DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

OFFICE OF AUDIT SERVICES, REGION V
233 NORTH MICHIGAN, SUITE 1360
CHICAGO, IL 60601

May 3, 2012

Report Number: A-05-10-00042

Mr. Rick Worstell
Chief Executive Officer
Marquis Mobility, Inc.
4051 Whipple Avenue NW, Suite E
Canton, OH 44718

Dear Mr. Worstell:

Enclosed is the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Power Mobility Devices Supplied by Marquis Mobility, Inc*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at http://oig.hhs.gov.

If you have any questions or comments about this report, please do not hesitate to call me, or contact Lynn Barker, Audit Manager, at (317) 226-7833, extension 21, or through email at Lynn.Barker@oig.hhs.gov. Please refer to report number A-05-10-00042 in all correspondence.

Sincerely,

/Sheri L. Fulcher/
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

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Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF POWER MOBILITY DEVICES SUPPLIED BY MARQUIS MOBILITY, INC.

Daniel R. Levinson
Inspector General

May 2012
A-05-10-00042

Office of Inspector General

http://oig.hhs.gov

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance coverage to people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Pursuant to sections 1832(a)(1) and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). CMS contracts with four durable medical equipment Medicare administrative contractors (DME MAC) to process and pay Part B claims for DMEPOS. Pursuant to section 1862(a)(1)(A) of the Act, no payment may be made under Part B for any expenses incurred for items that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Medicare Part B provides for the coverage of power mobility devices (PMD), such as power wheelchairs and power-operated vehicles (which are commonly referred to as scooters). Pursuant to 42 CFR § 410.38(c)(2), the physician or treating practitioner must (1) conduct a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan, (2) write a prescription (written order) that is provided to the beneficiary or the supplier and is received by the supplier within 45 days after the face-to-face examination, and (3) provide documentation to support the medical necessity of the PMD (including pertinent parts of the beneficiary's medical record) to the supplier within 45 days of the face-to-face examination.

Pursuant to 42 CFR § 410.38(c)(1), which refers to section 1861(r)(1) of the Act, a physician is a doctor of medicine who is legally authorized to practice medicine and surgery by the State in which he or she performs such function or action. Section 410.38(c)(2)(iii) states that supporting documentation for a PMD includes pertinent parts of the beneficiary's medical record, e.g., history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, and/or other information as may be appropriate, that supports the medical necessity of the PMD. The *Medicare Program Integrity Manual* (the Manual) states that the supplier should obtain as much documentation from the patient's medical record as the supplier determines is needed to ensure that the coverage criterion for an item has been met.

Marquis Mobility, Inc. (Marquis Mobility) is a durable medical equipment supplier in Canton, Ohio. From June 6, 2006, through June 30, 2009, Medicare paid Marquis Mobility $3,910,392 for 1,140 PMDs supplied during that period.

OBJECTIVE

Our objective was to determine whether Marquis Mobility claimed Federal reimbursement for PMDs in accordance with Medicare requirements.

SUMMARY OF FINDINGS

Marquis Mobility did not always claim Federal reimbursement for PMDs in accordance with Medicare requirements. From June 6, 2006, through June 30, 2009, we estimated that Marquis Mobility received Federal reimbursement for PMD claims totaling $680,024 that were not in accordance with Federal requirements.

Of the 200 randomly sampled claims, 157 claims met Medicare requirements, but 43 claims did not. Specifically, Marquis Mobility did not provide:

- adequate documentation to support the medical necessity of PMDs for 26 claims,
- all required documentation for 9 claims, and
- properly completed physician orders for 8 claims.

Marquis Mobility did not adequately develop and implement internal controls to ensure that it correctly obtained Medicare reimbursement. These controls did not ensure that PMDs provided to beneficiaries were medically necessary and that physician orders were in accordance with Medicare requirements.

RECOMMENDATIONS

We recommend that Marquis Mobility:

- refund to the Federal Government $680,024 in unallowable payments for PMDs and
- enhance controls to ensure that claims for PMDs are in accordance with Medicare requirements.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Marquis Mobility disagreed with our findings but did not address our recommendations. Marquis Mobility stated that recovery of overpayments for the claims in question is barred by Medicare recovery and reopening rules and are not subject to recoupment. Marquis Mobility also made comments disputing the lack of medical necessity and documentation related to specific claims in our sample. Marquis Mobility's comments are included in Appendix C. We redacted personally identifiable information in the comments.

After reviewing Marquis Mobility's comments, we maintain that our findings and recommendations are valid, including that the overpayments should be recovered to the extent allowable under law.

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INTRODUCTION

BACKGROUND

Medicare Program

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance coverage to people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program.

Pursuant to sections 1832(a)(1) and 1861(n) of the Act, Medicare Part B provides for the coverage of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). CMS contracts with four durable medical equipment Medicare administrative contractors (DME MAC)[1] to process and pay Medicare Part B claims for DMEPOS. Pursuant to section 1862(a)(1)(A) of the Act, no payment may be made under Part B for any expenses incurred for items that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Federal Requirements

Medicare Part B provides for the coverage of power mobility devices (PMD), such as power wheelchairs and power-operated vehicles (which are commonly referred to as scooters). Pursuant to 42 CFR § 410.38(c)(2), the physician or treating practitioner must (1) conduct a face-to-face examination of the beneficiary for the purpose of evaluating and treating the beneficiary for his or her medical condition and determining the medical necessity for the PMD as part of an appropriate overall treatment plan, (2) write a prescription (written order) that is provided to the beneficiary or the supplier and is received by the supplier within 45 days after the face-to-face examination, and (3) provide documentation to support medical necessity of the PMD (including pertinent parts of the beneficiary's medical record) to the supplier within 45 days of the face-to-face examination.[2]

Medicare contractors develop Local Coverage Determinations (LCD) for some covered DMEPOS, including PMDs. LCDs specify under what clinical circumstances the DMEPOS

[1] Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173 (Dec. 8, 2003), required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors (MAC) between October 2005 and October 2011. Most, but not all, of the MACs are fully operational; for jurisdictions where the MACs are not fully operational, the fiscal intermediaries and carriers continue to process claims. For purposes of this report, the term "Medicare contractor" means the fiscal intermediary, carrier, or MAC, whichever is applicable.

[2] Pursuant to 42 CFR § 410.38(c)(3), beneficiaries discharged from a hospital do not need to receive a separate face-to-face examination as long as the physician or treating practitioner who performed the face-to-face examination of the beneficiary in the hospital issues a PMD prescription and supporting documentation that is received by the supplier within 45 days after the date of discharge. Accessories for PMDs may be ordered by the physician or treating practitioner without conducting a face-to-face examination of the beneficiary.

item is considered reasonable and necessary. For a PMD to be covered, the LCDs[3] state that basic coverage criteria must be met. Specifically, documentation must demonstrate that the patient has (1) a mobility limitation that significantly impairs the ability to participate in one or more mobility-related activities of daily living (MRADL), (2) a mobility limitation that cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker, and (3) insufficient upper extremity function to self-propel an optimally configured manual wheelchair in the home to perform MRADL during a typical day.

Marquis Mobility, Inc.

Marquis Mobility, Inc. (Marquis Mobility) is a durable medical equipment supplier in Canton, Ohio, that sells and services PMDs. Marquis Mobility has sales representatives in approximately eight States, including Illinois, Indiana, Iowa, Kentucky, Michigan, Ohio, Pennsylvania, and West Virginia.

National Government Services, Inc.

National Government Services, Inc. (NGS) has been the Medicare administrative contractor for Jurisdiction B since July 1, 2006. NGS's main office is in Indianapolis, Indiana, and it processes claims from durable medical equipment suppliers in Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, and Wisconsin.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Marquis Mobility claimed Federal reimbursement for PMDs in accordance with Medicare requirements.

Scope

From June 6, 2006, through June 30, 2009, Medicare paid Marquis Mobility $3,910,392 for 1,140 PMDs supplied during that period. Our review covered the associated claims.

We did not review the overall internal control structure of Marquis Mobility. Rather, we limited our review of internal controls to those controls that were significant to the objective of our audit.

We performed fieldwork from March 2010 through March 2011 at Marquis Mobility as well as at prescribing physicians' offices in 11 States (Iowa, Illinois, Indiana, Kentucky, Michigan, New Jersey, Ohio, Pennsylvania, South Carolina, Tennessee, and West Virginia) and the beneficiaries' residences in 10 States (Colorado, Iowa, Illinois, Kentucky, Michigan, North Carolina, New Jersey, Ohio, Pennsylvania, and South Carolina).

[3] Medicare's four DME MACs have adopted the same LCD for PMDs. The relevant LCD policy statement numbers are L21271, L27239, L23613, and L23598.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- used CMS's National Claims History data to identify the 1,140 claims for which Marquis Mobility received Medicare payments from June 6, 2006, through June 30, 2009, for PMDs supplied during that period;

- selected a stratified random sample of 200 PMD claims totaling $684,661: 100 from the 678 claims associated with beneficiaries who resided in Ohio and 100 from the 462 claims associated with beneficiaries who resided outside Ohio (Appendix A);

- reviewed Marquis Mobility's policies and procedures and interviewed officials to obtain an understanding of the company's Medicare billing processes for PMDs;

- interviewed prescribing physicians and beneficiaries to obtain an understanding of the prescription process and obtained medical records from the physicians' offices associated with 196[4] of the 200 sampled claims;

- requested that NGS perform a medical review of documentation supporting PMDs provided to beneficiaries associated with 119[5] of the 200 sampled claims to determine whether medical necessity and coverage requirements were met;

- reviewed supporting documentation obtained from Marquis Mobility, the prescribing physicians, and beneficiaries to determine whether the 200 sampled claims met Federal regulations for Medicare reimbursement of the PMDs; and

- based on the results of our stratified sample, estimated the value of unallowable payments that Medicare made for PMDs from June 6, 2006, through June 30, 2009 (Appendix B).

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

[4] For four sample items, the prescribing physician offices were permanently closed. The audit team was not able to locate the prescribing physicians or the beneficiaries' medical records.

[5] The 119 claims included 93 claims for beneficiaries who died during our audit period and 26 claims for medical necessity. We determined that the remaining 81 sampled claims did not require medical review.

FINDINGS AND RECOMMENDATIONS

Marquis Mobility did not always claim Federal reimbursement for PMDs in accordance with Medicare requirements. Of the 200 sampled claims, 157 claims met Medicare requirements, but 43[6] claims did not. Specifically, Marquis Mobility did not provide:

- adequate documentation to support the medical necessity of PMDs for 26 claims,
- all required documentation for 9 claims, and
- properly completed physician orders for 8 claims.

From June 6, 2006, through June 30, 2009, we estimated that Medicare reimbursed Marquis Mobility for PMD claims totaling $680,024 that did not meet Federal requirements.

These errors occurred because Marquis Mobility did not have adequate controls to ensure that it claimed Federal reimbursement for PMDs in accordance with Medicare requirements.

INADEQUATE DOCUMENTATION SUPPORTING MEDICAL NECESSITY

Pursuant to 42 CFR § 410.38(c)(2)(iii), Medicare Part B pays for a PMD if the physician or treating practitioner provides supporting documentation, including pertinent parts of the beneficiary's medical record (e.g., history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, and/or other information as may be appropriate) that supports the medical necessity of the PMD, which is received by the supplier within 45 days after the face-to-face examination.

The *Medicare Program Integrity Manual,* Pub. No. 100-08, (the Manual), chapter 5, section 5.8, states that the supplier should obtain as much documentation from the patient's medical record as the supplier determines is needed to ensure that the coverage criterion for an item has been met.[7] Of the 119 claims reviewed for medical necessity, 26 claims were medically unnecessary because supporting documentation did not meet the basic coverage criteria for medical necessity. For example, several claims did not include documentation that supported an initial or face-to-face exam with the physician. In addition, other claims lacked supporting documentation of medical records, including physical therapist evaluations and progress notes to support medical necessity. Also, Marquis Mobility submitted documentation stating that the beneficiary could perform MRADLs, which meant that the PMD was medically unnecessary. For the 26 claims, Marquis Mobility received $96,317 in unallowable Medicare payments.

[6] In addition to the 26 medical necessity claims, NGS reviewed 13 of the 17 claims during its medical review. NGS and its medical director identified the remaining 4 claims based on their determination that these claims had similar problems to the 13 claims in the medical review.

[7] Prior to Transmittal #138, which took effect on October 1, 2006, this requirement was found in section 5.2.1 of the manual.

MISSING DOCUMENTATION

Pursuant to the relevant LCDs,[8] effective November 15, 2006, once the supplier has determined the specific PMD that is appropriate for the patient based on the physician's order, the supplier must prepare a separate written document (termed a detailed product description) that lists the wheelchair base and all options and accessories that will be separately billed.

For nine sampled claims totaling $28,806, Marquis Mobility did not submit a separate detailed product description as required by guidance.

IMPROPERLY COMPLETED PHYSICIAN ORDERS

Pursuant to 42 CFR § 410.38(c)(1), to be valid, a written order must be completed by the physician or treating practitioner who performed the face-to-face examination and include the beneficiary's name, the date of the face-to-face examination, the diagnoses and conditions that the PMD is expected to modify, a description of the item, the length of need, the physician or treating practitioner's signature, and the date the prescription was written. In addition, 42 CFR § 410.38(c)(4), states that the supplier must receive the order within 45 days after completion of the face-to-face examination.

Chapter 5, section 5.2.4, of the Manual states a new physician order is required when there is a change in the order.[9]

Medicare reimbursed Marquis Mobility $31,894 for eight claims that did not meet Medicare requirements because the physician orders were not correctly completed. Specifically:

- For four sampled claims totaling $18,139, the physicians did not complete a new order. [10]
- For three sampled claims totaling $10,536, the physicians did not include the date that the face-to-face evaluations were completed.
- For one sample totaling $3,219, the physician signed and dated the order before completing the face-to-face evaluation.

[8] The LCD policy statement numbers are L21271, L27239, L23613, and L23598. We only questioned samples with dates of service after Nov. 15, 2006, for which both the physician's order and the detailed product description appeared on a single form.

[9] Prior to Transmittal #138, which took effect on October 1, 2006, this requirement was found in Section 5.1.1.3 of the manual.

[10] According to the MAC medical directors, MACs generally allow suppliers to follow section 5.3.1 of the Manual if a change has been made to the written physician order, even though the provision applies specifically to a Certificate of Medical Necessity (CMN). The provision states that if a change is made to any section of a CMN after the physician has signed the CMN, the physician must line through the error, initial and date the correction (or the supplier may choose to have the physician complete a new CMN). We note that in the four sampled claims, the physicians did not initial and date changes to the order.

ESTIMATE OF UNALLOWABLE PAYMENTS

Of the 200 PMD claims sampled, 43 claims totaling $157,017 were not in compliance with Medicare requirements. Based on our sample results, we estimated that Marquis Mobility received Federal reimbursement for PMD claims totaling $680,024 that were not in accordance with Federal requirements. The details of our sample results and estimates are shown in Appendix B.

INTERNAL CONTROLS NOT IMPLEMENTED

Marquis Mobility's internal controls were not adequate to ensure that it correctly obtained Medicare reimbursement. These controls did not ensure that PMDs provided to beneficiaries were medically necessary and that physician orders were in accordance with Medicare requirements.

RECOMMENDATIONS

We recommend that Marquis Mobility:

- refund to the Federal Government $680,024 in unallowable payments for PMDs and
- enhance controls to ensure that claims for PMDs are in accordance with Medicare requirements.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Marquis Mobility disagreed with our findings but did not address our recommendations. Marquis Mobility stated that recovery of overpayments for the claims in question is barred by Medicare recovery and reopening rules and are not subject to recoupment. Marquis Mobility also made comments disputing the lack of medical necessity and documentation related to specific claims in our sample. Marquis Mobility's comments are included in Appendix C. We redacted personally identifiable information in the comments.

After reviewing Marquis Mobility's comments, we maintain that our findings and recommendations are valid, including that the overpayments should be recovered to the extent allowable under law.

APPENDIXES

APPENDIX A: SAMPLING METHODOLOGY

POPULATION

The population consisted of Medicare payments to Marquis Mobility, Inc. (Marquis Mobility), from June 6, 2006, through June 30, 2009, for power mobility devices (PMD) supplied to Medicare beneficiaries during that period. Each record represents an individual PMD supplied to a Medicare beneficiary for which Marquis Mobility received Medicare reimbursement.

SAMPLING FRAME

The advanced audit techniques staff provided a database of all Marquis Mobility PMD claims that were supplied to Medicare beneficiaries from June 6, 2006, through June 30, 2009. The frame was limited to PMD claims that had a reimbursement amount greater than zero. The frame did not contain PMD accessory or rental claims.

The sampling frame was an MS Access file containing 1,140 PMD claims with total Medicare reimbursement of $3,910,392. We sequentially numbered the records in the database from 1 to 1,140. We then separated the sampling frame into two strata and sequentially numbered again. Stratum 1 consisted of 678 PMD claims totaling $2,308,865 for which the Medicare beneficiary resided in Ohio. Stratum 2 consisted of 462 PMD claims totaling $1,601,527 for which the Medicare beneficiary resided outside Ohio.

SAMPLE UNIT

The sample unit was a claim for a PMD supplied to a Medicare beneficiary for which Marquis Mobility received Medicare reimbursement.

SAMPLE DESIGN

We used a stratified random sample.

SAMPLE SIZE

We selected 100 Medicare PMD claims from each stratum for a total of 200 claims.

SOURCE OF RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services (OAS), statistical software to generate the random numbers for each stratum.

METHOD OF SELECTING SAMPLE ITEMS

We sequentially numbered the sample units in each stratum. After generating 100 random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the total amount of unallowable PMD claims.

APPENDIX B: SAMPLE RESULTS AND ESTIMATES

Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of PMD Claims Not in Accordance With Medicare Requirements	Value of PMD Claims Not in Accordance With Medicare Requirements
1	678	$2,308,865	100	$341,715	17	$64,408
2	462	1,601,527	100	342,946	26	92,609
Total	**1,140**	**$3,910,392**	**200**	**$684,661**	**43**	**$157,017**

Estimates of Medicare Claims Not in Accordance With Medicare Requirements

(Limits Calculated for a 90-percent Confidence Interval)

Overall	Total Unallowable Federal Share
Point estimate	$864,541
Lower limit	680,024
Upper limit	1,049,059

APPENDIX C: AUDITEE COMMENTS

SNR DENTON

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November 30, 2011

By Regular and Electronic Mail

Sheri L. Fulcher
Regional Inspector General for Audit Services
U.S. Department of Health and Human Services
Office of Audit Services, Region V
233 North Michigan Avenue
Suite 1360
Chicago, Illinois 60601

Re: Response to U.S. Department of Health and Human Services, Office of Inspector General, Draft Audit Report No. A-05-10-00042

Dear Ms. Fulcher:

On behalf of Marquis Mobility, Inc., SNR Denton US LLP respectfully submits this letter and attachments in response to the draft audit report prepared by the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("HHS-OIG") entitled, "Review of Power Mobility Devices Supplied By Marquis Mobility, Inc.," OIG Draft Audit Report No. A-05-10-00042 (the "Draft Report").

I. Draft Report

On October 13, 2011, Marquis Mobility, Inc. ("Marquis") received the Draft Report with instructions to submit written comments, if any, to HHS-OIG within 30 days. At Marquis' request, HHS-OIG agreed to extend the response deadline to Wednesday, November 30, 2011.

The Draft Report stated that of the 200 randomly selected Marquis claims for power mobility devices ("PMDs") that were audited by HHS-OIG, 157 met Medicare requirements. Draft Report at 4. Conversely, the Draft Report found that 43 claims did not satisfy Medicare requirements. Draft Report at 4. A list of the 43 disputed claims is attached at **TAB A**. Specifically, the Draft Report determined that:

- Eight PMD claims were not supported by properly completed physician orders;
- Nine PMD claims were not supported by adequate documentation; and
- Twenty-six claims were not medically necessary, at least not based on the existing medical record.

The chart at **TAB A** is color coded to reflect HHS-OIG's determinations.

According to the Draft Report, in the period between June 6, 2006 and June 30, 2009, Medicare Part B reimbursed Marquis a total of $3,910,392 for PMDs. Draft Report at 4. Extrapolating from the forty-three claims found to fall short of Medicare requirements and applying the results to the total dollar volume, HHS-OIG recommends that Marquis refund a total amount of $680,024 in estimated unallowable payments to the federal government. HHS-OIG also recommends that Marquis take steps further to bolster its internal controls to ensure more accurate or complete claim submission.

II. Marquis' Response

A. The Claims at Issue are Time Barred

1. The Law

Under the Medicare Program, contractors are permitted to determine and recoup overpayments. However, such determination and recoupment is subject to certain, firm limits on the ability to recover alleged overpayments, such as when the recovery would be against equity and good conscience.[1] As noted by the Secretary of HHS (the "Secretary"), Section 1870 of the Social Security Act, 42 U.S.C. § 1395gg "provides a framework within which liability for Medicare overpayments is determined and recoupment of overpayments is pursued. This framework prescribes a certain flow of events (i.e., decision-making process) that must be followed when pursuing the recoupment of Medicare overpayments."[2]

The Medicare Program claim adjudication and decision-making process commences with an "initial determination" that establishes whether the charges are reasonable and whether payment should be made.[3] Stated differently, the decision of a contractor to make payment to a supplier (e.g., a supplier of PMDs) constitutes the "initial determination" that stands until revised by the contractor. The initial determination is binding upon all parties to the claim unless a party (whether the provider or contractor/adjudicator) reopens and revises the initial determination.[4] With respect to the 43 claims at issue here, the contractor or a DME Medicare Administrative Contractor ("MAC") initially determined that payment was authorized. Those initial determinations must stand unless revised by the contractors in compliance with legally mandated time-frames and procedures, as discussed below. To change or alter the initial determination the Medicare contractor must, by law, "reopen" the claim and initial payment determination. The contractor's revision to the original or initial determination constitutes a reopening.[5]

Absent application of the Medicare "without fault" provisions, Medicare may reopen a claim and subsequently recoup a properly-determined overpayment "for any reason" within the first 12 months after initial payment.[6] This protects the Medicare program from inadvertent errors made by its contractors.

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1 See 42 U.S.C § 1395gg; 42 C.F.R. § 405.358.
2 63 Fed. Reg. 14.506 (Mar. 25, 1998) (emphasis added).
3 See 42 C.F.R. § 405.803; 42 C.F.R. § 405.920.
4 See 42 C.F.R. § 405.810 - 405.812; 42 C.F.R. § 405.841; see also 42 C.F.R. § 405.928.
5 42 C.F.R. § 405.980(a)(1).
6 See 42 C.F.R. § 405.841(a); 42 C.F.R. § 405.980(b)(1); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 29, § 90.3.

This 12-month timeframe does not apply here, however, because all initial payment determination dates, the last of which was in 2008, are well over one year at this point in time.

Claims that are more than one year old, but less than four years old, may be reopened only if the contractor establishes "good cause."[7] Finally, if more than four years have passed from the initial payment determination, the initial payment determination may be reopened by the contractor if and only if there is "reliable evidence . . . that the initial determination was procured by fraud or similar fault."[8]

The law is clear that providers and suppliers are deemed to be "without fault" if the overpayment is discovered and the initial determination is re-opened subsequent to the third calendar year after the year of initial payment.[9] In essence, this creates a rebuttable presumption of no-fault on the part of the provider or supplier after the passage of three calendar years after the calendar year of initial determination and payment, creating a three-year statute of limitations.[10] The Medicare Financial Management Manual (CMS-Pub. 100-06), Chapter 3, Section 80.1, explains that in calculating the three year period:

> Only the year of payment and the year it was found to be an overpayment enters into the determination . . .. The day and the month are irrelevant. With respect to payments made in 2000, the third calendar year is 2003. For payments made in 2001, the third calendar year thereafter is 2004, etc. Thus, the rules apply to payments made in 2000 and discovered overpayments made after 2003, to payments made in 2001 and discovered to be overpayments after 2004, etc.

Finally, and as set forth above, a provider or supplier may be required to refund overpayments with respect to claims that are re-opened in the three calendar years following the year of initial determination, provided the contractor can establish good cause.[11] Good cause does not exist if a provider or supplier complied with all pertinent regulations, made full disclosure of all material facts, and on the basis of the information available, had a reasonable basis for assuming that the payment was correct.[12] Good cause or fault by the provider or supplier, in turn, can be established where:

- The provider or supplier made an incorrect statement, which it knew or should have known was incorrect;

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7 See 42 C.F.R. § 405.841(b); 42 C.F.R. § 405.980(b)(2); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 29, § 90.3.

8 See 42 C.F.R. § 405.841(c); 42 C.F.R. § 405.980(b)(3); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 29, § 90.3.

9 See 42 U.S.C § 1395gg;(b); 42 C.F.R. § 405.841(c); 42 C.F.R. § 405.980(b)(3); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 29, § 90.3.

10 Mt. Sinai Hospital of Greater Miami, Inc. v. Weinberger, 517 F.2d 329, 342 (5th Cir. 1975).

11 See 42 C.F.R. § 405.841(b); 42 C.F.R. § 405.980(b)(2); see also Medicare Claims Processing Manual (CMS Pub. 100-04) Ch. 29, § 90.3.

12 See Medicare Financial Management Manual (CMS-Pub. 100-06) Ch. 3, § 90.

- The provider or supplier failed to furnish information which it knew or should have known was material; or
- The provider or supplier accepted a payment, which it knew or should have known was incorrect.[13]

2. 33 of the 43 Claims Are Barred By the Applicable Three Year Statute of Limitations

As reflected in TAB A, 24 of the 43 claims at issue involve PMDs that were furnished to the patient and were adjudicated in 2006; an additional nine involve PMDs that were furnished to the patient and were adjudicated in 2007. Thus, 33 of the 43 claims at issue are presumed to be "without fault" and hence are not subject to recoupment, as a matter of law, unless the Medicare contractor can establish fraud or similar fault. There is no evidence whatsoever of fraud or similar fault in this case. The Draft Report is entirely silent in that regard and, in addition, the HHS-OIG auditors who were involved in the audit never raised fraud or similar fault in any of their multiple communications with Marquis. To the contrary, the auditors informed Marquis that they were generally pleased with Marquis' files and submissions and did not find any indicia of fraud or similar fraud.

3. The Remaining 10 Claims Also Are Time Barred Because There Is No Evidence of Good Cause or Supplier Fault

Although the remaining 10 claims (out of the 43 disputed claims) are currently within the three year statute of limitations, they are subject to recovery if and only if the contractor establishes good cause – in other words, that the supplier was at fault with respect to those ten claims. As set forth in subsequent sections of this Response, the government has not met (and will not be able to meet) its burden in this regard.

B. Physician Orders

The Draft Report identifies eight claims that did not meet Medicare reimbursement requirements because physician orders were not correctly completed.[14] Specifically, HHS-OIG contends that four claims required a new physician order, three claims did not include the date of the face to face evaluation of the patient, and one claim had a physician order that was signed and dated prior to the face to face evaluation.

1. New Orders

As set forth above, HHS-OIG concluded that with respect to four of the sampled claims, the ordering physicians had to, but did not, complete and sign a new order or initial and date his or her corrections. The four claims at issue are for [redacted], [redacted], [redacted], and [redacted]. See TAB A.

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[13] 20 C.F.R. 404.507. See also 42 C.F.R. § 405.986 (good cause may be established when there is new and material evidence that was not originally available or known or that shows on its face that an obvious error was made).

[14] See TAB A.

As an initial matter, all four of these claims are from 2006 and, as such, are time barred. Over and above that, Marquis respectfully submits that HHS-OIG's conclusions with respect to patients [redacted], [redacted] and [redacted] are wrong. Marquis' rationale is set forth below.

a) [redacted] and [redacted]

The Centers for Medicare & Medicaid Services ("CMS") uses various manuals to inform providers and suppliers regarding the type of documentation necessary to seek and obtain Medicare reimbursement. The applicable manual here is the Medicare DME MAC Supplier Manual.

The Supplier Manual's policy on physician orders provides that a supplier is required to obtain a new physician order when there has been "a change to the order for the accessory, supply, drug, etc."[15] In the claims for [redacted] and [redacted], the physician had ordered the PMD, and made no change to the product ordered. Rather, the physician corrected a misprint to the diagnosis that he or she had listed on the prescription. This correction did not affect the type of product or services provided to the beneficiary. Nor did it change any instruction to the supplier. A correction to the listed alpha-numeric diagnosis code, especially when the diagnosis is correctly written in narrative form, cannot reasonably be said to constitute a *change* to the accessory, supply, drug, etc. In the absence of *a change in the accessory, supply or drug ordered by the physician*, the physicians were not required to complete new orders.

The Draft Report further indicates that if the physicians wanted to avoid completing a new order, they were required to initial and date their corrections on the existing order. HHS-OIG is unable to cite to any applicable authority that suggests that Marquis should have know this to be the case. Rather, the HHS-OIG argument is one that borrows from the rules applicable to changing a Certificate of Medical Need ("CMN"). CMNs, however, are different from physician orders and there is no evidence whatsoever that Marquis knew or should have known that the "initial and date" requirements for CMNs necessarily applied to physician orders.

CMS demonstrated its ability to inform suppliers about making corrections to CMNs, and gave instruction on how to do so in the CMN policy. If CMS intends for suppliers to have physicians initial and date corrections to the detailed written order, CMS must educate and inform suppliers of this requirement in a similar manner as CMS did for the CMN policy. Neither CMS, nor the individual jurisdictions, have either instructed suppliers to use the CMN policy for correcting physician orders, or have given separate guidance for correcting mistakes on physician orders. While the draft report says that MAC medical directors "generally allow" suppliers to use the CMN policy, it does not cite to or reference where suppliers were informed of the medical directors' position. Simply put, a supplier cannot be held to a standard when CMS has failed to notify the supplier about the existence of the standard. Because CMS has not notified suppliers of the need to initial/date corrections on a physician order, Marquis is "without fault" as to these two claims.

b) [redacted]

Patient [redacted] had her power wheelchair delivered on June 9, 2006. At that time, suppliers were permitted to use template order forms and to complete the detailed information on the products being ordered. Specifically, suppliers were permitted to complete everything on the order form

[15] Jurisdiction B DME MAC Supplier Manual, Ch. 8 *Documentation* at 3.

except for the diagnosis, physician signature and date. Thus, in that timeframe, Marquis submitted physician orders to ordering physicians with the HCPC, quantity and description of product pre-populated on the form. The relevant physician would review the pre-populated information, list the diagnosis, insert the date of exam and sign and date the order.

When Marquis created the template order form (using its billing software) for [redacted] it made a mistake with respect to the printed description of the items. Marquis identified and corrected these mistakes by hand and then forwarded the pre-populated order to the physician for review, completion and signature. Thus, the physician did change or correct the physician order. Rather, the order that was reviewed and then signed by the physician had the handwritten notations on it. In other words, the physician reviewed the order as marked up and, thereafter signed and dated it.

The Supplier Manual does not prohibit the supplier from using handwriting to complete the equipment description on the detailed written order. Nor does the Supplier Manual require additional documentation if the supplier makes a correction to the order *before* it is signed by the physician. As set forth above, a new physician order is required only when there is a change to what the physician originally ordered, resulting in a change in the accessory, supply, drug, etc. Moreover, there is no applicable authority that states that a physician must sign and date the handwritten changes made in advance by the supplier, especially when he or she reviews the order with the handwritten changes and then, and only then, signs and dates it. Thus, Marquis is without fault as to this claim as well.

c) [redacted]

Marquis does not contest HHS-OIG's findings with respect to the claim for patient [redacted]. That said, and as noted above, this claim is time barred.

2. **Dates of Face-to-Face Evaluations**

The Draft Report states that three sampled claims–[redacted] and [redacted]–did not include the date of the face-to-face evaluation for the power wheelchair.

According to the applicable Local Coverage Determination, the physician order must include both the date of the face-to-face examination and the date of physician signature.[16] In compliance with this instruction, the orders for patients [redacted] and [redacted] have two dates listed on their respective prescriptions. Given that two dates are included on the physician orders, Marquis must assume that HHS-OIG purports to have the contractor re-open and deny these claims because the dates are not listed in a particular fashion or with a particular description.

The Local Coverage Determination, however, provides that the date of the face-to-face examination must be listed on the order. It does not require the physician to write "face-to-face exam" on the order or to include any other wording. Rather, the policy requires that two dates be listed on the order: one reflecting that date of the examination and one reflecting the date of the signature.

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[16] Jurisdiction B DME MAC Supplier Manual, Ch. 9 *Advance Determination of Medicare Coverage* at 3-4.

Patient [redacted] physician order has the date when it was written and signed at the top (08/18/2008) and a second date listed as "Start: 08/18/2008."[17] The medical records confirm that [redacted] was evaluated on August 18, 2008, and copies of the evaluation were delivered with the prescription showing the evaluation to be on August 18, 2008. Thus, there were two dates (albeit the same date) clearly included on the physician order, as required by Medicare.

The order for patient [redacted] also contains two dates: one on the top right hand and one next to the physician's signature. The date, December 3, 2007, matches the date of the face-to-face examination for a PMD.

In sum, the detailed orders for patients [redacted] and [redacted] include the two required dates and, as such, should not be revisited. Even if HHS-OIG were to disagree, we note that the claim for patient [redacted] is time barred.

The third and final claim that allegedly is missing the date of the face-to-face evaluation is for patient [redacted]. The physician order, however, contains two dates: the first date (9-8-06) is immediately to the right of the physician's signature; the second date (8-31-06) is set forth above the printed words, "Date of Exam."

At bottom, then, patient [redacted] was evaluated on August 31, 2006, with the physician completing and signing the order on September 8, 2006. There is nothing wrong with this order and, even if there were, the claim is time barred.

Marquis believes that the proposed denial for patient [redacted] may have occurred due to the patient obtaining a second, new power wheelchair after receiving the original power wheelchair from Marquis. The patient owned the power wheelchair delivered on October 7, 2006, and was free to use and dispose of the power wheelchair as he deemed fit. After receiving the power wheelchair, [redacted] returned to Marquis and negotiated the purchase a different power wheelchair, with Marquis accepting return of the original power wheelchair as part of the negotiation. Marquis did not submit a claim to Medicare for the second power wheelchair, as the second power wheelchair would not have qualified for payment under the replacement policy.[18] Thus, the second transaction has no bearing on the original order because it was not billed to Medicare, and does not change the medical need for the power wheelchair delivered on October 7, 2006. Since the physician order was properly completed prior to the delivery on October 7, 2006, any later purchases of equipment (not billed to Medicare) cannot be used to negate or cancel the appropriateness of the original purchase.

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[17] Because HHS-OIG already is in possession of the relevant documents, we do not re-attach them here. That said, if HHS-OIG requires any source document, Marquis stands ready to furnish it.

[18] Even though Marquis Mobility did not submit a claim for payment to Medicare for the second power wheelchair, Marquis Mobility did notify the physician that the patient was purchasing a different power wheelchair. The information on the second power wheelchair was sent to the physician on a template Detailed Written Physician Order, and the physician signed and returned that form to acknowledge his receipt. (See document # 000987) Since Medicare did not pay for the second power wheelchair, the fact that the physician was not requested to complete the Detailed Written Physician Order in its entirety cannot be used to deny the coverage for the power wheelchair sold to patient [redacted] on October 7, 2006.

3. Physician Order Pre-dates Evaluation Date

a) [redacted]

Marquis does not contest HHS-OIG's findings with respect to the claim for patient [redacted]. That said, and as noted above, this claim is time barred.

C. Missing Documentation

The Draft Report identifies nine claims that the Medicare contractor should have denied because the claims were not supported by a separate writing that provided a detailed description of the product.[19] The nine claims at issue are identified in **TAB A**.

1. Background

Historically, it was perfectly acceptable for a supplier of PMDs to include the detailed product description on the physician order. Effective November 15, 2006, suppliers were technically required to prepare a separate written document that lists the PMD and all options and accessories. HHS-OIG purports to have nine claims denied because they were not supported by a separate written document, even though all of the underlying product information is set forth in the relevant physician order.

Although the Local Coverage Determination was amended in the fall of 2006, Marquis respectfully submits that neither CMS nor the separate jurisdictions educated or instructed suppliers about the effects of the change until approximately one year later, on or about October 7, 2007. Moreover, the DME MACs did not appear to understand or enforce the revision in 2006 or early 2007. As will be discussed below, in the time frame at issue (late 2006 into the first quarter of 2007), the DME MACs continued to approve claims for PMDs that provided the detailed product description on the physician order rather than in a separate document, thereby demonstrating Marquis' lack of "fault".

2. DME MAC Rulings

As set forth above, the Draft Report identifies and questions nine claims from the time period of November 15, 2006 through February 28, 2007 because these claims placed the detailed product description on the physician order. During this same time period, however, Marquis appealed for Redetermination Review[20] five claims that had been denied electronically and that used the single form that is now being challenged by HHS-OIG. The DME MAC overturned all five denials, and could not have done so unless it had determined that all coverage and reimbursement requirements had in fact been met. The DME MACs rulings illustrate two things. First, no one, including the DME MACs, was enforcing the Local Coverage Determination at issue in the timeframe at issue. Second, it was perfectly reasonable

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19 Draft Report at 5.

20 The redetermination appeal is the first level of appeal and is conducted by the DME MAC. According to Jurisdiction B's Supplier Manual, a redetermination is a new, independent, and critical reexamination of a claim. It is conducted by reexamining the information in the file and any additional documentation submitted with the request for a redetermination.

for Marquis to submit the nine claims in the manner in which they were submitted and to expect that such claims would be paid.

It is noteworthy that one of the nine claims being contested by HHS-OIG—patient [redacted]—was the subject of an appeal to the DME MAC. Although DME MAC ended up down coding the PMD from a power wheelchair with elevating seat to a standard group 2, K0823, the DME MAC took no issue with the single form used by Marquis to comply with the physician order and the detailed written description requirements and paid the K0823. This fact notwithstanding, HHS-OIG purports to include this claim in the group of claims that the contractor should deny and for purposes of calculating the extrapolated repayment amount.

Given the lack of education and training and the fact that the DME MACs continued to approve and pay claims that were supported by detailed product descriptions on the physician orders, it was perfectly reasonable to assume that the payments at issue were correct. In other words, even if, assuming arguendo, the nine claims were not time barred (which they all are), we do not believe that the Medicare contractor could establish the existence of "good cause" with respect to any on the nine claims.

D. Medical Necessity

The Draft Report concludes that 26 claims did not meet the basic coverage criteria for medical necessity. The 26 claims at issue are identified by color code at **TAB A**.

1. Time Barred Claims

As an initial matter, we note that 17 of these claims are time barred by the three year statute of limitations. See **TAB A**.

Furthermore, as the following discussion demonstrates, the government cannot meet its burden of demonstrating good cause or supplier fault required to reopen and demand the refund of the remaining nine claims.

2. Previously Appealed Claims

Four of the 26 claims that were challenged by HHS-OIG on medical necessity grounds—[redacted], [redacted] and [redacted]—had been previously reviewed and approved by the DME MAC. Marquis respectfully submits that HHS-OIG cannot properly recommend that the Medicare contractor revisit claims that have been adjudicated to meet Medicare medical necessity requirements by the relevant DME MAC on a Redetermination Review.

Specifically:

- [redacted] original PMD was denied because Medicare does not cover power wheelchairs with elevating seat. Upon appeal, the claim was down coded to and paid as a standard K0823 power wheelchair, thereby establishing the medical necessity for this claim.

- Each of the claims for patients [redacted], [redacted] and [redacted] was reviewed as part of an appeal of the denial of an accessory. Importantly, the Local Coverage Determination for Wheelchair Options/Accessories (L11473) provides: options and accessories for wheelchairs are covered *if the patient has a wheelchair that meets Medicare coverage criteria* and the option/accessory itself is medically necessary.[21] Thus, Medicare will not pay for an accessory in the absence of medical necessity of the underlying wheelchair. Because all three accessory claims were approved and paid on appeal, it follows, a fortiori, that the DME MAC considered and found the medical necessity of each of the underlying PMDs.

3. MRADL

It is Marquis' understanding from HHS-OIG that 12 of the 26 medical necessity claims were deemed by HHS-OIG to lack medical necessity because the patient allegedly could perform his or her mobility related activity of daily living ("MRADL").

a) Background

One of the basic medical necessity criteria for power wheelchairs is whether or not the patient has a mobility limitation that interferes with his or her normal daily activities.

The Local Coverage Determination provides that MRADL includes such activities as toileting, feeding, dressing, grooming and bathing in customary locations in the home. The concept of a MRADL is separate, distinct and broader than the concept of an activity of daily living ("ADL"). A MRADL covers both the ADL itself and the attendant mobility or ambulatory component of the ADL. For example, a MRADL does not simply encompass toileting, bathing or grooming in a bathroom, but also the ability to ambulate to and in the bathroom. Similarly, a MRADL is not simply the task of putting on one's clothes, but reaching the bedroom in the first instance in order to put on the clothes. Likewise, the MRADL of feeding is not just sitting at the table and feeding oneself, but ambulating to the kitchen to get to the table in order to feed oneself. Thus, if a patient or healthcare provider says they can perform their ADLs independently, the analysis does not end there. The next question should be: "how did you get to the kitchen or bathroom to complete the ADL?"

In addition, a patient can still qualify for a power wheelchair even if he or she can physically complete the MRADL. The Local Coverage Determination provides that the patient have a "mobility limitation." A mobility limitation is more than the inability to complete a MRADL; it also encompasses the inability to complete a MRAD in a safe or timely manner. The analysis must cover safety concerns that are attendant to the patient's efforts to walk or propel a manual wheelchair on their own. Additionally, the analysis must also consider how long it takes the patient to independently walk or propel the manual wheelchair throughout the home. If the patient is placing him or herself at a heightened risk of injury due to a high risk of falls, or has a history of falls, the patient is considered to have a mobility limitation. Furthermore, if the patient can reach the kitchen or bathroom safely, but takes an unreasonable amount of time to get to the kitchen or bathroom, he or she also has a mobility limitation.

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[21] Jurisdiction B DME MAC Supplier Manual, Ch. 9 *Advance Determination of Medicare Coverage* at 5.

Finally, the Local Coverage Determination does not require the patient to be impaired from completing *all* or *most* of the MRADLs. Rather, the Local Coverage Determination only requires that at least one MRADL be impaired due to a mobility limitation.

b) Individual Claims

(1) [redacted]

[redacted] suffers from a combination of severe chronic obstructive pulmonary disease, the debilitating effects of dialysis and congestive heart failure ("CHF"). This combination has caused [redacted] to be unable to safely ambulate throughout his home.

[redacted] has been diagnosed with NYHA class IV CHF, demonstrating the significant problems and debilitation of the disease. Class IV CHF signifies that a patient is unable to carry out any physical activity without discomfort and symptoms of cardiac insufficiency at rest. [redacted] evaluation demonstrates his struggles with the disease, evidenced by his episodes of near syncope and dizziness. [redacted] has a history of falls, which occur at least once per month.

Consequently, [redacted] is unable to safely ambulate from one room in his home to another. Among other things, efforts at ambulation result in shortness of breath and dizziness, which, in turn, heighten the risk of falling. This is not hypothetical because, as the record reflects, [redacted] was actually falling on a regular basis when he tried to walk.

Marquis believes that HHS-OIG may have relied on the occupational therapy report to question this claim, and assert that [redacted] can perform his own MRADLs. While the occupational therapist documented that [redacted] can functionally perform the *activity* (i.e., the ADL task) when placed in front of him, she failed to address the safety or functionality of the mobility portion of the MRADL (e.g., walking to the kitchen to perform meal preparation, or walking to the bedroom for dressing, etc.). Rather, the occupational therapist only documented the ADL task itself (e.g., actually putting on his socks, etc.). [redacted] ability to perform the *mobility related* activity of daily living was addressed by his physician. According to the physician's documentation, [redacted] places himself at heightened risk of injury when attempting to ambulate in his home to perform the individual ADL.

The history of falls, combined with the continued risk of falling, demonstrate that [redacted] suffered from a mobility limitation that "placed the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL."

(2) [redacted]

[redacted] suffers from a severely painful disease process that has taken away her ability to functionally ambulate throughout her home. She has been diagnosed with both degenerative disc disease as well as lumbar disc displacement, which cause her excruciating pain if she attempts to stand for more than five to ten minutes. The pain also has caused her to have some generalized weakness, tested as 4 – 4+/5.

During her evaluation, [redacted] could only manage to ambulate ten feet with a walker. Likewise, she could only propel a manual wheelchair for ten feet before having to stop and rest due to severe and debilitating pain caused by degenerative disc disease and displacement.

To alleviate the pain and weakness when attempting to walk, [redacted] leans forward on the walker, resting her entire weight on the walker. This makes the walker unsafe and increases the risk of her falling. (She has suffered falls in the past, and her risk has increased as her pain and discomfort have increased.)

Like other claims addressed in this section, the physical therapist only addressed [redacted] ability to complete the actual ADL task itself; she did not address how [redacted] limited mobility impacted her ability to perform MRADLs. And, even then, the physical therapist documented that [redacted] requires assistance for the ADLs of grooming and bathing.

The face-to-face evaluation record does discuss [redacted] problems with completing MRADLs, in addition to its discussion regarding ADLs. According the physician record, [redacted] cannot complete feeding or grooming herself. The conclusion is further supported by the home assessment report. Based upon the layout of [redacted] home, she could not go the length of her living room without taking a rest, let alone travel from one end of her home to the other.

[redacted] therefore is prevented from "completing an MRADL within a reasonable time frame" because of having to take a rest break every ten feet. She is also at a "reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL" due to her risk and history of falls.

(3) [redacted]

[redacted] suffers from rheumatoid arthritis, end stage renal disease and chronic obstructive pulmonary disease. The rheumatoid arthritis has caused stiffness and weakness of multiple joints, including Mr. Snay's shoulders, wrists, hands and knees. He also undergoes dialysis three times a week, causing overall debility and fatigue.

The HHS-OIG reviewer may have found [redacted] to be able to independently perform his MRADLs because he was documented walking between 100 to 150 feet. It is important to note, however, that he was also documented as being *unsafe* when walking, leading to the conclusion that he cannot perform some of his MRADLs independently.

[redacted] was observed by both the physician and physical therapist as having decreased balance, walking with shuffling gait flexed at the hip. [redacted] balance problems were so severe that the physical therapist said he requires standby assistance of a caregiver when walking, even if using a cane or walker. As he fatigues, he becomes increasingly unstable and is at a high risk of falls.

After examining [redacted], the physical therapist stated that [redacted] could not independently perform two separate MRADLs: meal preparation and bathing. He becomes fatigued, easily loosing his balance, preventing him from completing the MRADLs. Therefore, the documentation established the medical necessity requirement that one or more MRADL is impaired by a mobility limitation, "preventing the patient from accomplishing an MRADL entirely."

Office of Inspector General Note - The deleted text has been redacted because it contains personally identifiable information.

(4) [redacted]

[redacted] suffers from a combination of renal disease (for which he has a dialysis port in his left arm), rheumatoid arthritis and neuropathy. These conditions have decreased [redacted] strength and endurance and cause him to experience painful movement. On dialysis days, [redacted] does not have the endurance to perform any activities, and requires complete assistance of caregivers.

Upon examination on a non-dialysis day, [redacted] was able to walk approximately sixty-five feet with a rolling walker. That said, he required contact guard assistance during the examination, and thus was not able to accomplish even this distance independently. [redacted] physician noted that on dialysis days, he requires complete care giver assistance for all of his activities due to his significant post-dialysis fatigue. Thus, on both dialysis and non-dialysis days, [redacted] is not capable of walking independently or safely with a cane or walker.

[redacted] cannot independently propel a manual wheelchair beyond ten feet. He suffers from a lack of endurance. The pain from the rheumatoid arthritis and a dialysis port further restrict the use of his arms. The situation is more dire on dialysis days when [redacted] cannot perform independent activities, relying heavily on the assistance of a caregiver.

In sum, [redacted] cannot independently move about his home without the assistance of a caregiver, either providing contact guard assistance or completing the task itself. In other words, [redacted] has a mobility limitation that "prevents him form accomplishing one or more MRADL entirely."

(5) [redacted]

The face-to-face evaluation described [redacted] as suffering from a long list of debilitating conditions, including chronic obstructive pulmonary disease, diabetes, coronary artery disease with stent placement, peripheral arterial disease, chronic kidney disease and degenerative arthritis. These chronic conditions were causing a steady decline in her health over the year leading up to the evaluation.

[redacted] does not have the strength, stamina or balance for independent use of a cane or walker, preventing her from independently performing her MRADLs. Upon examination, she was found to have decreased strength in her lower extremities of 4-/5. She was noted to have poor standing tolerance and decreased ability to maintain her legs in a standing position. Her knees would buckle when attempting to stand, demonstrating poor standing balance. Indeed, [redacted] could only walk a maximum of twenty-five feet, and even then only with a caregiver providing contact assistance. Her gait was slow and unsteady, demonstrating an inability to walk safely without the support of her caregiver. In fact, the record establishes that she has not been able to ambulate alone, even with a cane or walker, for some time because she falls backwards when she looses her balance.

Based upon her lack of balance and independence in walking, the physical therapist stated that [redacted] requires the assistance of a caregiver to ambulate to the bathroom for toileting. She also requires the assistance of a caregiver to go the short distance from the family room to the kitchen, but would be able to feed herself independently once there. She cannot propel a manual wheelchair on her own.

[redacted] is therefore completely dependent upon caregivers for performing her MRADLs. Her mobility limitation has significantly impaired her ability to perform one or more MRADLs, specifically feeding and toileting, as she is "prevented from accomplishing the MRADL entirely."

(6) [redacted]

The documentation of the face-to-face evaluation describes how [redacted] has been suffering from a recurrent, and now permanent, shoulder problem (a hematoma) that has taken away her ability to use her right shoulder in any functional manner. In addition, [redacted] can no longer move her right arm for activities above waist level. Furthermore, she suffers from significant edema in her legs, causing her to have an unsteady gait pattern. The problems with her shoulder and legs have prevented [redacted] from being able to safely ambulate throughout her home to complete her MRADLs.

[redacted] does not have the physical ability to walk safely or timely throughout her home to perform her normal MRADLs. She is at a high risk of falling due to her gait pattern, as well as the fact that she cannot effectively use her right arm to support herself with the walker. Her risk of injury is heightened by the fact that she takes Coumadin, a blood thinner, placing her at risk of bleeding injury or death from a fall.

[redacted] was observed to have a head down, forward flexed position. She walks with her hips circumducted due to the severe edema of her lower extremities. In other words, her legs cannot pass by one another in a normal gait pattern because of the amount of water retention in her legs. She requires the assistance of a caregiver when walking to give her continual verbal cues to correct her gait pattern. Without the caregiver assistance, she would be at an even higher risk of falls as she did not correct her posture and gait problems on her own, and continued to regress into the incorrect gait even after verbal reminders.

Currently, [redacted] does not have the requisite caregiver assistance and must attempt to independently ambulate to the bathroom and kitchen for her MRADLs. The fact that she attempts to perform the MRADL, or is able at times to perform the MRADL, does not disqualify her from obtaining a power wheelchair. The issue is whether she is safe and timely in performing the MRADLs and the documentation from the face-to-face evaluation demonstrates that she is neither. She is not only at risk of falls, as discussed above, but it takes her over five minutes to walk 140 feet. She then requires five additional minutes to rest after walking.

In sum, [redacted] cannot walk functional distances within a reasonable time frame. Most importantly, she has demonstrated that she is not safe when walking this distance, and cannot effectively use her right arm for support with the walker. [redacted] therefore is prevented from "completing an MRADL within a reasonable time frame." She is also at a "reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL" due to her risk of falls.

(7) [redacted]

[redacted] suffers from significant neuropathy in both of his hands, as well as weakness in all four extremities. [redacted] also underwent an above the knee amputation on his right leg, and has a prosthetic. Unfortunately, the prosthesis has not provided [redacted] with the assistance he needs for safe and timely independent ambulation.

Office of Inspector General Note - The deleted text has been redacted because it contains personally identifiable information.

[redacted] requires assistance from caregivers for performance of his MRADLs. [redacted] neuropathy in his hands prevents him from being able independently to don or doff his prosthetic, which he needs to attempt any walking within his home. Without the prosthetic, [redacted] is unable to walk any distance, and is completely wheelchair bound.

Even with the prosthetic on, [redacted] still requires assistance of a caregiver when he walks with the rolling walker and prosthetic due to a risk of falls. Because he does not have full, normal function of his hands, he cannot grip the walker to compensate for his lack of strength and coordination with the prosthetic.

Once [redacted] dons his prosthetic and has a caregiver available, he is still limited in the distance he can walk before resting or in total. When he uses both the prosthetic and the walker, [redacted] is only able to walk thirty feet before taking a rest break, and his maximum distance is seventy-five feet.

The physician specifically noted that [redacted] is unable to use a cane or walker to assist him to get to, or move about, his kitchen, as is necessary for feeding, an essential MRADL. The physical therapist agreed, noting that [redacted] requires assistance for the MRADL of feeding and toileting, and is completely prevented from bathing or grooming on his own.

Additionally [redacted] cannot use a manual wheelchair to resolve his MRADL problems. [redacted] neuropathy limits his ability to grip the manual wheelchair. He also has a dialysis shunt in his left arm that limits the use of the left arm for propelling purposes. Finally, he has decreased strength in both of his upper extremities, measured as 4+/5. As a result of the combination of neuropathy, shunt and weakness, [redacted] can only propel for a maximum of twenty feet, and it takes him at least three minutes to go this short distance.

Consequently, [redacted] mobility limitations completely "prevent him from completing MRADLs" such as meal preparation or grooming because he requires the assistance of a caregiver to don his prosthetic and assist with ambulation once the prosthetic is on. When he attempts to complete a MRADL without a caregiver, [redacted] is both "prevented from completed a MRADL within a reasonable timeframe," and he is placed at "heightened risk of morbidity or mortality."

(8) [redacted]

[redacted] suffers from a combination of medical conditions that have limited her ability to ambulate within her home. Specifically, she suffers from congestive heart failure, chronic obstructive pulmonary disease, a ruptured disc, carpal tunnel in both hands and nerve damage in her left foot.

[redacted] medical conditions cause her to experience significant pain and have limited her endurance. Her ruptured disc and nerve damage cause significant pain when she walks. The carpal tunnel syndrome makes it painful to try and grip a cane or walker. In addition, the neuropathy of her lower extremities places her at risk for falling and injury when she walks.

The debilitating pain causes her to become short of breath very quickly, which is exacerbated by her lack of respiratory reserves. She needs to take extended rest breaks after only a very short distance.

For instance, [redacted] can only walk five to ten steps after which she becomes too short of breath, experiences too much pain to continue and must stop and take an extended rest break.

[redacted] also cannot grip the wheels of the manual wheelchair due the pain from her carpal tunnel syndrome. Moreover, she does not have the endurance to self-propel the manual wheelchair as she rapidly becomes too short of breath. As such, she must be pushed by a caregiver in the manual wheelchair because she does not have the physical ability to use the device on her own.

As a result of her mobility limitations that cause her to stop and rest after only five to ten feet, [redacted] physician stated that she is prevented from completing all of her MRADLs within a "reasonable time frame."

(9) [redacted]

[redacted] has severe chronic obstructive pulmonary disease with severe dyspnea, demonstrating hypoxia symptoms. [redacted] also suffers from cor pulmonale, adding to his cardio-respiratory limitations. Consequently, [redacted] becomes dyspenic with minimal activity.

[redacted] pulmonary status limits the amount of activity he can accomplish before having to stop and take an extended rest break. For instance, his physician documented that once [redacted] walks short distances in his house, it takes him approximately fifteen minutes to recover from his shortness of breath. He also has dyspnea with minimal activities such as bathing, dressing and attempts at ambulating. In other words, he must rest for a long time before he can actually complete the task in the room (such as feeding, toileting, grooming or bathing).

[redacted] therefore has a mobility limitation that "prevents him from completing an MRADL within a reasonable timeframe."

(10) [redacted]

[redacted] has severe medical conditions that have limited her ambulation. For instance, she suffers from asthma and chronic obstructive pulmonary disease leading to continual use of supplemental oxygen, atherosclerotic heart disease, diabetes with diabetic neuropathy and degenerative arthritis. [redacted] has had her right 5th metatarsal and small toe amputated with incomplete healing, as well as leg problems leading to surgical bypass to the right lower extremity. She has also required a cardiac catherization and stent deployment to the right carotid artery. Finally, she suffers from lumbar degenerative disc disease, which was so severe that she required emergency decompressive surgery.

Upon examination by both her physician and physical therapist, [redacted] was found to be completely non-ambulatory even with the use of a cane or walker. She did not have the strength or endurance to ambulate due to the pain and weakness caused by the combination of her cardio-pulmonary problems and musculoskeletal issues.

[redacted] is also limited in her ability to use a manual wheelchair. Upon examination, she could only self propel for a maximum of twenty feet, which took her ten minutes to complete.

Based upon her inability to walk, and the extreme amount of time it takes for her to self propel a manual wheelchair, [redacted] physician determined that she cannot perform her activities such as bathing and toileting without caregiver assistance. The physical therapist stated that [redacted] was completely prevented from performing one or more MRADL, namely feeding/food preparation in the kitchen.

The face-to-face evaluation therefore provides that [redacted] is "completely prevented from performing one or more MRADLs," and the examination further demonstrates that she would not be able to independently "complete her MRADLs within a reasonable time frame."

(11) [redacted]

[redacted] suffers from chronic obstructive pulmonary disease requiring continuous use of supplemental oxygen at three liters per minute and, despite such treatment, still suffers from severe dyspnea with minimal activity. [redacted] also suffers from pulmonary fibrosis and cor pulmonale, both contributing to his hypoxemia.

[redacted] shortness of breath has caused significant limitations in his ability to perform normal activities within his home. For instance, after less than ten feet of ambulation, [redacted] becomes significantly short of breath, causing him to be unsteady on his feet and at risk for falling. He must take extended rest breaks of approximately fifteen minutes to recover after ten feet of ambulation.

[redacted] cannot traverse any farther using a manual wheelchair. He is limited to approximately ten feet when using his manual wheelchair himself, and then must take an extended rest break to recover from his shortness of breath.

Due to [redacted] severe shortness of breath with only ten feet of ambulation, and his requirement for at least a fifteen minute break to recover from this limited activity, his physician determined that [redacted] is not timely with bathing or dressing. Thus, [redacted] is "prevented from completing an MRADL within a reasonable time frame."

(12) [redacted]

[redacted] suffers from severe chronic obstructive pulmonary disease, which has caused diminished air flow leading to significant deficits in her endurance and activity tolerance. Her attempts to walk, even with a cane or walker, have caused exacerbation to her severe lung disease. The physician specifically stated that [redacted] cannot walk from room to room without serious respiratory issues. Moreover, [redacted] lacks strength to perform other daily activities due to her lack of respiratory reserves.

Consequently, [redacted] is "prevented from accomplishing an MRADL entirely" and requires the use of a power wheelchair to allow her to continue to live at home.

4. Patient Was Evaluated Face-to Face

The Draft Report purports to have the Medicare contractor deny three claims on the alleged ground that the medical documents do not establish that the ordering physician conducted a face-to-face

examination of the patient to assess his or her eligibility for a PMD. In all three cases, however, the medical record includes a record of the patient's evaluation by the physician. Thus, the claims should remain paid in full.

According to the Local Coverage Determination, the report of the face-to-face evaluation is to be documented in the physician's progress notes in a format similar to the format used for other entries. Although the record should demonstrate that the primary purpose of the patient visit was for a mobility examination, the physician is permitted to address other non-mobility issues during the visit.

a) [redacted]

HHS-OIG recommends denial of the claim for [redacted] for lack of documentation of a face-to-face evaluation. [redacted] progress note from August 18, 2006 starts with the following chief complaint: "Unable to ambulate due to gait instability." The progress note then discusses [redacted] current problems with performing his MRADLs, as well as why he cannot use a cane, walker or manual wheelchair to resolve his mobility limitations. The progress note also includes an impression/plan, which states, "gait abn". The information included in the progress note indicates that a primary purpose of the appointment was a mobility examination. Indeed, the note begins with mobility issues and ends with a plan to use a motor scooter. Five days later, on August 22, 2006, the physician's entry indicates that an electric wheelchair is needed because patient is "unable to use scooter due to space limitation." In sum we respectfully submit that there is no substantive basis for recommending the denial of this claim, even if, arguendo, it was not separately time barred.

b) [redacted]

The second claim allegedly lacking a face-to-face evaluation is [redacted]. [redacted] was examined by his physician on August 3, 2006. The physician documented his examination in a dictated note, which starts as follows: "This will serve as a progress note on [redacted], who at the present time has severe ambulation capacity." The entire note discusses [redacted] mobility limitations.

It is believed that the HHS-OIG reviewer may have sought to deny this claim on the basis that the progress note is written in a format similar to a letter. The Local Coverage Determination, however, does not require the face-to-face evaluation to be recorded in a particular format.

The physician who evaluated [redacted] is a specialist. It is quite common for specialists to document their encounters with patients in the format of a letter to be sent to a referring physician or family practitioner. The physician at issue documented that he evaluated [redacted] and described the findings of the evaluation. The only topic discussed in the report is the mobility examination, demonstrating that the primary (and only) reason for the visit was the mobility examination. The physician further stated that the document was the progress note for the encounter. Thus, the document should be accepted as such. The patient's medical record therefore includes a copy of the physician's face-to-face evaluation supporting the medical necessity of the power wheelchair.

c) [redacted]

The Draft Report also proposes to have the claim for [redacted] denied due to lacking support of a face-to-face examination. The medical record supplied in support of this claim, however, included the

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physician's progress note as well as an evaluation by an independent physical or occupational therapist. The therapy evaluation was performed by an independent therapist, and then reviewed by the physician prior to ordering the power wheelchair. As the Policy Article for Power Mobility Devices explains, a physician may have a physical or occupational therapist perform part of the face-to-face examination.

> The physician may refer the patient to a licensed/certified medical professional, such as a physical therapist (PT) or occupational therapist (OT), who has experience and training in mobility evaluations to perform part of the face-to-face examination. This person may have no financial relationship with the supplier. (Exception: If the supplier is owned by a hospital, PT or OT working in the inpatient or outpatient hospital setting may perform part of the face-to-face examination.)

The therapy report is thereafter viewed as *part of the physician notes*, relieving the physician from rewriting all of the medical necessity criteria from the therapy report into his/her progress notes. Jurisdiction B, Council A Questions and Answers, explained:

> 23. If a therapist conducts part of the face-to-face examination, must the physician address all of the major coverage criteria (address ambulation, rule out least costly alternatives, etc.) in the chart entry from his/her face-to-face examination? Even if the therapist documents some or all of the criteria?
>
> ANSWER: **If a part of the face-to-face exam is performed and documented by a PT/OT who has no financial relationship with the supplier, those parts of the exam do not have to addressed by the physician in his/her exam.**[22]

Consequently, the therapist's evaluation must be reviewed as though it was performed by the physician, given the same weight and consideration as the information actually written in the physician's chart notes. The two reports—the physician's and the therapist's—must be viewed as one.

[redacted] was evaluated by both her physician and an independent physical therapist. The physician first saw [redacted] on June 19, 2006. He created two separate documents of this encounter: handwritten short-hand note and a detailed typed note. The typed note states "power wheelchair discussed with the patient." The remainder of the typed note discusses [redacted] mobility limitations and the basis for his medical decision to prescribe a power wheelchair. [redacted] was further evaluated by an independent physical therapist one week later, on June 26, 2006. The physician thereafter reviewed and signed the physical therapy note on August 3, 2006, completing the face-to-face evaluation for the power wheelchair. Consequently, the face-to-face evaluation for [redacted] was fully and properly documented by the physician and the physical therapist and the two files must be viewed

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[22] National Government Services, Jurisdiction B DME MAC Council A Questions and Answers, *available at* http://www.regionbcouncil.sitecreatorplus.com/f/January_2009_Q_and_A_Document_FINAL.pdf (Jan. 22, 2009).

together as a single report that is included in the medical record. (Furthermore, and as noted above, this file was reviewed as part of a Redetermination Appeal for a wheelchair and approved for payment.)

5. The Medical Records Contained Supporting Documentation.

It is Marquis' understanding from the HHS-OIG that 11 of the 26 medical necessity claims were deemed by HHS-OIG to not be medical necessity because the medical record did not include supporting documentation.

a) Background

According to the Local Coverage Determination Policy, a physician must perform a face-to-face evaluation of a patient to determine and document the medical need for the power wheelchair. The Local Coverage Determination does not require the physician to include a specific list of facts or objective measurements in this review. Rather, the Local Coverage Determination states that the evaluation should be tailored to the individual patient's conditions. As the Local Coverage Determination explains, the physician may include the following elements in the report, but each element does not have to be addressed in every evaluation:

- Symptoms
- Related diagnoses
- History
  - How long the condition has been present
  - Clinical progression
  - Interventions that have been tried and the results
  - Past use of walker, manual wheelchair, POV, or power wheelchair and the results
- Physical exam
  - Weight
  - Impairment of strength, range of motion, sensation, or coordination of arms and legs
  - Presence of abnormal tone or deformity of arms, legs, or trunk
  - Neck, trunk, and pelvic posture and flexibility
  - Sitting and standing balance
- Functional assessment – any problems with performing the following activities including the need to use a cane, walker, or the assistance of another person

- Transferring between a bed, chair and PMD

- Walking around their home – to bathroom, kitchen, living room, etc. – provide information on distance walked, speed and balance

The patient files reviewed by the DHHS-OIG spanned over a three year time period, with the first files being over five years old from the date of the Draft Report. It is important to recognize that the type and amount of information documented in the face-to-face evaluation in 2006 through 2008 to support the medical need for a power wheelchair may be significantly different than the type of information documented in 2011. The review must be based upon the requirements and expectations at the time the document was made and cannot be based upon the requirements and expectations of today.

In June of 2006, the power wheelchair requirements were in their infancy, with little experience and understanding by any of the parties, including the physicians, providers and CMS itself. Over the next five years, CMS further developed and revised the policies, providing the supplier community with more education and instruction on how the policies were to be implemented. Thus, the suppliers did not have the same knowledge and experience in 2006 through 2008 that they possesses today.

The most fundamental change from the beginnings of the power wheelchair policy to today is the expectation that the physician's opinion or medical judgment must be supported by findings from objective tests. In 2006, 2007, and 2008 the Local Coverage Determination did not reference to, or require that, objective data be included in the face-to-face report. ***The reference to, and requirement of, including objective data was not added to the Local Coverage Determination until January 1, 2009***, when the Local Coverage Determination was revised to state that the face-to-face evaluation should "contain as must objective data as possible."

Likewise, in 2006 through 2008, the Local Coverage Determination suggests that physicians include discussion on the "impairment of strength, range or motion, sensation or coordination." The Local Coverage Determination did not mention or reference a requirement that specific strength testing measurements should be included in the face-to-face report. The Local Coverage Determination was not revised until January 1, 2009, to suggest that the physician include "arm and leg strength and range of motion." The change in wording in the Local Coverage Determination further demonstrates the need today for objective data such as strength measurements as opposed to 2006 through 2008, when the Local Coverage Determination only referred to a discussion or description of strength problems.

While the basic elements to establish the medical necessity for a power wheelchair have remained consistent from June 1, 2006 through today, it is important to note that the way in which the physician has been expected to document and defend his or her opinion of the patient's medical need for the power wheelchair has evolved. A reviewer must apply the standards that existed *at that time*, not the standards that *exist today*.

As the discussion below will demonstrate, the claims deemed to be improperly paid in the Draft Report for lack of supporting documentation did include evidence of the evaluation completed by the physician. The reports all included information explaining why the physician determined that the patient qualified for the power wheelchair, and thus had the necessary supporting documentation. The eleven claims therefore should remain paid.

b) Individual Claims

(1) [redacted]

[redacted] was evaluated on two separate occasions for his mobility examination; once by his physician and once by a physical therapist. The medical record shows that [redacted] suffers from both rheumatoid arthritis as well as osteoarthritis, which have caused significant decreases in his strength as well as severe pain with movement. [redacted] is further compromised from the effects of chronic obstructive pulmonary disease and diabetes with neuropathy. His circular problems were so severe that he had to undergo an above the knee amputation on his left leg, which combined with the fact that his right ankle was fused during childhood, made ambulating with a prosthesis nearly impossible.

The mobility examination included objective information supporting [redacted] need for a power wheelchair. For example, the mobility examination documented that he had developed decreasing strength in his right lower extremity, ranging from 3+/5 to 4+/5, leading the physical therapist to conclude that [redacted] had a deficit of 93% in his lower extremity function.

Likewise, his upper extremity function was evaluated with objective findings. [redacted] upper extremity strength is decreased significantly in his right shoulder to 3+/5, and is decreased in his left shoulder to 4/5. He also suffers from decreased range of motion in his shoulders and decreased grip strength in both hands. And finally, he suffers from significant pain in his shoulders that ranges from 3/10 (best) to 9/10 (worst), which is aggravated by attempting to propel a manual wheelchair. Based upon these objective findings, the physical therapist found [redacted] to have an 85% deficit in his upper extremity function.

The examination included a description of what the physical therapist observed when watching [redacted] walk and propel a manual wheelchair. [redacted] was observed leaning on the walker with his bilateral upper extremities taking most of the stress of his weight, and placing some limited weight on his right lower extremity. [redacted] walked a total of ten feet with the walker, which took him five minutes to complete. He also required the assistance of a caregiver during this distance due his poor dynamic standing balance.

In the clinical setting, [redacted] could only independently propel his manual wheelchair less than 100 feet, which took him five minutes to complete. His average speed was therefore 0.10 m/s, which is significantly below the average speed of a manual wheelchair user of 0.79 m/s.

Based upon these findings, the physician determined that [redacted] had a mobility limitation impairing his MRADLs, namely that he could not complete MRADLS within a reasonable time frame. Additionally, the physician determined that [redacted] could not resolve his mobility limitations with a cane, walker, manual wheelchair or scooter. Therefore, he prescribed a power wheelchair for [redacted]

(2) [redacted]

[redacted] was personally evaluated by her physician for a power wheelchair. She was found to be suffering from significant weakness, lack of endurance, and general debility due to the combined

effects of degenerative disc disease, osteoarthritis and congestive heart failure. She had been suffering from significant pain as well as shortness of breath, which left her at the mercy of her caregivers.

During the examination, [redacted] was not able to walk on her own for any distance, even with the assistance of a walker. She was noted to have had previous falls, resulting in a fractured wrist and elbow. The physician stated that [redacted] did not have the strength in her lower extremities, and had significant pain in her back and hips from the degenerative disc disease and osteoarthritis that prevented her from ambulating.

[redacted] was described by her physician as having extremely weakened upper extremity strength. She no longer had enough strength to position herself and shift her weight throughout the day, leading to the presence of decubitus ulcers. She also suffers from congestive heart failure and hypotension, both of which had caused her to have extremely decreased endurance. She became short of breath with any attempts at activity.

The physician determined that [redacted] was completely prevented from performing any of her MRADLs independently. She could no longer get to her kitchen for meal preparation or her bedroom or bathroom for grooming. She required the assistance of a caregiver for all of her daily activities and could not resolve these problems with a cane, walker or manual wheelchair. Consequently, the medical record included supporting information explaining how the physician determined that [redacted] qualified for a power wheelchair.

(3) [redacted]

[redacted] is a ninety-four year old female who suffers from degenerative joint disease that has caused significant weakness and debility, as well as significant pain in her joints. She was evaluated by both a physician and a physical therapist, providing ample supportive information to base the medical need for the power wheelchair.

For example, [redacted] bilateral lower extremity strength was tested and measured at only 3+/5. Moreover, she was found to have poor endurance, leading to the need for assistance with her activities and ambulation throughout her home. She was documented as only being able to walk a maximum of fifteen feet even with the assistance of a rolling walker. Even at such a short distance she required frequent rest breaks, some lasting up to five minutes. Her knees become weaker and more painful as she walked, resulted in a history of falls and placing her at a heightened risk of future falls.

Thus, the report included supportive information to demonstrate that [redacted] cannot walk function distances, nor can she walk safely around her home within a reasonable timeframe.

Her upper extremity strength was tested as 3+/5, demonstrating that she does not have the ability to propel herself in the manual wheelchair. Upon assessment, she was not able to propel the manual wheelchair for any distance due to her lack of strength and endurance.

The report of her mobility examination therefore included supporting documentation showing the reasons why [redacted] could not use a cane, walker or manual wheelchair. The report demonstrated the medical necessity of power wheelchair for [redacted] by including information on her limitations as well as attempts to use other assistive devices.

(4) [redacted]

[redacted] was evaluated one two separate occasions for his need for a power wheelchair, once by his physician and once by a physical therapist. The records of these two examinations include detailed information supporting the need for the power wheelchair.

[redacted] has significantly decreased lower extremity strength of 2/5. He also has fair tone in both lower extremities and has had a history of his knees buckling and giving way during attempts at walking. He is unsteady and requires moderate to maximum assistance of a caregiver for all ambulation and transfers.

[redacted] also has severe endurance limitations, as he uses three liters of supplemental oxygen. He becomes short of breath with limited exertion, limiting his walking to ten to fifteen feet maximum. Even though he only walked ten to fifteen feet, he needed rest breaks during this walk because he became too short of breath.

In addition, [redacted] has frozen shoulder syndrome, with only 30% active range of motion in his left shoulder. His left shoulder strength is 1/5 and his remaining left upper extremity and right upper extremity strength is limited to 3/5.

Upon examination, [redacted] was not able to independently propel the manual wheelchair for any distance, and was noted to require a caregiver to push him at all times when using a manual wheelchair. Furthermore, he does not have the endurance to propel his body in a manual wheelchair, as he becomes short of breath with minimal exertion, evidenced by his need for continuous use of supplemental oxygen at three liters per minute. Consequently, [redacted] is not able to use a manual wheelchair to resolve his mobility limitation.

The physical therapist documented that [redacted] was completely prevented from independently performing any of the MRADLs, including meal preparation, toileting, bathing and dressing/grooming himself. He required the assistance of a caregiver to perform any of these activities. Furthermore, the mobility examination included objective findings as to why [redacted] could not use a cane, walker, manual wheelchair or scooter to resolve his mobility limitations. Consequently, the mobility examinations appropriately supported and documented his need for a power wheelchair.

(5) [redacted]

[redacted] suffers from chronic obstructive pulmonary disease causing her to be oxygen dependent, congestive heart failure and degenerative disc disease. The report of her mobility examination includes objective facts supporting her need for the power wheelchair.

[redacted] was observed becoming short of breath and fatigued when she ambulating only twenty feet. After ambulation her oxygen level decreased to 84% while wearing oxygen at four liters per minute. Furthermore, she has a history of falls due to her unsteady gait which is caused in part due to her limited range of motion in her lower extremities. She is limited to 19° of flexion on the right and 18° of flexion on the left, with normal range of flexion being 0-130°.

[redacted] is unable to propel a manual wheelchair any distance with her upper extremities because the pain is too severe. She relies on her lower extremities to propel the manual wheelchair. When using her feet to move the manual wheelchair, she still required a rest break after only ten feet due to shortness of breath, and increased pain (8/10) in bilateral knees. Her oxygen level also decreased to 86% when pushing the manual wheelchair with her feet.

The mobility examination demonstrated through numerous objective findings that [redacted] does not have the upper and lower extremity function to use a cane, walker, manual wheelchair or scooter to safely and timely ambulate within her home. The supporting documentation provided with this claim demonstrates that [redacted] has a medical need for a power wheelchair in order to independently complete her MRADLs.

(6) [redacted]

[redacted] medical history includes chronic obstructive pulmonary disease and congestive heart failure, causing her to have peripheral edema and being oxygen dependent. Her cardio-respiratory status is further compromised by the fact that she is morbidly obese, weighing 407 lbs. She suffers from weakness in her lower extremities and hands, as well as significant shortness of breath.

[redacted] medical conditions have prevented her from being able to functionally ambulate. She can only walk ten feet and then needs to take a rest. She becomes short of breath as a result of her severe lung disease, coupled with knee pain and weakness caused in part from her obesity. Her need for continual rest breaks every ten feet prevents her from being able to complete her MRADLS in a timely manner.

[redacted] mobility examination demonstrates that a manual wheelchair cannot resolve her mobility limitations. During the examination, she propelled a manual wheelchair for five feet before needing to rest. [redacted] experienced numbness in her hands from the peripheral neuropathy, and decreased grip strength as well as progressive dyspnea. She cannot use a manual wheelchair to complete her MRADLs within a timely manner.

[redacted] physician described how her medical conditions and the associated symptoms of those conditions limited her ability to functionally ambulate within her home. The physician also described why alternative assistive devices such as a cane, walker, manual wheelchair or scooter would not resolve [redacted] mobility limitations. Therefore, the report of the face-to-face examination does include supportive documentation and information to find that the power wheelchair is medically necessary for [redacted]

(7) [redacted]

[redacted] suffers from significant shortness of breath and wheezing secondary to severe chronic obstructive pulmonary disease and chronic respiratory failure.

[redacted] does not have the respiratory reserves to enable him to ambulate in a safe and timely manner. He becomes significantly short of breath after walking only thirty feet. He has decreased strength and endurance, as well as pain in his legs that force him to take rest breaks after such short

distances. Neither a cane nor walker assist him in walking any further than thirty feet, or decrease the amount of rest breaks necessary when walking.

[redacted] also does not have the endurance or lung capacity to independently propel a manual wheelchair because he becomes too short of breath to use a manual wheelchair.

The mobility examination therefore demonstrated that [redacted] severe chronic obstructive pulmonary disease and chronic respiratory failure prohibit [redacted] from being able to ambulate around his home with any other type of assistive device, requiring the use of a power wheelchair.

(8) [redacted]

[redacted] suffers from hypoxia secondary to chronic obstructive pulmonary disease and cor pulmonale. His breathing problems have increased, causing profound shortness of breath with just minimal exertion. He requires the use of two to three liters of supplemental oxygen, twenty-four hours a day. His problems with breathing have progressed to where he becomes extremely short of breath with any activity and must take numerous rest breaks when attempting to perform normal, daily activities.

As the mobility examination discusses, [redacted] is only able to walk thirty feet prior to stopping and taking a rest due to significant shortness of breath. He can walk a maximum of 120 feet, but requires four rest breaks to go the entire distance. His shortness of breath quickly causes fatigue and weakness, leading to a risk of falls.

The continuous movement of walking exacerbates his severe chronic obstructive pulmonary disease, causing him to become too short of breath to continue walking. Neither a cane nor a walker relieves his problems, as the mere act of walking causes his hypoxia-related symptoms.

According to his physician, [redacted] does not have the lung capacity to self propel a manual wheelchair. The physician found that any attempt to propel a manual wheelchair would be too stressful on [redacted] due to his severe lung condition and severe shortness of breath with minimal exertion.

The mobility examination provided supporting information regarding [redacted] mobility limitations. The documentation provides the required details for supporting the physician's determination that [redacted] requires the use of a power wheelchair in order to safely and timely complete his MRADLs.

(9) [redacted]

[redacted] suffers from a litany of medical conditions that have left him unable to independently move throughout his home to complete his MRADLs. For instance, [redacted] medical history includes end stage renal disease, left lower extremity amputation, myopathy, insulin dependent diabetes, hypertension and peripheral vascular disease.

[redacted] is not able to use a cane or walker for more than a few feet without stopping to rest. Additionally, [redacted] has suffered falls in the past because he does not have adequate balance when using his prosthetic. He therefore is unsafe with either a cane or walker. Moreover, he has decreased upper extremity strength, making it difficult for him to use his arms to compensate for the lack of balance he has when using the prosthetic.

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The lack of upper extremity strength and the loss of endurance prevent [redacted] from independently using a manual wheelchair.

The mobility examination provided explanation as to why the physician believed [redacted] could not use a cane, walker, manual wheelchair or scooter to resolve his mobility limitations. The report further described [redacted] inability to complete his MRADLs without an appropriate assistive device. Thus, the mobility examination provided the necessary supportive documentation to determine the medical necessity of the power wheelchair.

(10) [redacted]

[redacted] suffers from end stage renal disease and diabetes, which have left her dependent upon caregivers for all activities. [redacted] has diminished strength and endurance that prevent her from being independent within her home.

[redacted] has attempted to use a cane and walker in the past, but has not been able to do so safely. She has suffered from numerous falls resulting in fractures to her collarbone and ankle. She has poor balance, decreased upper extremity strength and poor postural positioning, which all combine to make her an extremely unsafe ambulatory. She requires maximum assistance of a caregiver to go from the bedroom to the bathroom.

She is likewise limited in her ability to use a manual wheelchair. Upon examination, she can only independently propel a manual wheelchair for five to seven feet before stopping due to decreased upper extremity strength and poor endurance.

The mobility examination described a very frail, weak woman who had suffered injury due to prior attempts at walking. The examination included the detail supporting the physician's decision to prescribe a power wheelchair.

(11) [redacted]

[redacted] medical history includes Parkinson's disease, diabetes and dyspnea with minimal activities. She is primarily limited in her ambulation due to decreased endurance and a safety concern from lack of balance caused by the Parkinson's disease.

[redacted] is able to walk approximately twenty feet prior to stopping to rest due to shortness of breath. Her lack of endurance and shortness of breath cause her to be unsteady and have a lack of balance, leading to a risk of falls. This risk is heightened by the fact that she has a history of falling.

The physician's mobility examination is corroborated by a physical therapy evaluation where [redacted] walked fifteen feet and had to stop due to shortness of breath. Her heart rate increased dramatically from 72 to 120 beats per minute, as did her respiration rate from fifteen to twenty-five. Her oxygen saturation decreased from 96% to 88% after only fifteen feet. The physiological changes noted in the corroborating documentation support the physician's statement that [redacted] becomes dyspnic with minimal activity.

Moreover, the physical therapist corroborated the physician's finding that [redacted] is unsafe with ambulation, noting that [redacted] has problems with her legs unexpectedly buckling.

The physician also noted that [redacted] suffers from weakness that prevents safe ambulation with a walker, and prohibits independent use of a manual wheelchair. The physical therapy evaluation further corroborates this, as [redacted] was found to have decreased strength in all four extremities of 4-/5 and to have decreased bilateral grip strength.

Consequently, the physician's mobility examination has been corroborated and supported further by additional documentation in the medical record. As the medical records demonstrate, [redacted] cannot walk functional distances in a safe manner with a cane or walker. She also cannot use a manual wheelchair or scooter, and therefore is an appropriate candidate for a power wheelchair.

* * * *

Marquis appreciates the efforts of, and the opportunity to dialogue with, HHS-OIG over the course of the audit, has learned through the exchange of ideas and is more committed than ever to furnishing services to Medicare Part B beneficiaries in a prompt, curteous and ethical manner. That said, Marquis respectfully submits that for the reasons set forth in detail above, it has not received any overpayments from Medicare. As a matter of law, 33 of the claims at issue are time barred. Moreover, there is no good cause to support the re-opening and recoupment of the remaining ten claims.

Both Marquis representatives and the undersigned counsel will make themselves available to HHS-OIG to answer any questions or address any concerns with respect to any matter raised above.

We thank you in advance for your consideration of our response to the Draft Response.

Sincerely,

Gadi Weinreich
SNR Denton US LLP

Office of Inspector General Note - The deleted text has been redacted because it contains personally identifiable information.