MEMORANDUM
April 23, 2013

To: Members of the Subcommittee on Financial and Contracting Oversight
Fr: Majority Staff
Re: Hearing: "Oversight and Business Practices of Durable Medical Equipment Companies."

On Wednesday, April 24, 2013, at 10:00 a.m., the Subcommittee on Financial and Contracting Oversight will hold a hearing entitled, "Oversight and Business Practices of Durable Medical Equipment Companies."

The purpose of the hearing is to examine payments by the Centers for Medicare & Medicaid Services (CMS) under Medicare Part B to suppliers of medical products such as diabetic testing equipment, CPAP machines, power mobility devices, and back braces, also known as durable medical equipment. The hearing will also examine durable medical equipment suppliers' promotion and marketing of these types of products to patients and their doctors. In addition, the hearing will assess CMS' oversight of durable medical equipment reimbursements under Medicare Part B, including its efforts to control costs and detect and prevent abusive practices and improper payments.

In preparation for the hearing, this memorandum provides background information on Medicare coverage of durable medical equipment and the laws and regulations governing marketing of medical equipment to Medicare beneficiaries. This memorandum also provides information obtained during the Subcommittee's investigation of two companies: (1) Med-Care Diabetic and Medical Supplies, Inc., and (2) U.S. Healthcare Supply, LLC.

I. MEDICARE COVERAGE OF DURABLE MEDICAL EQUIPMENT

In 2012, the federal government spent nearly $9 billion on payments for durable medical equipment under Medicare.[1] Durable medical equipment, covered under Medicare Part B, is defined as equipment that can withstand repeated use, serves a medical purpose, and is appropriate for use in the home. Examples include oxygen supplies, power wheelchairs, diabetic supplies, hospital beds, and respiratory assistance devices.[2]

Durable medical equipment suppliers may receive payment from the federal government for items supplied to Medicare beneficiaries only if the equipment is both medically necessary and prescribed by a doctor for use in a patient's home or care facility.[3] In addition, to qualify for

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[1] Centers for Medicare & Medicaid Services, *CMS Statistics* (online at http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ResearchGenInfo/CMSStatistics.html) (accessed April 21, 2013).

[2] Centers for Medicare & Medicaid Services, *Medicare Claims Processing Manual* (Rev. 2629, January 4, 2013) (online at www.cms.gov); Congressional Research Service, *Medicare Primer* (Feb. 28, 2013).

[3] Pub. L. 89-87, 79 Stat. 286-423, *Health Insurance for the Aged Act* (1965); Congressional Research Service, *Medicare Primer* (Feb. 28, 2013).

reimbursement, the equipment must be obtained from a supplier accredited to provide durable medical equipment. As of 2010, there were approximately 100,000 durable medical equipment suppliers in the U.S. with billing privileges under Medicare.[4]

Approved suppliers must obtain a National Provider Identifier (NPI) through CMS, must receive accreditation from a CMS-approved accrediting organization, and must obtain a durable medical equipment surety bond. Approved suppliers are also required to register with the National Supplier Clearinghouse, a CMS contractor-operated program to ensure that durable medical equipment suppliers comply with Medicare standards.[5]

Medicare does not reimburse the entire cost of durable medical equipment. After the patient pays the Medicare deductible, she or he pays 20% of the Medicare-approved amount for the equipment, and Medicare pays the other 80%. If the patient has secondary insurance, that insurance may cover some or all of the co-payment.[6]

CMS contracts out the different aspects of its responsibilities for managing and overseeing durable medical equipment, along with other responsibilities under Medicare Parts A and B, to a variety of contractors. Medicare Administrative Contractors (MACs) are responsible for Medicare claims processing and payment services. Recovery Audit Contractors (RACs) are charged with identifying and recovering improper payments, and making fraud referrals. Zone Program Integrity Contractors (ZPICs) are responsible for detecting and reporting potential fraud and abuse. These contractors are also responsible for recommending appropriate administrative action to CMS that may help prevent fraud or overpayment.[7]

II. SALE AND MARKETING OF DURABLE MEDICAL EQUIPMENT

The sale and marketing of durable medical equipment to Medicare beneficiaries is broadly governed by two areas of law: (1) regulations under the Medicare program and (2) general consumer protections enforced by the Federal Trade Commission (FTC).

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[4] Congressional Research Service, *Medicare Durable Medical Equipment: The Competitive Bidding Program* (Aug. 6, 2010); Department of Health and Human Services, *The Basics of Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation* (online at medicare.gov); Centers for Medicare & Medicaid Services, *Briefing for Subcommittee Staff* (April 17, 2013).

[5] National Heritage Insurance Company (NHIC), *DME MAC Jurisdiction A Supplier Manual* (March 2013 edition) (online at www.medicarenhic.com).

[6] Congressional Research Service, *Medicare Primer* (Feb. 28, 2013).

[7] Department of Health and Human Services, Office of Inspector General, *Recovery Audit Contractors Fraud Referrals* (Feb. 2010) (OEI-03-09-00130); Department of Health and Human Services, Office of Inspector General, *Vulnerabilities in CMS's and Contractors' Activities to Detect and Deter Fraud in Community Mental Health Centers* (Jan. 14, 2013) (OEI-04-11-00101).

A. Medicare Restrictions on Durable Medical Equipment Marketing

Durable medical equipment suppliers are specifically prohibited from contacting individuals enrolled in Medicare by telephone unless (1) the individual gives written permission to be contacted, (2) the supplier has provided that specific piece of equipment to the individual before, or (3) the supplier has furnished at least one other piece of equipment to that individual in the last 15 months. Suppliers are prohibited from receiving reimbursements for supplies sold in violation of this law. If a pattern of violations is established, suppliers can be excluded from participation under Medicare.[8]

In 2010, CMS proposed revised regulations that would have prohibited in-person contacts, email, and instant messaging by suppliers. The final rule adopted in March 2012, however, prohibits only telephone contact, other than as permitted by the original rule.[9]

Medicare rules also prevent durable medical suppliers from giving certain types of gifts, including free equipment.[10] The Office of the Inspector General has interpreted this restriction to prohibit one-time gifts with a retail value of $10 or more and gifts whose cumulative value exceeds $50 annually. An Inspector General Advisory clarified that penalties for these types of inducements can apply regardless of whether the marketing activity is directly or indirectly promoted to the beneficiary. Companies can be fined up to $10,000 for each violation.[11]

B. General Consumer Protection Provisions

Several statutes enforced by the Federal Trade Commission affect how durable medical equipment suppliers may solicit beneficiaries. Section 5(a) of the Federal Trade Commission Act makes any "unfair" or deceptive act or practice unlawful to the extent that such acts or practices affect commerce.[12] The FTC has used this authority to protect Medicare beneficiaries who may be victims of unfair or deceptive practices by durable medical equipment suppliers, including suits alleging deceptive acts related to telemarketing practices aimed at Medicare beneficiaries or private consumer health care services.[13]

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[8] 42 U.S.C. §1395m.

[9] Department of Health and Human Services, Centers for Medicare and Medicaid Services, *Medicare Program; Revisions to the Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DEMPOS) Supplier Safeguards*, Fed. Reg. 14989, Vol. 77, No. 50 (March 14, 2012) (final rule).

[10] 42 U.S.C. §1320a-7.

[11] Department of Health and Human Services Office of Inspector General, *Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002).

[12] 15 U.S.C. § 45.

[13] Federal Trade Commission v. Independence Medical, Inc., et. al., Civil No. 2:95-1581-18 (U.S. Dist. Ct. D.SC) (Aug. 26, 1996); Federal Trade Commission v. XTel Marketing, Inc., et. al., Civil Action No. 04 C 7238 (U.S. Dist. Ct. N.D. Ill.) (Aug. 16, 2005); Federal Trade Commission v. NHS Systems, Inc., et. al., Civil Action No. 08-2215 (U.S. Dist. Ct. E.D.PA) (March 28, 2013).

In 2003, the Federal Trade Commission (FTC) established the National Do Not Call Registry to protect consumers from unwanted or harassing phone calls from telemarketers. With few exceptions, it constitutes an abusive act for telemarketers to contact any person who has placed his or her name or number on the Do Not Call registry and can result in law enforcement action by the FTC.[14]

The Senior Citizens Against Marketing Scams Act includes enhanced penalties for identity theft, credit card fraud, mail fraud, wire fraud, or bank fraud committed in connection with telemarketing if the person targeted as the victim is over the age of 55. The penalties include up to 5 years imprisonment in addition to an existing sentence.[15]

III. FRAUD AND IMPROPER PAYMENTS FOR DURABLE MEDICAL EQUIPMENT

Durable medical equipment has proven to be an area ripe for fraud and improper payments. Medicare estimates for the last four years indicate that more than 60% of payments for durable medical equipment may be improper. In addition, durable medical equipment suppliers are among the most frequent subjects of criminal fraud prosecutions in Medicare, Medicaid, and the Children's Health Insurance Program.

A. Improper Payments

Improper payments under Medicare represent a potentially huge loss to the taxpayer. From 2009 to 2012, Medicare paid more than $34 billion for durable medical equipment under Medicare Part B. Of that amount, more than $21 billion may have been improperly paid. *See* Table A.

[14] 15 U.S.C. § 6101; 15 U.S.C. § 6151; 16 C.F.R. Part 310; Federal Trade Commission, *National Do Not Call Registry*, http://www.consumer.ftc.gov/articles/0108-national-do-not-call-registry (accessed April 12, 2013).

[15] 18 U.S.C. § 2326; Congressional Research Service, *Telemarketing: Dealing with Unwanted Telemarketing Calls* (Oct. 5, 2004).

Table A: Estimated Improper Payments for Durable Medical Equipment (DME)				
	2009	**2010**	**2011**	**2012**
Total DME Payments[16]	$8.8 billion	$8.3 billion	$8.5 billion	$8.8 billion
Error Rate[17]	52%	74%	61%	66%
Est. Improper Payments	$4.6 billion	$6.1 billion	$5.2 billion	$5.8 billion

The improper payment rate for durable medical equipment is significantly higher than the improper payment rate for Medicare's fee-for-service programs as a whole. In 2012, the estimated improper payment rate for Medicare fee-for-service was 8.5%.[18] The improper payment rate for durable medical equipment, which is part of the fee-for-service program, was 66%.[19]

CMS has failed to recover the overwhelming majority of improper payments for durable medical equipment. CMS recovers only around 3% of Medicare overpayments to durable medical equipment suppliers nationwide. In a 2010 review, the Office of Inspector General for the Department of Health and Human Services found that for one high-risk area in Southern Florida, the rate of recovery was only 1%.[20] In 2011, CMS recovered only $34 million in overpayments out of an estimated $5.2 billion in improper payments, less than 1% of the total. *See* Table B.

[16] Centers for Medicare & Medicaid Services, *CMS Statistics* (online at http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ResearchGenInfo/CMSStatistics.html) (accessed April 21, 2013).

[17] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 18, 2013).

[18] Department of Health and Human Services, Office of Inspector General, *U.S Department of Health and Human Services Met Many Requirements of the Improper Payments Information Act of 2002 But Was Not Fully Compliant* (March 2013).

[19] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 18, 2013).

[20] Department of Health and Human Services, Office of Inspector General, *Memorandum Report: Collection Rate for Overpayments Made to Medicare Suppliers in South Florida* (May 12, 2010) (OEI-03-09-00570).

Table B: Amounts Recovered from Overpayments				
	2009	**2010**	**2011**	**2012**
Est. Improper Payments	$4.6 billion	$6.1 billion	$5.2 billion	$5.8 billion
Amount Recovered[21]	--	$18.8 million	$34 million	*Not yet available*

CMS has failed to take sufficient steps to combat fraud and prevent improper payments among durable medical equipment suppliers and other businesses that seek reimbursement under Medicare. CMS has taken some positive steps, including efforts to prevent payment for ineligible suppliers, tracking licensing, accreditation, and enrollment of providers and suppliers, and implementing measures from the Affordable Care Act that require screening providers based on risk level. However, GAO found that CMS has failed to implement a number of GAO recommendations, including recommendations to strengthen provider enrollment screening and improve information technology systems that identify suspected claims.[22]

Improper payments are particularly high for power mobility devices, including power wheelchairs and scooters. Over 80% of power mobility devices provided by suppliers do not meet Medicare standards for coverage. According to CMS, it paid over $700 million in reimbursements for power wheelchairs in 2011. To combat the high error rate, CMS instituted a pilot program in September 2012 requiring pre-authorization prior to payment for power mobility devices. However, the pilot is only being conducted in 7 states and does not apply to other durable medical equipment covered under Part B.[23]

One way for CMS to recover more improper payments is through the use of surety bonds for providers with high overall Medicare payment amounts. CMS instituted surety requirements for suppliers of durable medical equipment in 2011. However, CMS has collected just over $263,000 of the millions in overpayments eligible for surety bond recovery. According to the

[21] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 18, 2013); Centers For Medicare & Medicaid Services, *Recovery Auditing in the Medicare and Medicaid Programs for Fiscal Year 2011*.

[22] U.S. Government Accountability Office, *Health Care Fraud: Types of Providers Involved in Medicare Cases, and CMS Efforts to Reduce Fraud* (Nov. 28, 2012) (GAO-13-213T).

[23] Senate Special Committee on Aging, *Hearing on Eliminating Waste and Fraud in Medicare: An Examination of Prior Authorization Requirements for Power Mobility Devices* (Sept. 19, 2012).

Inspector General, who conducted a sample review of just under 1,500 suppliers, almost $70 million in overpayments to durable medical equipment suppliers remains unrecovered.[24]

B. Fraud

In 2010, the most recent year for which information is available, durable medical equipment suppliers were among the most frequent subjects of criminal fraud prosecutions in the Medicare, Medicaid, and the Children's Health Insurance Programs. According to the Government Accountability Office (GAO), which searched thousands of court records in its review, approximately 19% of all health care fraud criminal convictions or plea agreements were related to durable medical equipment suppliers. Durable medical equipment suppliers made up approximately 4% of civil judgments or settlements of health care fraud cases.[25]

The amount of fraud by durable medical equipment suppliers is likely even higher. GAO has found that CMS does not have any reliable way to estimate the size or scale of fraud being committed by suppliers and businesses providing health care assistance.[26]

Telemarketing of durable medical equipment is an area of particular concern. The Office of Inspector General for the Department of Health and Human Services issued fraud warnings relating to telemarketing in 2003 and again in 2010. According to the Inspector General, durable medical equipment suppliers were using independent marketing firms to make calls to Medicare beneficiaries. The Inspector General noted that suppliers are prohibited from hiring other marketing firms to engage in unsolicited telemarketing.[27]

CMS relies on its Zone Program Integrity Contractors to detect and mitigate fraud. However, Zone Program Integrity Contractors have failed to adequately detect and deter fraudulent activities, despite having jurisdiction over known at risk areas for fraud. The Inspector General for the Department of Health and Human Services has recommended

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[24] Department of Health and Human Services, Office of Inspector General, *Surety Bonds Remain an Underutilized Tool to Protect Medicare from Supplier Overpayments* (March 21, 2013) (OEI-03-11-00350).

[25] U.S. Government Accountability Office, *Health Care Fraud: Types of Providers Involved in Medicare Cases, and CMS Efforts to Reduce Fraud* (Nov. 28, 2012) (GAO-13-213T); U.S. Government Accountability Office, *Health Care Fraud: Types of Providers Involved in Medicare, Medicaid, and the Children's Health Insurance Program* (Sept. 7, 2012) (GAO-12-820).

[26] U.S. Government Accountability Office, *Health Care Fraud: Types of Providers Involved in Medicare Cases, and CMS Efforts to Reduce Fraud* (Nov. 28, 2012) (GAO-13-213T).

[27] Department of Health and Human Services Office of Inspector General, *Special Fraud Alert: Telemarketing By Durable Medical Equipment Suppliers* (March 3, 2003); Department of Health and Human Services Office of Inspector General, *Updated Special Fraud Alert: Telemarketing By Durable Medical Equipment Suppliers* (Jan. 13, 2010).

implementing additional fraud mitigation activities in these areas and developing a system to track revocation recommendations.[28]

IV. NEW INFORMATION REGARDING MED-CARE DIABETIC AND MEDICAL SUPPLIES, INC. AND U.S. HEALTHCARE SUPPLY, LLC

The topic of this hearing was brought to the Subcommittee's attention by Dr. Charlotte Kennedy of Chesterfield, MO, who was concerned by aggressive marketing by durable medical equipment companies to her patients without her prior approval. The Subcommittee requested information and documents regarding several companies from CMS as well as from the companies.[29] This memorandum provides information obtained during the Subcommittee's investigation of two companies: Med-Care Diabetic and Medical Supplies, Inc. ("Med-Care") and U.S. Healthcare Supply, LLC ("U.S. Healthcare").

A. Med-Care

Med-Care, a medical supply company based in Boca Raton, Florida, is a national supplier of durable medical equipment to Medicare beneficiaries. From 2009 to 2012, Med-Care received more than $84 million from Medicare for durable medical equipment. Over that time period, Med-Care's annual payments increased by more than 270%, from $9.3 million in 2009 to $34.8 million in 2012.[30] *See* Table C.

Table C: Medicare Payments to Med-Care[31]

	2009	2010	2011	2012	Total (2009-2012)
Total Medicare Payments	$9.3 million	$15.4 million	$25 million	$34.8 million	$84.5 million
Medicare Claims Paid	74,393	123,312	201,506	261,626	660,837

[28] Department of Health and Human Services, Office of Inspector General, *Vulnerabilities in CMS's and Contractors' Activities to Detect and Deter Fraud in Community Mental Health Centers* (January 2013) (OEI-04-11-00101).

[29] Information related to Med-Care Diabetic and Medical Supplies, Inc. and U.S. Healthcare Supply, LLC regarding audits, improper payment rates, and overpayments was provided by CMS. The information did not contain associated date ranges or sample pools and is not statistically valid.

[30] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 10, 2013).

[31] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 10, 2013); Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 22, 2013).

A sample of claims paid to Med-Care revealed that approximately 68% of Med-Care's claims were improper. CMS' regional Recovery Audit Contractor, a contractor charged with identifying and recovering improper payments and making fraud referrals, found that over 400 of the more than 590 Med-Care claims reviewed were improper and demanded that Med-Care return $146,689 in overpayments.[32] If CMS were to determine that the same rate of error exists throughout Med-Care's claims, Med-Care could owe up to $57 million in overpayments to the federal government.

Sample reviews of Med-Care claims by Medicare Administrative Contractors (MACs), contractors responsible for Medicare claims processing and payment reviews, have resulted in very high error rates. Since 2011, Noridian, one of several MACs working for CMS, has reviewed more than 3,300 claims by Med-Care and denied 62% to 99% of claims depending on the review. Another MAC, National Government Services, reviewed a sample of 1,202 Med-Care claims and denied payment for 1,186, or approximately 99%. A third MAC, National Heritage Insurance Company, reviewed 138 Med-Care claims for diabetic testing supplies since August 2012 and denied payment for 85%.[33]

B. U.S. Healthcare

U.S. Healthcare, a medical supply company based in Milford, New Jersey, is a national supplier of durable medical equipment to Medicare beneficiaries. From 2010 to 2012, U.S. Healthcare reported receiving more than $83.06 million in payments from Medicare.[34] During that time period, according to information provided by CMS, U.S. Healthcare's annual payments increased by more than 1,189%, from $3.1 million in 2010 to $39.8 million in 2012.[35] Medicare payments represent 78% of the company's total revenue between 2010 and 2012.[36] *See* Table D.

[32] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 10, 2013).

[33] *Id.*

[34] U.S. Healthcare Supply provided information to the Subcommittee showing that total assets, operating expenses and revenue also increased over this time. *See U.S. Healthcare Supply Response to Subcommittee Request for Information* (April 12, 2013).

[35] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 10, 2013).

[36] U.S. Healthcare Supply, LLC, *Response to Subcommittee Request for Information* (April 12, 2013).

Table D: Medicare Payments to U.S. Healthcare[37]					
	2009	2010	2011	2012	Total (2009-2012)
Total Medicare Payments	$0	$3.1 million	$11.8 million	$39.8 million	$54.7 million
Medicare Claims Paid	0	20,067	79,962	197,666	297,695

A sample of claims paid to U.S. Healthcare revealed that more than 92% of U.S. Healthcare's claims were improper. CMS' Recovery Audit Contractor found that more than 5,600 of the 6,100 U.S. Healthcare claims reviewed were improper and demanded that U.S. Healthcare return $100,635 in overpayments to Medicare.[38] If CMS were to determine that the same rate of error exists throughout U.S. Healthcare's claims, U.S. Healthcare could owe up to $50 million in overpayments to the federal government.

Smaller samples of U.S. Healthcare claims have also shown very high error rates. An initial review by the National Heritage Insurance Company, one of several MACs working for CMS, resulted in a denial rate of 79.2% for U.S. Healthcare's claims for diabetic testing strips. Another MAC, National Government Services, reviewed 2,569 U.S. Healthcare claims and denied 2,419, or approximately 94%. Since 2011, Noridian, a third MAC, has reviewed more than 4,700 claims by U.S. Healthcare and denied 49% to 99% of claims, depending on the review.[39]

V. WITNESSES

The following witnesses have been invited to testify at the hearing:

[37] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 10, 2013); Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 22, 2013). The information on total Medicare payments provided by CMS differed from the information provided by US Healthcare by over $28 million. *See* Centers for Medicare & Medicaid Services, *Response to Subcommittee Request* for *Information* (April 10, 2013) and U.S. Healthcare Supply, LLC, *Response to Subcommittee Request for Information* (April 12, 2013).

[38] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 10, 2013).

[39] Centers for Medicare & Medicaid Services, *Response to Subcommittee Request for Information* (April 10, 2013).

Panel I

Jon Letko
U.S. Healthcare Supply, LLC

Dr. Steve Silverman
Med-Care Diabetic & Medical Supplies

Panel II

Peter Budetti
Deputy Administrator and Director
Center for Program Integrity
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Laurence Wilson
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AdvanceMed Corporation