could take to strength the provider enrollment process.

In 2007, OIG expanded its review of DMEPOS supplier enrollment by conducting unannounced site visits to 905 suppliers in Los Angeles County.[3] We found that 13 percent of suppliers did not maintain a physical facility or were not open when we visited and that an additional 9 percent did not meet additional standards we reviewed. We again recommended that CMS strengthen the supplier enrollment process and ensure that suppliers meet Medicare supplier standards. In response to our recommendations, CMS stated that, among other actions, it had increased the frequency of unannounced site visits; begun targeted background checks of suppliers in high-fraud areas; and implemented a mandatory accreditation process, in part, to prepare for the Competitive Bidding Program.

Payment: Medicare pays too much for certain DME items, resulting in waste for legitimate claims and making fraudulent billing more lucrative

It is imperative that Medicare payments for items and services be reasonable and consistent with market prices. When reimbursement methodologies do not respond effectively to changes in the marketplace, the program and its beneficiaries bear the cost in the form of increased Trust Fund expenditures, increased out-of-pocket costs for beneficiaries, and higher Part B premiums. Misalignment between payments and market prices and costs can also lead to excessive profits, which makes DME in particular a lucrative target for criminals, who can even reinvest some of their profits in kickbacks for additional referrals. If Medicare acted as a more prudent purchaser of DME, the Trust Fund and beneficiaries could save billions of dollars lost to waste, fraud, and abuse.

OIG reviews over the past two decades have determined that for certain items, the program pays too much. We have identified payment misalignments for a wide variety of DMEPOS items, ranging from power wheelchairs and oxygen equipment to wound care supplies and saline solution. For example, we found that in 2007, Medicare allowed, on average, about $4,000 for standard power wheelchairs that cost suppliers, on average, about $1,000 to acquire. Based on these findings, OIG recommended that CMS better align payment amounts with acquisition costs

[2] "South Florida Suppliers' Compliance With Medicare Standards: Results From Unannounced Visits" (OEI-03-07-00150). March 2007.
[3] "Los Angeles County Suppliers' Compliance With Medicare Standards: Results From Unannounced Site Visits" (OEI-09-07-00550). February 2008.

by (1) using information from the Competitive Bidding Program, (2) seeking legislation to ensure that fee schedule amounts are reasonable and responsive to market changes, or (3) using its inherent reasonableness authority.

This pricing disparity also makes wheelchairs an attractive target for fraud. We have found that fraudulent suppliers often supply unneeded and unwanted wheelchairs to beneficiaries because the payment from Medicare exceeds their purchase costs by such a large margin that it is lucrative to supply unnecessary wheelchairs.

In 2009, we found significantly misaligned prices for negative pressure wound therapy pumps, a type of DME used to treat serious wounds. In 2007, Medicare reimbursed suppliers for these pumps based on a purchase price of more than $17,000. We found that by comparison, suppliers paid, on average, approximately $3,600 for new pump models. The reason for this disparity lies in the history of this item and Medicare's inability to keep pace with market prices. When Medicare first started covering the pumps in 2001, it covered only one model, which was manufactured and supplied by only one company. In 2005, Medicare expanded its coverage to include several new pump models manufactured by other companies. While new pump models were significantly less expensive than the original model, Medicare continued to reimburse suppliers for these new pumps based on the original pump's purchase price. OIG recommended that to correct this pricing disparity, CMS use its inherent reasonableness authority to reduce the reimbursement amount for the pump and include the pump in the Competitive Bidding Program.

In addition, for over 20 years, OIG has identified and reported on misalignments in payments for home oxygen equipment. In 2006, we reported that Medicare allowed approximately $7,200 in rental payments over 36 months for an oxygen concentrator that cost approximately $600 to purchase. Beneficiary coinsurance alone for renting an oxygen concentrator for 36 months exceeded $1,400 – more than double the purchase price. The same study found that maintenance and servicing requirements for oxygen concentrators are minimal, making the difference between Medicare payments for rentals and acquisition cost more troubling. Since our report was issued, CMS has changed its payment methodology for home oxygen equipment to more accurately take into account maintenance and servicing costs, although we continue to recommend that the statutory rental period be shortened to from 36 to 13 months.

<u>Compliance</u>: Compliance programs and education can assist legitimate DME suppliers in billing appropriately

While much of OIG's work focuses on unscrupulous suppliers, they are the minority. Most DMEPOS suppliers are legitimate suppliers seeking to provide necessary items to beneficiaries. A key part of OIG's health care integrity strategy is to educate and assist these well-intentioned providers in fully complying with Medicare laws and regulations.

OIG is planning a Provider Compliance Training Initiative to bring together representatives from a variety of government agencies to deliver compliance training at no cost to local provider, legal, and compliance communities. The training sessions are scheduled to be held in 2011 in several locations across the country. We aim to educate communities about fraud risk areas uncovered by OIG's work and to share compliance best practices so that providers can

strengthen their own compliance efforts and more effectively identify and avoid illegal schemes that may be targeting their communities. This initiative will supplement OIG's extensive written guidance in these areas that is available on our Web site, including our compliance program guidance tailored specifically to the DME sector. We believe these efforts to educate provider communities, including DME suppliers, can help foster a culture of compliance and protect the Federal health care programs and beneficiaries.

OIG also incorporates compliance requirements into the resolution of certain civil and administrative cases that the Government has settled with DMEPOS suppliers. Frequently, the wrongdoing in these cases involves failure to support the medical necessity of the DMEPOS billed to Medicare. In such cases, OIG may enter into corporate integrity agreements with these suppliers. Under a corporate integrity agreement, the supplier must implement a compliance program, train employees, and hire an outside auditor to annually test a sample of its claims. This impetus to devote resources to compliance often leads to improved attention to and compliance with Medicare laws governing reimbursement and saves the Government money and resources in combating fraud. We are hopeful that the compliance programs mandated by the Affordable Care Act (ACA) will similarly improve compliance in the industry.

Oversight: Vigilant monitoring through data analysis and claims review is critical to preventing and detecting fraud, waste, and abuse

In addition, it is critical that the Government vigilantly monitor the Medicare program to swiftly detect and respond to fraud, waste, and abuse when it does occur. Recently, innovative uses of information technology and data analysis have dramatically enhanced the Government's ability to take a proactive approach to fighting fraud and abuse. Finally, a thorough review of claims and supporting documentation is sometimes necessary to determine whether DMEPOS claims were appropriately paid. Improper payments are a serious issue for DMEPOS in particular. In 2009, CMS reported an overall Medicare fee-for-service error rate of 7.8 percent; however, the payment error rate for Medicare DMEPOS claims was 51.9 percent.

In 2009, OIG organized the multidisciplinary, multiagency Advanced Data Intelligence and Analytics Team (Data Team) to support the work of the Health Care Fraud Prevention and Enforcement Action Team (HEAT). The Data Team is composed of experienced OIG special agents, statisticians, programmers, auditors, analysts, and DOJ analysts. Their work combines sophisticated data analysis with criminal intelligence gathered from special agents in the field to more quickly identify health care fraud schemes, trends, and geographic "hot spots" to support the efficient and effective deployment of law enforcement resources.

Such advanced data analysis also enables OIG to alert CMS to patterns of potential fraud and abuse so that it can take appropriate prevention and oversight measures. For example, an OIG claims analysis revealed that in 2007, Medicare allowed more than $6 million for DME claims with invalid referring physician identifiers and $28 million for claims with inactive physician identifiers. Based on this analysis, we recommended that CMS update its claims-processing system to ensure that referring physician identifiers are valid and active. Had this capability been in place in 2007, Medicare could have avoided $34 million in improper payments.

Similarly, in an April 2009 study, OIG reported that south Florida accounted for 17 percent of Medicare's total spending for inhalation drugs in 2007, although only 2 percent of Medicare beneficiaries live in that area. Medicare Part B covers inhalation drugs when they are used in conjunction with DME. On 62 percent of these south Florida claims, the beneficiaries did not have Medicare-billed office visits or other services in the preceding 3 years with the physicians who reportedly prescribed the drugs. Using claims edits to detect these and other suspicious patterns in real time could greatly reduce vulnerability to fraud and abuse by preventing and allowing swift recovery of improper payments.

OIG has also conducted numerous in-depth reviews of DMEPOS claims and background documentation to determine whether items were provided and claims were paid appropriately. We have consistently found patterns of overutilization and failure to comply with Medicare requirements. For example, a recent review determined that 60 percent of Medicare claims for standard and complex rehabilitation power wheelchairs that beneficiaries received in the first half of 2007 did not meet documentation requirements. These claims accounted for $112 million in improper Medicare payments. Beneficiaries were responsible for paying $22 million of this amount. In another review, OIG examined whether suppliers that had expressly indicated (through a claims modifier) that they maintained required documentation on file in fact had that documentation. Most suppliers did not, resulting in estimated $126 million in improper payments.

Similarly, in 2009 we reviewed claims for pressure reducing support surfaces, which are used to treat and prevent bedsores. We found that for the first half of 2007, 86 percent of claims for certain categories of support surfaces did not meet Medicare coverage criteria. This amounted to an estimated $33 million in inappropriate payments during that time. Errors included undocumented or insufficiently documented claims, medically unnecessary claims, and other billing errors.

<u>Response</u>: OIG-DOJ Strike Forces have responded swiftly and effectively to DME fraud schemes; CMS efforts to remedy program vulnerabilities are also essential

OIG and DOJ are working in partnership to accelerate the Government's response to fraud schemes by reducing the time needed to detect, investigate, and prosecute fraud. We have deployed Strike Forces in geographic "hot spots" with high concentrations of Medicare fraud. Each Strike Force team includes agents from OIG and the Federal Bureau of Investigation and attorneys from DOJ and often State and local law enforcement. The team uses data analysis, combined with field intelligence from our special agents, to identify criminals committing health care fraud and to track fraud trends.

The Strike Force model has proven highly successful, particularly for combating DMEPOS fraud, and is a powerful antifraud tool. This collaborative, data-driven model has significantly reduced the time it takes from fraud detection to prosecution. Strike Forces also have a powerful deterrent effect. For example, according to Medicare data, in the first 12 months of establishing our Strike Force in Miami, Medicare billing for DMEPOS in Miami decreased by 63 percent, a drop of more than $1.7 billion, compared to billing in the year before.

Unfortunately, some of CMS's administrative efforts to shut down fraudulent DMEPOS suppliers have met challenges. For example, as a result of the OIG site visits in south Florida, CMS revoked the billing numbers of 491 suppliers. However, OIG found that nearly half of these suppliers appealed and received hearings; hearing officers reinstated the billing privileges for 91 percent of these suppliers. Two-thirds of suppliers whose billing privileges were reinstated have subsequently had their privileges revoked or inactivated. Further, the U.S. Attorney's Office has indicted 18 individuals connected to 15 of the 222 reinstated suppliers. To date, 16 of these 18 defendants have been convicted and were each ordered to pay between $25,000 and $11 million in restitution. These 16 defendants were also sentenced to jail terms ranging from 1 to 4 years. Improvements are needed to ensure that once identified, fraudulent suppliers are not allowed to reenter the program and continue to defraud Medicare.

CMS has taken several positive steps to respond to DMEPOS fraud vulnerabilities by implementing program safeguards. For example, CMS's most significant recent action was to require that all DMEPOS suppliers obtain accreditation and purchase surety bonds that protect Medicare in the event that a supplier is unable to make restitution for improper payments. Both of these requirements were implemented in preparation for the Competitive Bidding Program, although they apply to DMEPOS suppliers more broadly. CMS also reports that it is enhancing its field operations to more closely monitor areas of high vulnerability, including DMEPOS fraud. Lastly, a final rule published at the end of August strengthens enrollment standards in a variety of ways, including requiring that DMEPOS suppliers be open at least 30 hours per week and requiring that they maintain an appropriate physical facility that is accessible to the public.

The Affordable Care Act establishes new authorities and requirements to strengthen enrollment scrutiny, oversight, and response to address fraud vulnerabilities

The ACA provides the Secretary with new authorities and imposes new requirements consistent with OIG's health care integrity strategy and recommendations. These include promoting data access and integrity; requiring actions to strengthen provider enrollment standards; promoting compliance with program requirements; and enhancing program oversight, including requiring greater reporting and transparency. Among the most significant statutory changes are provisions requiring that only Medicare-enrolled providers may order or prescribe DMEPOS for Medicare beneficiaries; authorizing enhanced, risk-based screening for Medicare providers and suppliers; and permitting CMS to impose temporary enrollment moratoriums on providers and suppliers if necessary to prevent and combat fraud.

Specifically, the ACA requires the Secretary to establish procedures for screening providers and suppliers participating in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP). The Secretary is to determine the level of screening according to the risk of fraud, waste, and abuse with respect to each category of provider or supplier. At a minimum, providers and suppliers will be subject to licensure checks. The ACA also authorizes the Secretary to impose additional screening measures based on risk, including fingerprinting, criminal background checks, multi-State database inquiries, and random or unannounced site visits.

Ensuring the integrity of information is also crucial, and the ACA provides new accountability measures toward this end. The ACA authorizes OIG to exclude from the Federal health care

programs entities that provide false information on any application to enroll or participate in a Federal health care program. The ACA also provides new civil monetary penalties for making false statements on enrollment applications; knowingly failing to repay an overpayment; and failing to grant timely access to OIG for investigations, audits, or evaluations.

Changes to align payments for DMEPOS are still needed to address waste, fraud, and abuse

Although these new ACA requirements and CMS program integrity efforts represent important steps forward in combating fraud in the DMEPOS program, they do not fully address all vulnerabilities associated with this important benefit. Most notably, they do not fix misalignments between Medicare payments and market prices. The program will continue to be vulnerable to excessive costs and bad actors will continue to be attracted by the prospect of excessive profits so long as the payment misalignments highlighted in OIG's work persist.

OIG's body of work has consistently highlighted the need for Medicare to change payment methodologies in order to pay appropriately for DMEPOS. The ongoing price disparities that OIG has found exist largely because payments are based on charge data submitted to the program in 1986. Although CMS has the authority to make certain adjustments to the DMEPOS fee schedule, congressional action would be needed to reform the DMEPOS fee schedule to align initial payment rates more closely with market prices and enable CMS to adjust payments in response to changes in market prices. Competitive bidding is one mechanism to better align payments with market prices; however, the Competitive Bidding Program has not been implemented yet and not all DMEPOS items will be subject to competitive bidding.

The Competitive Bidding Program is one potential solution to address payment misalignments and further facilitate program integrity oversight

The Competitive Bidding Program has the potential to address vulnerabilities identified by OIG's work. Primarily, it holds the promise to address payment vulnerabilities for the items subject to competitive bidding by better aligning reimbursement for these items with market prices. It also includes important enrollment safeguards, such as licensure requirements, and provides a mechanism for ensuring that CMS has better information about the suppliers when granting billing privileges. Finally, it may facilitate oversight efforts by limiting the pool of providers to only those who have been approved through the competitive bidding process and pass rigorous enrollment standards.

It is critical that these and other program vulnerabilities be addressed, be it through competitive bidding or otherwise. Whatever processes are implemented, the end result must be Medicare payments that appropriately compensate providers, ensure adequate access for beneficiaries, are responsive to market changes, and allow Medicare to use its size to be a prudent purchaser of services. If the Competitive Bidding Program is not implemented as currently planned, other solutions to these problems must be found. Otherwise, the Medicare program and its beneficiaries will continue to lose scarce health care dollars to fraud, waste, and abuse.

Conclusion

I appreciate the opportunity to appear before you today to discuss OIG's substantial body of work on fraud, waste, and abuse associated with Medicare's DMEPOS benefit. OIG has a long history of analyzing these issues from investigative, audit, evaluation, and compliance standpoints. We have consistently made recommendations to correct the vulnerabilities we have identified and, often, CMS or Congress has implemented changes. Despite this, we continue to find significant problems, often to an alarming extent. We remain committed to any effort that will address the issues we have identified. The Medicare Competitive Bidding Program holds promise to address problems associated with supplier enrollment and payment misalignments. If policymakers consider a different course, it remains imperative to take prompt, appropriate corrective action to ensure that the DMEPOS benefit is protected from fraud, waste, and abuse. If competitive bidding or other action is implemented, my office remains committed to effective monitoring to ensure that beneficiaries continue to have access to reasonably priced, medically necessary, quality services.

Thank you for your commitment to ensuring the integrity of the Medicare program. I would be happy to answer any questions.