Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HOVEROUND CORPORATION CLAIMED MILLIONS IN FEDERAL REIMBURSEMENT FOR POWER MOBILITY DEVICES THAT DID NOT MEET MEDICARE REQUIREMENTS

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Office of Inspector General

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EXECUTIVE SUMMARY

Hoveround Corporation claimed at least $27 million in Federal reimbursement for power mobility devices that did not meet Medicare requirements.

WHY WE DID THIS REVIEW

Medicare Part B covers power mobility devices (PMDs), which include power wheelchairs and power-operated vehicles. High incidences of fraud and improper payments have been historically associated with PMDs. In its *Medicare Fee-for-Service 2011 Improper Payments Report*, the Centers for Medicare & Medicaid Services (CMS) reported a Medicare improper payment rate for PMDs of 81.8 percent, accounting for approximately $492 million in improper payments for 2011. Prior Office of Inspector General (OIG) work found that a supplier claimed Federal reimbursement for PMD claims that did not comply with medical necessity and documentation requirements. In 2010, Medicare payments for PMDs totaled $722 million. For that year, Hoveround Corporation received $49,697,392, the second-largest Federal reimbursement for PMDs supplied to Medicare beneficiaries.

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

BACKGROUND

Medicare Part B pays for beneficiaries' PMDs for in-home use that is reasonable and necessary for the treatment of illness or injury or to improve functioning of a malformed body member. Medicare does not pay for PMDs for use solely outside of the home. To meet Medicare guidelines, the PMD must be deemed medically necessary on the basis of a number of factors, including whether the PMD would help the beneficiary perform mobility-related activities of daily living (MRADL) and whether a different type of equipment, such as a cane, walker, or manual wheelchair, would meet the beneficiary's medical needs.

Medicare pays for a PMD if the physician or treating practitioner (1) conducts a face-to-face examination of the individual, (2) writes a prescription that is given to the beneficiary or the supplier and is received by the supplier within 45 days after the face-to-face examination, and (3) provides documentation to the supplier that supports the medical necessity of the PMD within 45 days of the face-to-face examination. Supporting documentation for a PMD includes parts of the beneficiary's medical record, such as a patient history, physical examination, and summary of findings. Before submitting a claim, the supplier must have the above information on file and should obtain as much information as possible from the patient's medical records to ensure that coverage criteria have been met. Documentation must be maintained in the supplier's files for 7 years. The supplier is liable to Medicare if the information in the patient's medical records does not support medical necessity. Also, the supplier must submit to CMS and its agents upon request additional documentation to support or substantiate the medical necessity for the PMD.

HOW WE CONDUCTED THIS REVIEW

Our review covered payments for PMDs supplied to 13,025 Medicare beneficiaries from Hoveround's largest provider number, totaling $40,570,854. We selected a stratified random sample of 200 beneficiaries who received new, used, or rented PMDs from Hoveround. For each sampled beneficiary, we obtained and reviewed the supporting documentation maintained by Hoveround.

WHAT WE FOUND

Hoveround often did not claim Medicare reimbursement for PMDs in accordance with Medicare requirements. Hoveround complied with Medicare requirements for 46 of the sampled beneficiaries. However, for the remaining 154 sampled beneficiaries, Hoveround received payments for claims that did not comply with Medicare requirements. Specifically:

- For 144 sampled beneficiaries, Hoveround did not support the medical necessity of PMDs.

- For 10 sampled beneficiaries, Hoveround provided incomplete documentation to support the PMD claims.

On the basis of our sample results, we estimated that Medicare paid Hoveround at least $27,027,579 for PMDs that did not meet Medicare requirements during 2010.

These deficiencies occurred because Hoveround's internal controls did not ensure that Medicare requirements were followed to support the medical necessity of PMDs and that supporting documentation was completed in accordance with Medicare requirements. Medical records and documentation must demonstrate that the patient has (1) a mobility limitation that significantly impairs the ability to participate in one or more MRADLs, (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 MRADLs during a typical day.

WHAT WE RECOMMEND

We recommend that Hoveround:

- refund $27,027,579 to the Federal Government and

- implement internal controls to:

    - ensure that Medicare requirements are followed to support beneficiaries' medical needs for PMDs and

    - ensure that supporting documentation for PMDs meets Medicare requirements before providing PMDs to beneficiaries.

AUDITEE COMMENTS AND OUR RESPONSE

In written comments on our draft report, Hoveround disagreed with our recommendations. Hoveround stated that OIG did not inform Hoveround that it was conducting a medical necessity review, and as a result Hoveround was not able to submit all of the necessary supporting evidence. Hoveround stated that OIG influenced the medical review performed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and biased the results. Hoveround stated that the DME MACs' conclusions were wrong because the DME MACs did not apply the correct standards. Hoveround also stated that OIG's extrapolation of the audit results was improper.

We maintain that Hoveround was informed of the need to provide OIG with medical records to support the medical necessity of its claims. OIG did not influence or bias the result of the DME MACs' medical necessity review. We maintain that the DME MACs used the correct Medicare standards in conducting their medical review. Finally, our extrapolation of the audit results was appropriate. For reasons we explain in the report, we stand by our audit methodology, procedures, findings, and recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

Medicare Part B covers power mobility devices (PMDs), which in this report refer to both power wheelchairs and power-operated vehicles.[1] High incidences of fraud and improper payments have been historically associated with PMDs. In its *Medicare Fee-for-Service 2011 Improper Payments Report*, the Centers for Medicare & Medicaid Services (CMS) reported a Medicare improper payment rate for PMDs of 81.8 percent, accounting for approximately $492 million in improper payments for 2011. Prior Office of Inspector General (OIG) work found that a supplier claimed Federal reimbursement for PMD claims that did not comply with medical necessity and documentation requirements.[2] In 2010, Medicare payments for PMDs totaled $722 million. For that year, Hoveround Corporation received $49,697,392—the second-largest Federal reimbursement for PMDs supplied to Medicare beneficiaries.

OBJECTIVE

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

BACKGROUND

Medicare Requirements for Claiming Reimbursement for Power Mobility Devices

Medicare Part B pays for beneficiaries' PMDs for in-home use that is reasonable and necessary for the treatment of illness or injury or to improve functioning of a malformed body member.[3] Medicare does not pay for PMDs for use solely outside of the home.[4] To meet Medicare guidelines, the PMD must be deemed medically necessary on the basis of a number of factors, including whether the PMD would help the beneficiary perform mobility-related activities of daily living (MRADLs) and whether a different type of equipment, such as a cane, walker, or manual wheelchair, would meet the beneficiary's medical needs.[5]

Medicare pays for a PMD if the physician or treating practitioner (1) conducts a face-to-face examination of the individual, (2) writes a prescription that is given to the beneficiary or the supplier and is received by the supplier within 45 days after the face-to-face examination, and (3) provides documentation to the supplier that supports the medical necessity of the PMD within

[1] 42 CFR § 410.38(a).

[2] *Review of Power Mobility Devices Supplied by Marquis Mobility, Inc.* (A-05-10-00042, issued May 3, 2012).

[3] Social Security Act (the Act) §§ 1861(n) and 1862(a)(1)(A), 42 CFR §§ 410.38(a) and 410.38(c).

[4] Durable Medical Equipment Medicare Administrative Contractors (DME MACs) power mobility device policy articles are A47122, A36239, A41127, and A41136.

[5] Local Coverage Determinations (LCDs) L21271, L23598, L27239, and L23613.

45 days of the face-to-face examination.[6] Supporting documentation for a PMD includes parts of the beneficiary's medical record (e.g., patient history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans, or other appropriate information) that supports the medical necessity of the PMD.[7] Once the supplier has reviewed the physician's written order and determined the specific PMD that is appropriate for the patient, the supplier must prepare a written document (the detailed product description) that lists the wheelchair model, options, and accessories. The physician must sign and date this detailed product description, and the supplier must receive it before delivering the PMD. A supplier must date-stamp the detailed product description or otherwise document the date that it receives the detailed product description from the physician.[8] Before submitting a claim, the supplier must have the above information on file and should obtain as much information as possible from the patient's medical records to ensure that coverage criteria have been met. Documentation must be maintained in the supplier's files for 7 years. The supplier is liable to Medicare if the information in the patient's medical records does not support medical necessity.[9] A supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request. Upon request by CMS or its agents, a supplier must submit additional documentation to support or substantiate the medical necessity for the PMD.[10]

Medicare contractors develop LCDs for many durable medical equipment (DME) items, including PMDs. LCDs specify under what clinical circumstances the item is considered reasonable and necessary. For a PMD to be covered, the LCDs 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 MRADLs, (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 MRADLs during a typical day.[11]

Hoveround Corporation

Hoveround was founded in 1992 and is headquartered in Sarasota, Florida. It designs, manufactures, delivers, and services all Hoveround power chairs. Hoveround services 44 States

[6] 42 CFR §§ 410.38(c)(2)(i–iii).

[7] 42 CFR § 410.38(c)(2)(iii).

[8] LCDs L21271, L23598, L27239, and L23613.

[9] *Medicare Program Integrity Manual*, Pub. No. 100-08, (the Manual) chapter 5, § 5.8.

[10] 42 CFR § 410.38(c)(5).

[11] LCDs L21271, L23598, L27239, and L23613.

nationwide.[12] Hoveround was Medicare's second-largest PMD supplier in 2010; it received payment through nine unique national provider identifiers (NPIs),[13] totaling $49,697,392.

HOW WE CONDUCTED THIS REVIEW

Our review covered payments for PMDs supplied to 13,025 Medicare beneficiaries from Hoveround's largest NPI, totaling $40,570,854 in 2010. We selected a stratified random sample of 200 beneficiaries who received either new, used, or rented PMDs from Hoveround. For each sampled beneficiary, we obtained and reviewed the supporting documentation maintained by Hoveround. One hundred and seventy-one of the 200 beneficiaries were determined to not meet medical necessity requirements by a medical necessity review contractor used by OIG. We received additional medical documentation from Hoveround in response to our draft report. As a result, we requested that the DME MACs perform an additional medical review of all of the supporting documentation to determine whether medical necessity and coverage requirements were met.[14]

We conducted this performance audit in accordance with generally accepted government auditing standards (GAGAS). 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix B contains our sample design and methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Hoveround often did not claim Medicare reimbursement for PMDs in accordance with Medicare requirements. Hoveround complied with Medicare requirements for 46 of the sampled beneficiaries. However, for the remaining 154 sampled beneficiaries, Hoveround received payments for claims that did not comply with Medicare requirements. Specifically:

- For 144 sampled beneficiaries, Hoveround did not support the medical necessity of PMDs.

- For 10 sampled beneficiaries, Hoveround provided incomplete documentation to support the PMD claims.

[12] Hoveround does not handle sales or service in Alaska, Hawaii, Montana, North Dakota, South Dakota, and Wyoming.

[13] NPIs are unique identification numbers for covered health care providers.

[14] The DME MACs did not perform a medical necessity review for those claims that were reviewed and approved for medical necessity by OIG's initial medical review contractor.

On the basis of our sample results, we estimated that Medicare paid Hoveround at least $27,027,579 for PMDs that did not meet Medicare requirements during 2010.

These deficiencies occurred because Hoveround's internal controls did not ensure that Medicare requirements were followed to support the medical necessity of PMDs and that supporting documentation was completed in accordance with Medicare requirements. Medical records and documentation must demonstrate that the patient has (1) a mobility limitation that significantly impairs the ability to participate in one or more MRADLs, (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 MRADLs during a typical day.

For details on the Federal requirements for PMDs covered by Medicare Part B, see Appendix D.

HOVEROUND DOCUMENTATION DID NOT SUPPORT MEDICAL NECESSITY

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, or other appropriate information) that supports the medical necessity of the PMD, which is received by the supplier within 45 days after the face-to-face examination.[15] 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.[16] A supplier must maintain the prescription and supporting documentation and make it available upon request.[17]

Hoveround provided PMDs that were not medically necessary for 144 of the 200 sampled beneficiaries. Specifically:

- For 71 beneficiaries, the records of the face-to-face examinations did not specify the beneficiaries' mobility limitations that would establish significant impairment to participate in MRADLs in their homes. The medical record must demonstrate that a beneficiary's mobility limitations significantly impair his or her ability to participate in one or more MRADLs.[18]

- For 46 beneficiaries, the records of the face-to-face examinations did not indicate whether the beneficiaries' mobility limitation could have been resolved by different equipment, such as a cane, walker, or manual wheelchair. The medical record must demonstrate that a beneficiary's mobility limitation cannot be sufficiently and safely

[15] 42 CFR § 410.38(c)(2)(iii).

[16] The Manual, chapter 5, § 5.8.

[17] 42 CFR § 410.38(c)(5).

[18] LCDs L21271, L23598, L27239, L23613, and the Manual, chapter 5, § 5.7.

resolved by the use of an appropriately fitted cane, walker, or manual wheelchair to perform MRADLs.[19]

- For 22 beneficiaries, the records of the face-to-face examinations had insufficient detail, incomplete narratives from the physicians, or conflicting information. For example, the progress note for one beneficiary did not document the beneficiary's lack of strength, range of motion, or functional skills. Physicians are required to provide supporting documentation, such as a physical examination, that supports medical necessity for PMDs.[20]

- For three beneficiaries, the records of the face-to-face examinations did not indicate whether the beneficiaries' mobility limitation could have been resolved by a power-operated vehicle (POV), commonly referred to as a "scooter." The medical record must demonstrate that the use of a POV was ruled out before a power wheelchair was prescribed.[21]

- For one beneficiary, the record of the face-to-face examination was insufficient to establish that one of the major reasons for the examination was for a mobility evaluation. The progress note for that beneficiary stated that the beneficiary was seen for refills and pain. The note did not indicate the reason for the visit was for a mobility evaluation. Physicians are required to conduct face-to-face examinations of the beneficiaries to determine medical necessity for PMDs.[22]

- For one beneficiary, the record of the face-to-face examination did not specify that the beneficiary had the physical and mental capability to safely operate the PMD being requested. Physicians are required to determine whether beneficiaries have the mental and physical capabilities to safely operate PMDs.[23]

These errors occurred because Hoveround's internal controls did not ensure that documentation in the beneficiaries' medical records met Medicare requirements for the beneficiaries' medical needs for PMDs.

HOVEROUND DOCUMENTATION WAS INCOMPLETE

For 10 of the 200 sampled beneficiaries, Hoveround gave us supporting documentation that was incomplete. Specifically:

[19] LCDs L21271, L23598, L27239, and L23613.

[20] 42 CFR § 410.38(c)(2)(iii).

[21] LCDs L21271, L23598, L27239, and L23613.

[22] 42 CFR § 410.38(c)(2)(i).

[23] LCDs L21271, L23598, L27239, and L23613.

- For three beneficiaries, some or all of the elements of the written order were not completed by the treating physician. The treating physician should complete the face-to-face examination and complete all elements of the written order.[24]

- For two beneficiaries, the date that Hoveround received the written order was missing. The written order provided must have the date the face-to-face examination was completed, and the supplier must receive the written order within 45 days of the face-to-face examination. Suppliers must date-stamp the written order to document its receipt date.[25]

- For two beneficiaries, the detailed product description did not include the physician's signature, the date, or both. The physician must sign and date the detailed product description, and the supplier must receive it before delivery of the PMD.[26]

- For two beneficiaries, the detailed product description was missing the supplier's date stamp (or equivalent) indicating when the supplier received it. When a supplier receives a detailed product description from the physician, the supplier must date-stamp it or otherwise document the receipt date.[27]

- For one beneficiary, the physician reviewed, signed, and dated the detailed product description before the supplier received the written order for the PMD. The physician should have reviewed, signed, and dated the detailed product description after providing the written order to the supplier.[28]

These errors occurred because Hoveround's internal controls did not ensure that Hoveround verified the completeness of medical records.

RECOMMENDATIONS

We recommend that Hoveround:

- refund $27,027,579 to the Federal Government and

- implement internal controls to:

    - ensure that Medicare requirements are followed to support beneficiaries' medical needs for PMDs and

[24] 42 CFR § 410.38(c)(1).

[25] LCDs L21271, L23598, L27239, and L23613.

[26] LCDs L21271, L23598, L27239, and L23613.

[27] LCDs L21271, L23598, L27239, and L23613.

[28] LCDs L21271, L23598, L27239, and L23613.

- ensure that supporting documentation for PMDs meets Medicare requirements before providing PMDs to beneficiaries.

HOVEROUND COMMENTS AND OIG RESPONSE

In written comments on our draft report, Hoveround disagreed with our recommendations. Hoveround stated that OIG did not inform Hoveround that it was conducting a medical necessity review, and as a result Hoveround was not able to submit all of the necessary supporting evidence. Hoveround stated that OIG influenced the medical review performed by the DME MACs and biased the results. Hoveround stated that the DME MACs' conclusions were wrong because the DME MACs did not apply the correct standards. Hoveround also stated that OIG's extrapolation of the audit results was improper.

Hoveround's response discusses in detail the audit process and the steps OIG took to complete this audit. As a result, we explain below why and how we conducted our audit of Hoveround. This provides the appropriate context needed to understand our response to a number of the concerns that Hoveround raised. After providing this overview of our audit, we will address the remaining concerns raised by Hoveround. For reasons we explain in the report, we stand by our audit methodology, procedures, findings, and recommendations.

BACKGROUND

In its *Medicare Fee-for-Service 2011 Improper Payments Report*, CMS reported a Medicare improper payment rate for PMDs of 81.8 percent, accounting for approximately $492 million in improper payments for 2011. Accordingly, OIG chose to audit this high-risk area. We chose to audit Hoveround because it was Medicare's second-largest PMD supplier in 2010. Hoveround's largest NPI received more than $40 million in Medicare payments in 2010. We focused our review solely on the largest NPI and the resulting payments for PMDs supplied to 13,025 Medicare beneficiaries. We conducted this audit in accordance with GAGAS.

We used a statistically valid methodology to select a random sample of 200 beneficiaries who received new, used, or rented PMDs from Hoveround that were paid for in 2010. We also made every effort to exclude Recovery Audit Contractor (RAC)-reviewed and canceled claims for beneficiaries from our sample universe. However, we recognize that some RAC-reviewed and canceled claims may have been included in our sampling frame of beneficiaries because of the timing of when we obtained the data. To remedy this, we treated any such claims as non-errors when observed in our sample, and we recommend recovery at the statistical lower limit, which means that our recommended recovery amount will be less than the actual overpayment amount 95 percent of the time no matter how many RAC-reviewed or canceled claims are in the frame. Regarding the claims covered by our audit, we analyzed our sample data to ensure that the claims we reviewed were not reviewed by the RACs. The sample items we reviewed were also removed from the pool of claims that the RACs could have potentially reviewed. Additionally, we treated as non-errors claims for 13 sampled beneficiaries that had already been reviewed for compliance with coding and documentation requirements and approved by the DME MACs.

Hoveround states that it was not aware that OIG was conducting a medical necessity review. But OIG made certain Hoveround knew at the very start of our audit work of the need to provide the medical record documentation necessary to support the medical necessity of the PMD claims that were the subject of the audit. We first contacted Hoveround on May 23, 2012, by sending an engagement letter explicitly stating that we would be "requesting the Medicare beneficiaries' medical records to determine the need for the PMD." OIG again contacted Hoveround on June 5, 2013, in an email requesting specific records for the beneficiaries in our sample, including "Face-to-face Examination/Medical Records—Relevant to beneficiaries' mobility needs, History of present condition and relevant past medical history."

OIG auditors were onsite at Hoveround in June 2012 working with Hoveround to gather the necessary documents. From late May 2012 through January 2013, OIG was actively working with Hoveround to gather and fully understand the documentation produced by Hoveround. When we believed we might be missing information, we sought additional documentation or clarification from Hoveround. At each step of the audit, OIG auditors made every effort to ensure that OIG had all of the documentation needed to objectively review and assess the claims at issue. During this initial phase of the audit, we gathered more than 10,000 documents, which resulted in our findings and recommendations in the draft report.

OIG auditors carefully reviewed and analyzed all of the documents provided. Those documents were then submitted to a medical necessity review contractor to determine whether the PMDs received by the sampled beneficiaries were medically necessary under the Medicare criteria in place in 2010. We received the results of the medical necessity review 6 months later, in June 2013, and carefully analyzed the results and drafted our report. In November 2013, we issued the draft report to Hoveround and provided Hoveround with 30 days to give us comments on the draft report. In accordance with GAGAS and for all audits with recommendations, we issue a draft report to the auditee and solicit its comments before issuing a final report. OIG then carefully reviews, considers, and incorporates those comments and any additional documentation provided, as appropriate, into its findings and recommendations. This process ensures that the final report is fair, complete, and objective and complies with GAGAS.

Within a week of our issuance of the draft report, Hoveround requested, and OIG granted, a 2-week extension for Hoveround to respond to the draft report. Hoveround requested an in-person meeting with OIG in December 2013, and OIG met in-person with Hoveround's counsel on December 13, 2013. At the meeting, Hoveround stated that it needed an extended amount of time to respond to OIG's draft report. Hoveround requested a second extension to provide additional medical records to support its claims for the sampled beneficiaries. In an effort to ensure that we had all of the relevant documents to evaluate these claims, OIG agreed to an unusually lengthy extension, until February 14, 2014. Despite receiving this extension, Hoveround began responding to the draft audit within days of receiving it. Hoveround sent numerous letters and emails raising concerns with the audit findings and recommendations and demanding that OIG not complete or publish its audit of Hoveround. OIG reviewed, analyzed, and considered each of these letters and emails carefully to determine whether the issues raised by Hoveround had an impact on our audit methodology, findings, and recommendations.

On February 14, 2014, OIG received Hoveround's complete response, consisting of a 32-page letter and approximately 4,600 pages of additional documentation in support of the claims for the sampled beneficiaries. In compliance with GAGAS and as with all audits, when an auditee provides additional documentation in response to the draft report, OIG reviews, analyzes and considers that documentation to determine whether it changes OIG's findings and recommendations. In this case, OIG auditors immediately began the lengthy and time-consuming process of reviewing and analyzing the new documentation associated with the sample beneficiaries. Following the OIG auditors' review of the documents, OIG contacted its medical necessity review contractor. OIG provided all of the original and new medical record documentation to the medical necessity review contractor for its review; this was the first medical necessity review of the now "complete" medical record. This ensured that the now "complete" medical record (including the original and new documents provided by Hoveround) would be reviewed and analyzed under the same standards, and OIG would be in the best possible position to objectively assess whether these claims met the Medicare medical necessity standards in place in 2010.

While the medical necessity review of the now "complete" medical record was underway, Hoveround sent a letter on August 18, 2014, stating that having the additional documentation reviewed by the original medical necessity review contractor would create a bias in the results. OIG took Hoveround's arguments under careful consideration and does not agree with Hoveround's assertion. However, to ensure that even the appearance of bias would not be present and to ensure that our review was fair and objective, we engaged the DME MACs. We provided the now "complete" medical records and the original draft report to the DME MACs so they could complete an independent medical necessity review using the criteria in place in 2010; this was the second medical necessity review of the now "complete" medical record. Contrary to Hoveround's assertion, OIG did not share the results of the medical necessity review contractor's findings with the DME MACs. The DME MACs then completed an independent and unbiased medical review of the claims for the 171 sampled beneficiaries that we found in our draft report not to have met medical necessity or documentation requirements. The process of completing two separate medical necessity reviews of the now "complete" medical records (over 14,000 documents) was extremely time consuming, and OIG did not receive the final results from the DME MACs until late in May 2015.

The DME MACs determined an error rate that was slightly lower but not significantly different than our medical necessity review contractor's error rate from the draft report. Once we received the results of the DME MACs' medical necessity review, we carefully analyzed the results and drafted our final report. To be conservative, we revised our findings and recommendations using only the results from the DME MACs' medical necessity review. In September 2015, we were ready to issue the final report. However, in the late summer of 2015, Hoveround made numerous calls and sent numerous emails and letters to OIG continuing to request that OIG stop its audit and not publish its report. Hoveround also requested another in-person meeting with OIG, which occurred on September 11, 2015.

At that meeting, Hoveround continued to insist that OIG not complete its audit. As an alternative, Hoveround requested an additional opportunity to review and comment on the report before it was published. These requests were highly unusual. OIG had performed an extensive

analysis of a large number of medical documents. OIG had made initial findings in a draft report and provided Hoveround an opportunity to respond (including a lengthy extension to ensure a complete response). OIG then received a voluminous amount of additional documentation from Hoveround. The now "complete" medical record was subjected to not one but two separate medical necessity reviews, which came to substantially similar results as those reported in the draft audit. However, once again, OIG, in an effort to avoid even the appearance of a lack of objectivity or fairness, provided Hoveround with an opportunity to review and comment on the current version of the report.

We received Hoveround's response to the second draft report on October 21, 2015.[29] Following our normal process and in compliance with GAGAS, we have carefully reviewed and analyzed the 44-page comments and the more than 1,000 pages of additional documentation Hoveround has provided. Hoveround's response did not require additional medical review. Hoveround, once again, requested that OIG not complete its audit. A summary of Hoveround's specific arguments and our responses are detailed below.

Hoveround's October 21, 2015, comments on our draft report are included as Appendix E. We have not included the supporting documentation Hoveround sent with its comments because the documentation contains personally identifiable information.

HOVEROUND DISAGREED WITH THE DURABLE MEDICAL EQUIPMENT MEDICARE ADMINISTRATIVE CONTRACTORS' CONCLUSIONS

Hoveround stated that the DME MACs' conclusions about the medical necessity of PMDs were incorrect. Hoveround stated that other Medicare review contractors, including the DME MACs, reached different results than the DME MACs when reviewing claims from 2010 involving the same issues and standards.

Comparison to Reviews Conducted by Medicare Review Contractors

Hoveround Comments

Hoveround stated that DME MACs and RACs evaluated 2010 claims involving the same issues under the same standards as our initial medical review contractor and the DME MACs when they performed the medical necessity review for our audit but reached different results. Specifically, Hoveround stated that the DME MACs reviewed more than 1,600 of Hoveround's PMD claims from 2010 and found an error rate of 40 percent. Hoveround also stated that the RACs found an error rate of only 1 percent on more than 700 Hoveround claims from 2010.

OIG Response

We disagree with Hoveround's statement that the DME MACs and RACS evaluated the 2010 claims under the same standards. Hoveround did not provide us with the specific claims that the DME MACs reviewed and the associated findings, so we were unable to verify Hoveround's assertions. However, we interviewed officials from the four DME MACs and determined that

[29] The date of the response in Appendix E is incorrectly dated October 20, 2015.

they did not routinely conduct medical necessity reviews on Hoveround's PMD claims. When three of the four did conduct medical necessity reviews of Hoveround's 2010 claims, the reviews were (1) similar to the ones conducted by our contractors and (2) had significantly higher error rates than the error rate Hoveround presented in its comments. In fact, the data we received from the DME MACs show that their medical necessity review of Hoveround's 2010 PMD claims identified an average error rate of 56 percent. Table 1 shows what the DME MACs reported related to their reviews of Hoveround's 2010 PMD claims specific to the same NPI that was the subject of our audit.

Table 1: The Reviews of Hoveround's 2010 Power Mobility Device Claims by the Durable Medical Equipment Medicare Administrative Contractors

MAC	Claims Reviewed	Claims in Error	Claim Error Rate	Review Type
CGS	2,031	1,129	55.59%	Medical Necessity Review
NGS	222	127	57.21%	Medical Necessity Review
Noridian	51	37	72.55%	Medical Necessity Review
	2,304	**1,293**	**56.12%**	

Hoveround did provide us with the RAC claims that had been reviewed. As a result, we also interviewed officials from CMS and four RACs and presented these data to CMS. We determined that the RACs' claim reviews were not the same in scope as our medical necessity review audit. RAC officials explained their process to us, and it did not include medical necessity reviews. The RAC reviews of Hoveround's PMD claims for 2010 were limited to a review of coding and documentation requirements. Accordingly, it is not surprising that the RACs had significantly different results.

Medicare Standards Used by the Durable Medical Equipment Medicare Administrative Contractors When Reviewing OIG's Sample

Hoveround Comments

Hoveround stated that the DME MACs' review relied on medical necessity review standards that were adopted after the dates of service of the claims at issue and that the DME MACs misapplied those Medicare standards. Hoveround also provided physician signature attestations or logs for five claims that were denied for missing physician signatures.

OIG Response

We maintain that the DME MACs used the correct Medicare standards in conducting the medical necessity review. One DME MAC relied on language that is substantially similar to the standard articulated in a 2013 LCD. However, that same standard existed in a 2010 provision in the Manual, though it was stated differently. After reviewing Hoveround's response, we contacted

the DME MACs and asked for clarification about what standards they had applied in their review of our sample beneficiaries' medical records. Uniformly, the DME MACs answered that they applied those Medicare standards in place in 2010.[30] We also accepted the physician signature attestations or logs that Hoveround provided for sample items 8, 68, 109, 160, and 184. However, three of these claims were denied for multiple reasons in addition to the lack of physician signature. As a result, these claims continued to be errors. We allowed the other two claims, which had no other associated errors, and changed our findings and recommendations accordingly.

HOVEROUND STATED THAT EXTRAPOLATION WAS NOT APPROPRIATE IN THIS AUDIT

Hoveround Comments

Hoveround stated that extrapolation was not appropriate in this audit. Hoveround argued that our sample size of 100 beneficiaries was too small to properly extrapolate to the universe of 12,024 beneficiaries in stratum one. Hoveround also argued that the fact that this particular audit took longer than some OIG audits meant that OIG should not extrapolate the results. Finally, Hoveround argued that OIG's hospital compliance audits were not extrapolated and, therefore, this audit should not be extrapolated.

OIG Response

We believe extrapolation is appropriate to determine the value of overpayments in this audit. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare.[31] Small sample sizes (e.g., smaller than 100) have routinely been upheld by the Departmental Appeals Board and Federal courts.[32] The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.[33] Sampling and extrapolation may be used to determine the total number and dollar value of claims for medically unnecessary services. The presence of unique characteristics in a population (i.e., the heterogeneity of the claims) does not preclude the use of

[30] The Manual, chapter 5, § 5.7 in effect for our audit period states: "However, neither a physician's order nor a CMN [Certificates of Medical Necessity] nor a DIF [DME Information Form] nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable)."

[31] See Momentum EMS, Inc. v. Sebelius, 2014 WL 199061 at *9 (S.D. Tex. 2014); Anghel v. Sebelius, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); Miniet v. Sebelius, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); Bend v. Sebelius, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

[32] See Transyd Enter., LLC v. Sebelius, 2012 U.S. Dist. LEXIS 42491 at *30-31 (S.D. Tex. 2012) (upholding a sample size of 30 out of 9,982 claims); Anghel v. Sebelius, 912 F. Supp. 2d 4, 10 (E.D.N.Y. 2012) (upholding a sample size of 95 out of 1,042 claims).

[33] See John Balko & Assoc. v. Sebelius, 2012 WL 6738246 at *12 (W.D. Pa. 2012), aff'd 555 F. App'x 188 (3d Cir. 2014); Miniet v. Sebelius, 2012 U.S.Dist. LEXIS 99517 at *17 (S.D. Fla. 2012).

statistical sampling.[34] By recommending recovery in the current audit at the lower limit of a 90-percent confidence interval, we account for the sample size, the universe size, and the differences between claims in a manner that is favorable to Hoveround. In fact, if OIG had used a larger sample size, the expected result would be a higher recommended recovery.

Our audit of Hoveround took longer than some audits we perform. However, OIG performs each audit individually and makes decisions based on the specific facts and circumstances of each audit. In this case, OIG spent considerable time ensuring that we had all of the documentation needed to objectively and completely assess the medical necessity of these claims. We gave Hoveround multiple opportunities to provide documentation and comments on our findings and recommendations. We conducted three separate medical necessity reviews—one on the original documentation we received and two subsequent reviews on the now "complete" medical records. We also reviewed and analyzed the numerous letters and emails that Hoveround sent raising concerns during the course of the audit and met with Hoveround multiple times. All of this caused this particular audit to take longer. However, these same decisions were necessary to ensure that OIG had all of the relevant facts and provided a fair and objective analysis in its findings and recommendations.

Similarly, OIG makes the decision about when to extrapolate its findings based on the specific facts at issue in each audit. We did not choose to extrapolate our findings in the initial hospital compliance audits. As the hospital compliance review initiative matured, we refined our audit methodologies. Some reviews use statistical sampling and estimation techniques to draw conclusions about a larger portion of the provider's claims while other reviews use judgmental sampling. Each audit is unique, and the sampling method used in each of these reviews will vary.

Extrapolation is an important tool in our work. Determining the overpayment through sampling and extrapolation, rather than reviewing each claim, is both economical and in the best interest of the provider and the Federal Government. OIG uses a conservative method under which overpayment estimates will almost always be lower than the estimates that would result from reviewing every claim. Accordingly, we stand behind our decision to extrapolate our results in the Hoveround audit.

[34] See U.S. ex rel. Martin v. Life Care Ctrs. Of America, Inc., 2014 U.S. Dist. LEXIS 142660 at *46-50 (E.D. Tenn. 2014).

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered payments for PMDs supplied to 13,025 Medicare beneficiaries from Hoveround's largest NPI, totaling $40,570,854.

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

We performed fieldwork from June 2012 to June 2013 at Hoveround, in Sarasota, Florida, as well as at prescribing physicians' offices in 34 States[35] and the beneficiaries' residences in 33 States.[36]

METHODOLOGY

To accomplish our audit objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- used CMS's National Claims History file to obtain a list of Medicare Part B DME claims for calendar year 2010, extracted all claims for new, used, or rented PMDs associated with Hoveround by NPI, summarized these claims by beneficiary (e.g., a beneficiary renting a PMD could have up to 12 claims), and created a sampling frame of 13,025 Medicare beneficiaries and related PMD claims associated with the largest Hoveround NPI;
- interviewed Hoveround officials to obtain an understanding of their Medicare billing process for PMDs;
- selected a stratified random sample of 200 beneficiaries from the sampling frame of 13,025 beneficiaries, and for each of the 200 beneficiaries, we:
    - obtained and reviewed supporting documentation maintained by Hoveround and the prescribing physicians;

[35] The physicians' offices were located in the following 34 States: Alabama, California, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Missouri, Mississippi, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, Washington, Wisconsin, and West Virginia.

[36] The beneficiaries' residences were located in the following 33 States: Alabama, Arkansas, California, Delaware, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Massachusetts, Maryland, Maine, Michigan, Missouri, Mississippi, North Carolina, New Jersey, New Mexico, Nevada, New York, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, Washington, Wisconsin, and West Virginia.

- interviewed (if available) the prescribing physicians and Medicare beneficiaries to obtain an understanding of the prescription process; and

- requested that a contractor perform a medical review of supporting documentation for the PMD claims of 187 of the 200[37] beneficiaries to determine whether medical necessity and coverage requirements were met;

- discussed the results of our review with Hoveround officials;

- received supporting documentation from Hoveround in response to the draft report; and

- requested that the DME MACs perform a medical review of supporting documentation for the PMD claims of 171 of the 200[38] beneficiaries to determine whether medical necessity and coverage requirements were met.

See Appendix B for the details of our statistical sampling methodology and Appendix C for our sample results and estimates.

We conducted this performance audit in accordance with GAGAS. 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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[37] We did not submit the remaining 13 beneficiaries' claims for medical review because those 13 claims were reviewed and approved by a DME MAC or appealed and approved through Administrative Law Judge decisions.

[38] The remaining 29 beneficiaries' claims were not submitted for a followup medical review because 13 claims were reviewed and approved by a DME MAC or appealed and approved through Administrative Law Judge decisions and 16 claims were reviewed and approved for medical necessity by OIG's medical review contractor.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

POPULATION

The population consisted of Medicare Part B DME payments to Hoveround for PMDs provided to Medicare beneficiaries during calendar year 2010.

SAMPLING FRAME

The sampling frame consisted of 13,025 Medicare beneficiaries supplied with new, used, or rented PMDs from Hoveround, with claims totaling $40,570,854. The Medicare Part B DME payments were extracted from CMS's National Claims History file.

SAMPLE UNIT

The sample unit was a Medicare beneficiary who received a new, used, or rented PMD purchased or rented by Medicare from Hoveround.

SAMPLE DESIGN

We used a stratified random sample.

SAMPLE SIZE

We selected a sample of 200 Medicare beneficiaries as follows:

- Stratum 1: 100 beneficiaries for whom Medicare purchased new PMDs from Hoveround.
- Stratum 2: 50 beneficiaries for whom Medicare purchased used PMDs from Hoveround.
- Stratum 3: 50 beneficiaries for whom Medicare rented PMDs from Hoveround.

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the beneficiaries in each of the three strata. After generating the random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to calculate our estimates. We used the lower limit of the 90-percent confidence interval to estimate the amount of unallowable payments to Hoveround.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results

Stratum	Frame Size	Value of Frame	Sample Size	Value of Sample	Number of Beneficiaries With Errors	Overpayments
1 (New)	12,024	$38,544,692	100	$315,727	74	$235,147
2 (Used)	663	1,620,998	50	121,048	40	96,473
3 (Rental)	338	405,164	50	60,490	40	48,701
Total	**13,025**	**$40,570,854**	**200**	**$497,265**	**154**	**$380,321**

Table 3: Estimated Unallowable Payments (Limits Calculated for a 90-Percent Confidence Interval)

Overall	Total Unallowable Federal Share
Point estimate	$29,882,476
Lower limit	$27,027,579
Upper limit	$32,737,373

APPENDIX D: FEDERAL REQUIREMENTS FOR DURABLE MEDICAL EQUIPMENT AND POWER MOBILITY DEVICES

MEDICARE COVERAGE OF DURABLE MEDICAL EQUIPMENT

Section 1861(n)) of the Act states that the term "durable medical equipment" includes

> ... wheelchairs (which may include a power-operated vehicle that may be appropriately used as a wheelchair, but only where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition and the vehicle meets such safety requirements as the Secretary may prescribe) used in the patient's home (including an institution used as his home … whether furnished on a rental basis or purchased….

Section 1862(a)(1)(A)) of the Act states that "no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, 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 regulations at 42 CFR § 410.38(a) state: "Medicare Part B pays for the rental or purchase of durable medical equipment, including … wheelchairs, if the equipment is used in the patient's home or in an institution that is used as a home."

MEDICARE DEFINITIONS OF POWER MOBILITY DEVICES

Federal regulations at 42 CFR § 410.38(c)(1) state:

> Power mobility device means a covered item of durable medical equipment that is in a class of wheelchairs that includes a power wheelchair (a four-wheeled motorized vehicle whose steering is operated by an electronic device or a joystick to control direction and turning) or a power-operated vehicle (a three or four-wheeled motorized scooter that is operated by a tiller) that a beneficiary uses in the home. Prescription means a written order completed by the physician or treating practitioner who performed the face-to-face examination and that includes 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 (for example, a narrative description of the specific type of PMD), the length of need, and the physician or treating practitioner's signature and the date the prescription was written. Treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist … who has conducted a face-to-face examination of the beneficiary.

MEDICARE CONDITIONS OF PAYMENT AND DISPENSING OF POWER MOBILITY DEVICES

Federal regulations at 42 CFR § 410.38(c)(2) state that Medicare Part B pays for a PMD if the physician or treating practitioner meets the following conditions:

> (i) Conducts 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. (ii) Writes a prescription, as defined … [above] that is provided to the beneficiary or supplier, and is received by the supplier within 45 days after the face-to-face examination. (iii) Provides supporting documentation, including pertinent parts of the beneficiary's medical record (for example, history, physical examination, diagnostic tests, summary of findings, diagnoses, treatment plans and/or other information as may be appropriate) that supports the medical necessity for the power mobility device, which is received by the supplier within 45 days after the face-to-face examination.

Federal regulations at 42 CFR § 410.38(c)(4) state that "[s]uppliers may not dispense a PMD to a beneficiary until the PMD prescription and the supporting documentation have been received from the physician or treating practitioner who performed the face-to-face examination of the beneficiary. These documents must be received within 45 days after the date of the face-to-face examination."

Federal regulations at 42 CFR § 410.38(c)(5) state that "[a] supplier must maintain the prescription and the supporting documentation provided by the physician or treating practitioner and make them available to CMS and its agents upon request. Upon request by CMS or its agents, a supplier must submit additional documentation to CMS or its agents to support and/or substantiate the medical necessity for the power mobility device."

The Manual, chapter 3, section 3.4.1.1, states that Medicare requires a legible identifier for services provided or ordered. The method used shall be a handwritten or an electronic signature (stamp signatures are not acceptable) on an order or other medical record documentation for medical review purposes.

The Manual, chapter 5, § 5.7, states that for any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient's diagnosis and other pertinent information, including, but not limited to, duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If an item requires a CMN or DIF, it is recommended that a copy of the completed CMN or DIF be kept in the patient's record. However, neither a physician's order nor a CMN nor a DIF nor a supplier-prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or

supplier. There must be information in the patient's medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier-prepared statement or physician attestation (if applicable).

The Manual, chapter 5, section 5.8, states that the supplier should also obtain as much documentation from the patient's medical record as the supplier determines it needs to assure itself that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable to Medicare for the dollar amount involved unless a properly executed advance beneficiary notice of possible denial has been obtained by the supplier.

LOCAL COVERAGE DETERMINATIONS FOR POWER MOBILITY DEVICES

The relevant LCDs for PMDs are L21271, L23598, L27239, and L23613, which state that:

> All of the following basic coverage criteria (A-C) must be met for a power mobility device … to be covered … (A) The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs) such as toileting, feeding, dressing, grooming, and bathing in the customary location in the home.… (B) The patient's mobility limitation cannot be sufficiently and safely resolved by the use of an appropriately fitted cane or walker. (C) The patient does not have sufficient upper extremity function to self-propel an optimally configured manual wheelchair in the home to perform MRADLs during a typical day… The patient does not meet coverage criterion D, E, or F, for a POV …. A POV is covered if all of the basic coverage criteria (A-C) have been met and if criteria D-I are also met. (D) The patient is able to safely transfer to and from a POV, and operate the tiller steering system, and maintain postural stability and position while operating the POV in the home. (E) The patient's mental capabilities (e.g., cognition, judgment) and physical capabilities (e.g., vision) are sufficient for safe mobility using a POV in the home. (F) The patient's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the POV that is provided. (G) The patient's weight is less than or equal to the weight capacity of the POV that is provided. (H) Use of a POV will significantly improve the patient's ability to participate in MRADLs and the patient will use it in the home. (I) The patient has not expressed an unwillingness to use a POV in the home.

According to the LCDs, the written order, referred to as the 7-element order, that the supplier must receive within 45 days after the face-to-face examination must contain all of the following elements: (1) beneficiary's name, (2) description of the item ordered, (3) date of the face-to-face examination, (4) pertinent diagnoses or conditions that relate to the need for the PMD, (5) length of need, (6) physician's signature, and (7) date of physician's signature.

According to the LCDs, the patient must have the mental and physical capabilities to safely operate the power wheelchair that is provided.

According to the LCDs, a date stamp or equivalent must be used to document the receipt date.

According to the LCDs, 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 written document (a detailed product description) that lists the wheelchair base and all options and accessories that will be billed separately.

According to the LCDs, the physician must sign and date the detailed product description, and the supplier must receive it before delivering the PMD. A date stamp or equivalent must be used to document the receipt date. The supplier must have the detailed product description available upon request.

POLICY ARTICLES FOR POWER MOBILITY DEVICES

The DME MAC policy articles for PMDs are A47122, A36239, A41127, and A41136. According to the policy articles, if a PMD is for use only outside the home, the claim will be denied as noncovered.

APPENDIX E: AUDITEE COMMENTS

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File No. 025147

October 20, 2015

VIA FEDEX

Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Hoveround Corporation's Response to Draft Report A-05-12-0057 by the U.S. Department of Health & Human Services Office of Inspector General

Ms. Fulcher:

In response to the September 21, 2015 correspondence and the above-captioned draft report issued by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), Hoveround Corporation, through its counsel, Latham & Watkins LLP, respectfully submits the attached response.

Regards,

Stuart S. Kurlander
of LATHAM & WATKINS LLP

Enclosure

cc: Abid R. Qureshi, Latham & Watkins LLP
Eric C. Greig, Latham & Watkins LLP

HOVEROUND CORPORATION

RESPONSE TO DRAFT NO. A-05-12-00057 ISSUED BY
THE DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

LATHAM & WATKINS LLP
October 21, 2015

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I. SUMMARY & OVERVIEW OF RESPONSE

Hoveround Corporation ("Hoveround" or the "Company") respectfully submits this report in response to the above-captioned draft report issued by the U.S. Department of Health and Human Services Office of Inspector General ("OIG"), dated September 2015 (the "Second Draft Audit Report").[1]

The Second Draft Audit Report—like an earlier draft report issued in November 2013 (the "First Draft Audit Report")—evaluated 200 claims submitted by Hoveround for new, used, or rented power mobility devices ("PMDs") provided to Medicare beneficiaries in 2009 and 2010. The Second Draft Audit Report concluded that 44 of the sampled PMD claims audited by OIG met Medicare requirements. OIG further concluded that the remaining 156 claims did not meet requirements for Medicare coverage, determining 141 claims lacked sufficient support for medical necessity and 15 claims had incomplete documentation to support the claims. On the basis of the 156 allegedly deficient claims, OIG calculated an overpayment of $387,205. Extrapolating the results of the 200-claim sample to a universe of 13,025 claims for PMDs provided by Hoveround to Medicare beneficiaries in 2010, OIG recommended that Hoveround refund $27,918,298 to the federal government. This Second Draft Audit Report also recommended that Hoveround implement internal controls to ensure Medicare requirements are followed to support beneficiaries' medical needs for PMDs and to ensure supporting documentation for PMD claims meets Medicare requirements.

Hoveround respectfully and strenuously disagrees with the recommendations in the Second Draft Audit Report. Like the First Draft Audit Report issued approximately two years ago, the Second Draft Audit Report is substantively flawed: The medical necessity review underlying the Second Draft Audit Report improperly applies heightened documentation and medical necessity criteria that were not published until years after the dates of service of the sampled claims. Moreover, the medical records themselves expressly contradict the findings in the Second Draft Audit Report. These flaws are particularly glaring because of the context in which they occurred. OIG presented the results of its first medical necessity review to Hoveround in November 2013 when it provided the First Draft Audit Report to the Company. The results of this review were spectacularly inconsistent with the results of medical necessity reviews conducted by other CMS contractors who had examined the very same 2010 claims Hoveround submitted to Medicare. These contractors validated the medical necessity of the vast

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[1] This report and the accompanying documents contain Hoveround's proprietary and sensitive business information, as well as protected health information, the disclosure of which would seriously harm Hoveround. Such information is exempt from disclosure under the Freedom of Information Act and disclosure of such information by OIG would violate the Health Insurance Portability and Accountability Act. Accordingly, in the event that OIG determines to publish this report, we request that OIG notify Hoveround thirty (30) days in advance of the intended publication date to discuss any necessary redactions or revisions.

majority of claims from 2010, while the First Draft Audit Report concluded that most of the claims sampled from that period were lacking in medical necessity.

In an effort to reconcile this discrepancy, the Company retained two expert and renowned consulting firms to conduct independent medical necessity examinations of the same claims OIG had reviewed. These independent experts reached conclusions markedly different than those described in the First Draft Audit Report. In addition, Hoveround determined OIG had deviated significantly from the audit standards and processes to which it is required to adhere. Because of serious substantive and procedural errors underlying its First Draft Audit Report, OIG conducted a second medical necessity review, relying on a different contractor to review the same claims. As detailed below, the Second Draft Audit Report suffers from many of the same substantive flaws and procedural irregularities. As detailed below, OIG's continued and significant deviations from standard audit processes and the long delay between the dates of service and the Second Draft Audit Report create unacceptable conflicts of interest and undermine attempts to extrapolate the results of the review to a larger sample of claims not reviewed by OIG.

In particular, in light of numerous deficiencies in the OIG audit processes, its medical review analysis, and its statistical calculations, Hoveround respectfully disagrees with recommendations in the Second Draft Audit Report. **First**, based on the conclusions of independent third-party reviews, Hoveround disagrees that it should refund the recommended amount to the federal government, since 188 of 200 sampled claims were documented and submitted in accordance with Medicare requirements. **Second**, Hoveround disagrees that OIG obtained sufficient or appropriate evidence to extrapolate the findings of the sample described in the Second Draft Audit Report, and accordingly, the Company urges OIG to limit its findings and recommendations to the sample of claims actually reviewed. **Third**, Hoveround already maintains comprehensive internal controls and strives for full compliance with Medicare requirements regarding: (a) the medical necessity criteria for PMDs, and (b) obtaining supporting documentation that meets Medicare requirements before providing PMDs to Medicare beneficiaries.

Hoveround's response is divided into seven sections detailed below. **Section I** provides the procedural background underlying the issuances of both the First and Second Draft Audit Reports. **Section II** details the comprehensive and robust compliance infrastructure Hoveround maintains to ensure consistency with Medicare requirements. **Section III** compares the results of the Second Draft Audit Report with analysis of the very same claims undertaken by other CMS contractors, as well as two renown consulting firms—all of whom reached conclusions significantly different than OIG. **Section IV** highlights the particular substantive flaws in the Second Draft Audit Report, including the improper retroactive application of post 2009-2010 medical necessity standards to 2009-2010 claims. **Section V** identifies methodological and procedural errors in the audit process which undermine the validity of the conclusions in the Second Draft Audit Report. **Section VI** explains that, because of serious substantive and

procedural flaws, extrapolation of results is inappropriate. And **Section VII** memorializes the Company's disagreement with the recommendations in the Second Draft Audit Report.

A. OIG's Initial Review Was Insufficient to Support the Findings and Recommendations in the First Draft Audit Report Provided to Hoveround in November 2013.

In May and June of 2012, Hoveround received communications from OIG notifying Hoveround of OIG's intention to undertake a review of Medicare claims for calendar year 2010. During the initial meeting among OIG auditors, Hoveround personnel, and Hoveround's representatives, OIG expressly represented that the audit would involve only a review of documentation required for Medicare coverage—in Medicare parlance, a documentation compliance review—rather than a complex medical review that would include a clinical evaluation of medical necessity documentation. OIG personnel further represented that OIG would later determine whether the audit would include a medical necessity review and would affirmatively inform Hoveround of that decision in order to provide Hoveround an opportunity to collect the necessary documentation for a complex medical necessity review. For several months following the on-site visit by OIG auditors in connection with the initial audit, Hoveround provided additional documentation to OIG auditors in response to requests for clarification or to supplement the file with documents related to the documentation compliance review.

Hoveround was unaware that OIG's initial audit involved a medical necessity review until it received the First Draft Audit Report on November 15, 2013. Instead of identifying objective deficiencies in Hoveround's documentation, the First Draft Audit Report alleged that nearly all of the claims identified as problematic by OIG were denied on the subjective clinical basis of medical necessity.[2] For the first time, Hoveround also learned that OIG had retained the services of a medical review contractor to perform a complex medical review of the medical necessity of claims (the "Initial Review Contractor"). This action was taken without any notice to Hoveround, though the Company had inquired with the assigned OIG auditor whether, in fact, a medical necessity review would be undertaken. Had this development been communicated to the Company, Hoveround would have followed its standard compliance protocol of gathering additional medical records from treating physicians and other providers to submit to OIG for its substantive medical record review. Though OIG personnel spent over 12 months conducting their own fieldwork for the initial audit, OIG provided Hoveround with only 30 days to review and comment on the First Draft Audit Report.

Hoveround immediately sought to engage directly with OIG personnel to discuss the misrepresented scope and the necessity to engage in the record collection effort Hoveround

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[2] In fact, the First Draft Audit Report alleged only 4 out of 200 claims had any objective documentation deficiencies, with 3 claims allegedly missing date stamps and one claim in which a written order was not received within the required 45 days of the face-to-face examination.

would have undertaken had OIG notified the Company of the complex medical review. When Hoveround pressed OIG on its failure to provide adequate notice and the impossibility of obtaining the medical records required to support the medical necessity of three-year-old claims, OIG finally agreed to a sixty-day extension for Hoveround to review and comment on the Initial Audit Report. Hoveround also began the process of attempting to understand how the OIG's Initial Review Contractor reached results on the question of medical necessity that were wildly inconsistent with the results of Medicare contractors tasked with evaluating the medical necessity of PMDs on a daily basis—the Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") and the Medicare Recovery Audit Contractors ("RACs"). Independent reviews of more than 2,300 of Hoveround's 2010 claims conducted by six (6) different Medicare contractors determined that Hoveround achieved an overall rate of 91 percent (91%)—a claim payment rate far in excess of industry standards and entirely inconsistent with OIG's initial audit findings.

In the short window provided by OIG, Hoveround undertook significant efforts—at considerable expense—to request and obtain the medical records it would have obtained had it been aware the initial audit included a medical necessity review. Throughout the remainder of 2013 and early 2014, Hoveround engaged additional personnel at considerable expense to collect and review medical record documentation from physician offices, the beneficiaries, and other sources—records that OIG had never previously requested. These supplemental records were also provided to OIG on a rolling basis on and around January 3, 2014.

Furthermore, Hoveround engaged the services of two nationally recognized consulting firms—firms used by HHS and other federal agencies for audits of this type—with experience conducting Medicare compliance reviews of PMDs (the "Independent Consultants") to conduct an independent medical review of the claims identified by OIG as problematic. The Independent Consultants spent thousands of hours reviewing medical records for each of the claims, preparing a detailed, multi-paged summary of their reviewers' findings, including responses to the claim-specific issues identified in OIG's review. The Independent Consultants, with the benefit of the original and supplemental medical record documentation obtained by Hoveround, concluded that ninety-four percent (94%) of the claims in the OIG's sample met Medicare documentation and medical necessity requirements. In an explanation of the significant disparity in review results between the OIG's initial audit and the independent review, the Independent Consultants also concluded that "[t]he findings presented in the [First Draft Audit Report] appear to be based on a fundamentally incorrect claims review standard and/or incorrect application of relevant guidance by [the Initial Review Contractor]."

On February 14, 2014, Hoveround submitted its response to the First Draft Audit Report, disputing the findings and recommendations of the report and identifying materially fatal substantive, procedural, and methodological flaws that invalidated its findings, and urging that

the Report be withdrawn. Along with its comments, Hoveround submitted over 4,600 pages of medical record documentation and analysis. The summary report of the Independent Consultants was provided to OIG, in addition to the individual claim review reports generated by the independent medical reviewers.

B. OIG's Second Review Compounded the Errors of the Initial Review and Continues to Undermine OIG's Findings and Recommendations.

As a result of Hoveround's substantive comments and explanations of OIG's procedural errors, OIG determined that it could not finalize its November 2013 draft report without conducting a new clinical review of Hoveround's claims. After OIG suggested that its Initial Review Contractor could conduct this second review—and Hoveround identified an improper conflict of interest that would arise from asking that same entity to re-review its own determinations after the Company had identified significant errors—OIG agreed to conduct second review relying on an "independent" entity (the "Second Review").

Despite these assurances and without any notice to Hoveround, OIG engaged four entities that are hardly independent: the same four DME MACs that have day-to-day oversight of the PMD benefit and Hoveround's ongoing business. While the DME MACs are certainly familiar with the PMD benefit, their daily familiarity with implementing the more stringent documentation requirements imposed after 2010 directly impacted their reviews of Hoveround's sample claims, resulting in clear errors when post-2010 requirements were applied to 2009 and 2010 claims. As described in further detail in **Section IV.B** below, the denial reasons provided by the DME MACs often referenced standards and even explicit coverage language that was not adopted until well after Hoveround provided the services subject to this audit. The retroactive application of standards that were not in place at the date of service resulted in a significant number of clear review errors that must be overturned.

The significant delay that has now occurred between the dates of service, the initiation of OIG's audit work, and the publication of this Second Draft Audit Report also undermine the accuracy of the findings and recommendations. Based on Hoveround's review of public OIG audit reports, the delay between the publication of OIG's initial draft report (November 2013) and the anticipated publication date of its final report (early 2016) would easily exceed the delay in any other Medicare provider or supplier audit since 2000. The only other OIG Medicare audits with similar delays between draft and final reports were conducted on four Medicare Advantage plans and resulted in OIG revising its initial recommendations to remove the recommendation for the audited entity to refund an extrapolated amount. This decision was based, in part, on the fact that CMS had changed the standards by which medical reviews for the subject claims proceeded—the same circumstance we have in this audit.

The delay has also allowed federal courts to continue to voice their displeasure with, and overrule, post-payment review denials of Medicare claims based on incorrect or over-zealous interpretations of documentation and coverage criteria. For instance, the court in *Heart 4 Heart, Inc. v. Sebelius* reversed the medical necessity denials of the Medicare Appeals Council because the denials were "not supported by substantial evidence" when reviewers placed too great an emphasis on evidence justifying denial while disregarding evidence in support of coverage.[3] Even more compelling is the recently published *Albert v. Burwell* case where the court again overturned Medicare denials from the Medicare Appeals Council (stemming from a post-payment audit by a Medicare contractor), concluding that the Council's interpretation of the relevant LCD was unreasonable, even under a deferential standard.[4] This case is particularly persuasive due to the court's rejection of denials that attempt to impose stringent documentation requirements for medical records based on LCD language stating certain elements "should" be present, similar to the PMD LCD's medical record documentation discussion. The courts' rejections of auditors' attempts to impose over-aggressive review standards years after the fact must be acknowledged by OIG, as its own contractors and auditors have imposed the same wrongful standard.

C. OIG's Audit Fails to Provide Sufficient and Appropriate Evidence to Support the Second Draft Audit Report's Findings and Recommendations.

For all of the reasons noted above and below, OIG's Second Draft Audit Report suffers from many of the original procedural and substantive deficiencies identified in the OIG's November 2013 initial draft report, as well as additional concerns unique to the Second Review. Since the inception of this audit, OIG auditors and their contractors have departed significantly from regular audit processes, violating procedures mandated by the generally accepted government auditing standards published by the U.S. Government Accountability Office (the "GAGAS" or "Yellow Book") and further undermining the Second Draft Audit Report's findings and recommendations:

- OIG failed to inform Hoveround of the scope of the audit, including a failure to indicate that the audit would include a medical necessity review, in violation of Yellow Book §§ 6.06, 6.09, and 6.47;
- OIG initially failed to request, obtain, and review the full universe of documents necessary to effectively conduct a medical necessity audit, in violation of Yellow Book §§ 6.03, 6.56-6.57;

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[3] Nos. 13-cv-03156, 1-756545121, M-11-2558, 2014 WL 3028684 (C.D. Ill. July 1, 2014).

[4] *See Albert v. Burwell*, 13-CV-4542 (RB) (RML), 2015 WL 240684 at (E.D.N.Y. July 28, 2015).

- The OIG contractors failed to apply the correct legal and regulatory standards when conducting the medical necessity reviews, in violation of Yellow Book §§ 3.72, 6.11, 6.15, and 6.37;

- OIG failed to properly supervise its medical review contractors to ensure the contractors followed applicable requirements when conducting the medical necessity review, in violation of Yellow Book §§ 6.53-6.55; and

- OIG failed to utilize an initial review contractor with the "technical knowledge, skills, and experience necessary to perform the audit competently," in violation of Yellow Book §§ 3.72 and 6.45.

As described in greater detail below, OIG's deviations from the GAGAS resulted in its failure to obtain reasonable assurance that the evidence was sufficient and appropriate to support the Draft Report's findings and conclusions in relation to the audit objectives,[5] mandating withdrawal or significant limitation of the findings and recommendations.

II. HOVEROUND IS COMMITTED TO COMPLIANCE WITH MEDICARE REQUIREMENTS.

Throughout its longstanding relationship with the Medicare program, Hoveround has always remained fully committed to compliance with the requirements of the program. Since 1993, Hoveround and its team (now reaching a total of more than 400 employees) have been dedicated to providing high-quality mobility solutions to American seniors and the disabled who require PMDs to perform mobility-related activities of daily living. In 1999, Hoveround was the first manufacturer/supplier to be accredited by the Joint Commission as an equipment management and rehabilitation technology supplier. Hoveround's operations are centralized at its corporate headquarters and manufacturing facilities in Sarasota, Florida. The Company's centralized base of operations allows it to implement standard policies and procedures across its nationwide business and to monitor adherence to those policies on a continuous basis. In fact, Hoveround has a robust compliance program already in place, consisting of (1) written policies and procedures governing compliance with Medicare requirements; (2) regular training and education related to those policies; and (3) annual external audits of a sample of Hoveround's PMD claims. Even as Medicare contractors audited thousands of Hoveround claims each year, the Company expended additional time and resources to engage an independent, internationally recognized auditor to conduct additional claim reviews of Medicare claims. This annual review, including a review of 2010 claims conducted in 2011, provided the additional benefit of confirming Hoveround's material compliance with Medicare coverage criteria. The sum of these compliance efforts have resulted in a twenty-

[5] *See* Yellow Book § 6.03

year history free from any corporate integrity agreements; public allegations related to fraud, waste, or abuse; or significant overpayment demands from Medicare contractors.

The Medicare PMD benefit fills an important role in the lives of beneficiaries by allowing them to stay in their homes and avoid costly and inconvenient stays in hospitals or long-term care facilities. Since 1993, the Company has been delivering PMDs to Medicare beneficiaries. Hoveround is enrolled in the Medicare program as a supplier of durable medical equipment ("DME") on a nationwide basis, and is also a contract supplier of PMDs for the Medicare program in 88 competitive bidding areas through the Medicare DMEPOS Competitive Bidding Program.

Hoveround has remained an active and engaged partner with CMS, its contractors, and other Medicare stakeholders. In recognition of its leading role within the PMD industry, the Company volunteered and was selected to participate in a number of educational and advisory entities that operate in conjunction with the Medicare DME MACs, including the Jurisdiction A Provider Outreach and Education Committee and the Durable Medical Equipment Advisory Councils for Jurisdictions B, C, and D. The Company also engages with leading industry groups, such as the American Association for Homecare, in which the Company actively participates on the Regulatory Council, Complex Rehabilitation and Mobility Council, and as a Member of the Board of Directors.

Despite significant fluctuations in government reimbursement policies and frequent changes in documentation requirements for PMDs, as well as additional and significant administrative demands placed on suppliers through multiple levels of oversight, Hoveround has maintained consistently high levels of quality and compliance, routinely exceeding the expectations placed on it by the Medicare DME MACs, as well as the error rates identified by OIG industry audit reports. For example, the DME MAC for Jurisdiction C reported prepayment review results for all PMD supplier claims in its jurisdiction in the fourth quarter of 2012, reaching an overall error rate of 63 percent (63%), denying 1,465 of 2,311 claims based on medical necessity and documentation deficiencies identified in suppliers' responses to the DME MACs' Additional Documentation Requests ("ADRs").[6] In contrast, in the last four months of 2012, Hoveround responded to over 340 ADRs in Jurisdiction C and has achieved an ultimate error rate of less than 12 percent (12%).

In 2012, CMS also implemented the Medicare Prior Authorization of PMDs Demonstration ("Demonstration"), a program designed to impose an even greater level of scrutiny to claims submitted by suppliers of PMDs before the claim is paid. Under this Demonstration, the DME MACs review every PMD claim submitted by Hoveround to CMS in

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[6] *See* CGS, *Status Report for Quarter 4 – 2012 – HCPCS Code K0823 Service-Specific Prepayment Review*, Mar. 13, 2013, http://www.cgsmedicare.com/jc/pubs/news/2013/0313/cope21577.html.

19 states—covering 71% of the nationwide PMD claims—for medical necessity and compliance with documentation requirements before each claim is submitted. As of June 30, 2015, the aggregate claim approval rate for all PMD suppliers in the Demonstration was 47%. Proving the Company's focus on compliance with Medicare coverage criteria, Hoveround consistently achieves prior authorization approval rates above 84% across all states in the Demonstration—nearly double the aggregate approval rate of non-Hoveround PMD suppliers. These industry-leading Medicare compliance rates result from Hoveround's consistent, robust compliance and oversight efforts.

III. THE CONCLUSIONS IN THE SECOND DRAFT AUDIT REPORT ARE SUBSTANTIVELY DEFICIENT.

The frequent errors present in the OIG Contractors' medical necessity review reports from the initial and second medical reviews demonstrate that the OIG's review contractors performed a substantively deficient review, resulting in findings and recommendations that are unsupported by the evidence. The contractors' flawed review resulted in OIG finding an alleged error rate that is an outlier from every other review of Hoveround's 2010 claims conducted by experienced Medicare contractors that conducted analogous medical necessity reviews. The fact that these very same DME MACs upheld the validity of Hoveround's claims when undertaking comprehensive medical necessity reviews of *eight times* as many claims provides compelling evidence of the defects in the OIG's medical necessity findings, even in the absence of an independent third-party review of these claims. Moreover, in the case of the RACs that reviewed Hoveround's claims, the contractors had a direct financial interest in finding a higher error rate.[7] A letter from more than 100 members of Congress recently highlighted the well-recognized issues with RACs finding high error rates, noting that "RACs are incentivized to deny claims, even when the claims are correct."[8] Despite this acknowledged incentive to deny claims, the RACs concluded that nearly all of Hoveround's claims under review in the same time period of the OIG audit complied with Medicare documentation and medical necessity standards.

To provide additional corroboration of the DME MACs' and RACs' consistent findings that almost all of Hoveround's 2010 claims complied with medical necessity and documentation

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7 CMS's payment to the RACs is based on a percentage of the overpayments collected as a result of the RACs' reviews, with a higher error rate resulting in a larger overpayment collection and larger fee for the RAC. *See* 42 U.S.C. § 1395ddd(h) (requiring RACs to be paid on a contingent basis for collecting overpayments from reviews); *see also* Federal Business Opportunities, *Recovery Audit Contractor (RAC)*, Solicitation Number RFP-CMS-2007-0022 (Oct. 3, 2008), https://www.fbo.gov/index?s=opportunity&mode=form&id=5c8c7d4b00249ba579d4d77d64bd0aea&tab=core&_cview=1&cck=1&au=&ck= (accessed Feb. 6, 2014) (identifying RAC contingency fees of between 9% and 12.5% of overpayments collected).

8 Letter from Members of the Congress of the United States to Kathleen Sebelius, Secretary of the U.S. Department of Health and Human Services (Feb. 10, 2014), *available at* http://op.bna.com/hl.nsf/id/jswn-9g8mrd/$File/RACCongressLetter.pdf.

requirements, Hoveround engaged FTI and KPMG—two nationally recognized consulting firms experienced in the review of Medicare claims, including PMD claims—to evaluate the claims identified as problematic by the Initial Review Contractor. Using nurses, physicians, and other experienced claims reviewers, the Independent Consultants reached almost exactly the same conclusions as the review conducted by Medicare contractors in 2010—conclusions that stand in direct opposition to the OIG's review contractors. While the Independent Consultants' report attached at Appendix 2 provides detailed explanations for each claim, Section IV provides specific examples drawn from these explanations to highlight some of the more common errors of the OIG Contractor.

A. Six Different Medicare Review Contractors Evaluating the Same Claims and Same Issues as OIG Reached Dramatically Different Results.

Hoveround's claims for PMDs delivered to Medicare beneficiaries in 2010 were subject to multiple levels of government review prior to OIG's audit. First, in 2010, three of the four DME MACs reviewed Hoveround's PMD claims pursuant to prepayment review programs that evaluated Hoveround's claims for medical necessity and compliance with documentation requirements. During this time, the DME MACs would send ADRs to PMD suppliers, requiring those suppliers to provide documentation sufficient to support coverage of the PMD claims before the DME MAC would pay the claims. In addition, three of Medicare's RACs reviewed samples of Hoveround's 2010 claims on a post-payment basis to evaluate the claims for compliance with Medicare coverage criteria. Combined, these contractors reviewed 2,325 of the approximately 13,000 claims Hoveround submitted in 2010—approximately 17% of all 2010 claims, more than 1 out of 6. As detailed below, the ADR and RAC audits affirmed an overwhelming percentage of claims:

AUDIT TYPE	CLAIMS SUBJECT TO MEDICAL REVIEW[9]	CLAIMS AFFIRMED	PERCENTAGE OF CLAIMS AFFIRMED
ADR (2010)	1,617 (12.2% of total 2010 claims)	1,417	87.7%
RAC (2010)	708 (5.4% of total 2010 claims)	700	98.9%
OIG (2015)	187 (1.4% of total 2010 claims)	31	16.6%

The ADR and RAC audits involved rigorous and thorough medical necessity evaluations of Hoveround's PMD claims, reviewing similar claims, from the same time frame as those

[9] To calculate the percentage of claims subject to ADR audit, the Company used the total number of claims for PMDs delivered by Hoveround in 2010 (13,224). The RAC and OIG audits occurred on a post-payment basis, so these percentages were calculated using total claims paid for PMDs delivered in 2010 (13,025).

reviewed by OIG, and supposedly utilizing the same Medicare coverage criteria as OIG. Appendix D to the Second Draft Audit Report identifies the relevant review criteria for the 187 sample claims referred for medical review (and the 171 claims referred to the DME MACs for a second medical review), including excerpts from the Social Security Act, Medicare regulations, Local Coverage Determinations ("LCDs") published by the DME MACs, and associated articles for PMD coding and documentation. These criteria are the very same ones used by the DME MACs for their pre-payment reviews and by the RACs for their post-payment reviews. OIG acknowledges the controlling impact of these prior audits by excluding from its review 13 claims in the 200-claim sample favorably adjudicated by other Medicare contractors or otherwise deemed appropriate on appeal.[10]

1. The DME MACs conducted the same reviews of Hoverround's 2010 claims and reached opposite results.

The difference in claim review results is even more baffling since OIG engaged the very same DME MACs that reviewed and approved Hoverround's 2010 claims in 2010 to again review Hoverround's 2010 claims in 2015. As noted above, in 2010 the DME MACs in three regions (B, C, and D) conducted prepayment medical necessity reviews of more than 1,600 of Hoverround's PMD claims (approximately 12% of Hoverround's 2010 claims). Direct communications from the contractors and audit instructions from CMS confirmed that these DME MACs performed complex medical reviews, which included an evaluation of medical necessity, in their 2010 prepayment reviews of Hoverround's claims. Despite reviewing claims from the same year, developed by Hoverround in the same manner, and allegedly using the same standards to review for the same criteria, these contractors reached wildly divergent results in their 2010 reviews and the 2015 reviews conducted on OIG's behalf. The DME MACs' timely reviews of Hoverround's claims in 2010 resulted in initial approval of approximately sixty percent (60%) of Hoverround's claims—a claim approval rate approaching nine times the approval rate of the claims reviewed by OIG's Initial Review Contractor, and a rate that increased to 87.7% through later claim development and appeals. In contrast, when undertaking the same review five years later, at the request of OIG, these same DME MACs approved only 10.5% of Hoverround's claims, with three of the four contractors finding zero or one claim to approve from a universe of ninety-five claims:

- In Jurisdiction B, Hoverround obtained a 78% approval rate for claims identified and reviewed through ADRs in 2010. In 2015, when conducting this review on OIG's behalf, the DME MAC for Jurisdiction B approved only 2.8% of Hoverround's 2010 claims (1 out of 36).

[10] OIG cannot credibly claim that its contractors conducted a medical necessity review while the ADR and RAC audits involved another type of review because the Draft Report expressly excludes from its analysis thirteen particular claims that were subject to prior audits. The only reason these claims were excluded is because they were already subject to the same review pursuant to the same medical necessity standards.

- In Jurisdiction C, Hoveround obtained a 90.6% approval rate for claims identified and reviewed through ADRs in 2010 (1,239 out of 1,368). In 2015, when conducting this review on OIG's behalf, the DME MAC for Jurisdiction C approved only 21% of Hoveround's 2010 claims (15 out of 76).

- In Jurisdiction D, Hoveround obtained a 54.6% approval rate for claims identified and reviewed through ADRs in 2010. In 2015, when conducting this review on OIG's behalf, the DME MAC for Jurisdiction D approved only 4% of Hoveround's 2010 claims (1 out of 25).

The conspicuously low approval rates reached by the DME MACs in their unique engagement by OIG are also refuted by contemporaneous, direct communications from the DME MACs to Hoveround. Immediately following 2010—a year in which Hoveround submitted documentation for 1,368 claims for the Jurisdiction C DME MAC to review—the Medical Review Department for Jurisdiction C decided to terminate its prepayment review efforts with Hoveround. In a letter dated January 27, 2011, the Medical Claim Review Specialist for Jurisdiction C concluded that the Company's performance since the initiation of prepayment review in August 2009 justified the removal of the prepayment screen, which required Hoveround to reach, at minimum, an error rate below twenty percent (20%). Similarly, Hoveround is not able to directly compare claim approval rates for 2010 claims in Jurisdiction A to the approval rates in the OIG sample because in late 2009, the DME MAC for Jurisdiction A removed Hoveround from prepayment review. In that jurisdiction as well, Hoveround's rate of compliance with PMD coverage criteria exceeded the DME MAC's required claim approval threshold. Yet, despite conducting voluminous claim reviews in 2010 and affirmatively communicating to Hoveround that the Company's processes and claim approval rates exceeded required standards, three of these DME MACs effectively concluded for OIG that none of Hoveround's claims met applicable coverage criteria, and the remaining contractor found on average that 4 out of 5 claims were in error.

2. Medicare RACs conducting the same reviews of Hoveround's 2010 claims reached the opposite results as OIG.

Similar to the DME MACs, Medicare RACs reviewed Hoveround's 2010 claims on a complex medical review basis and reached conclusions even more favorable to Hoveround—and disparate from the OIG's conclusions. CMS mandates that RACs must apply the same recognized and controlling Medicare criteria for claims reviews that DME MACs apply:

> [RACs] shall comply with all National Coverage Determinations (NCDs), Coverage Provisions in Interpretive Manuals, national coverage and coding articles, local coverage determinations

> (LCDs) (formerly called local medical review policies (LMRPs)) and local coverage/coding articles in their jurisdiction.[11]

RACs must obtain approvals from CMS before proceeding with the issues they are auditing. These issues are approved either for "automated" or "complex" reviews. For each of the RACs conducting post-payment audits of PMD claims, CMS approved the issue for the "complex review" category. Complex reviews, by CMS definition, require human elements, meaning that the review involves "requesting, receiving, and medical review of additional documentation associated with a claim," and the reviews must be conducted by appropriately credentialed individuals with training in the area, using nurse and physician reviewers.[12] Reviews of the specific issue approvals show that the RACs were auditing for the same issues under review by OIG: compliance with Medicare coding, documentation, and medical necessity requirements. For example, the Region C RAC received approval from CMS to pursue a PMD issue, noting that "[f]or any item to be covered by Medicare, it must meet all applicable Medicare statutory and regulatory requirements. We will review documentation to see if it supports the power mobility device claim."[13] More specifically, the Region B RAC requested and received approval for a review program related to power wheelchair claims with dates of service beginning October 1, 2007:

> Power Wheelchairs (Groups 1, 2, 3) are covered if the equipment is properly coded and meets coverage criteria/documentation requirements specified in the National Government Services (NGS) Local Coverage Determination (LCD) L27239, effective 10/01/2006. Medical records will be reviewed for new, purchased PWC . . . for appropriate coding, documentation requirements and medical necessity criteria.[14]

Although these Medicare contractors and the OIG's Contractors were purportedly examining the very same issues in their respective medical necessity reviews, the conclusions reached by the Medicare contractors and the OIG are almost exactly opposite. The RACs alone found Hoveround maintained a 99 percent (99%) compliance rate over a sample of more than 700 claims. In contrast, OIG's Initial Review Contractor affirmed only seven percent (7%) of the

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11 CMS, *Medicare Fee-for-Service Recovery Audit Program Myths* at 2 (Dec. 17, 2012), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/RAC-Program-Myths-12-18-12.pdf.

12 *See* CMS, *Medicare Program Integrity Manual* ("PIM") (100-08), Ch. 3, §§ 3.3.1 and 3.3.1.1.A.

13 Connolly LLC, *CMS Approved Audit Issues* (approved Aug. 8, 2012), http://www.connolly.com/healthcare/pages/approvedissues.aspx.

14 *See* CGI Federal, *Medicare RAC Region B Website*, Issues (approved Oct. 26, 2011), https://racb.cgi.com/Issues.aspx.

187 claims it reviewed, and the DME MACs affirmed only 10.5 percent (10.5%) of the 171 claims on which they performed a second review for OIG.

These findings are so vastly different and disparate as to create an inexplicable and unexplainable result. Based on the relative sample sizes (over twelve times more 2010 claims were reviewed by the DME MACs and RACs on a prepayment and post-payment basis), and the variety of different entities that found consistently low error rates in the ADR and RAC reviews (three different DME MACs and three different RACs), the OIG Contractors' review clearly is the outlier and reveals fatal flaws with the OIG audit processes and claim review determinations.

B. Nationally Prominent Consultants Reviewing the Same Claims Under the Same Standards As Those Evaluated by the OIG Contractors Reached Opposite Results.

After obtaining and reviewing medical record documentation provided by Hoveround for each of the 174 claims identified as problematic by OIG in the First Draft Audit Report, the Independent Consultants found support for Medicare coverage in 162 of those claims (over 93 percent (93%) approval). The review protocol utilized the same Medicare coverage requirements and guidance OIG's Contractors were required to consider. In many cases, because Hoveround was aware that the Independent Consultants were conducting a medical necessity review, Hoveround was able to request and obtain additional medical records to provide support for medical necessity. Accordingly, the Independent Consultants were able to review additional documentation corroborating the beneficiary's medical condition and the medical necessity of the PMD, beyond the documentation submitted by Hoveround to the OIG prior publication of the First Draft Audit Report.

Medical record documentation, along with claim review reports of the Independent Consultants, were provided to OIG on a weekly rolling basis commencing on January 3, 2014. This thorough external review and production process, in total, has cost the Company approximately [redacted] and has imposed significant operational burdens on the Company. The results of this robust review protocol provide further corroboration of the findings of every other Medicare contractors' review of Hoveround's 2010 claims that reviewed the claims in the time period.

Before reaching a coverage decision on any of the 174 claims, the Independent Consultants went through a multi-step review process for each claim, designed to yield appropriate, supportable conclusions through the use of systematic disciplines and safeguards to maximize consistency. Medicare billing and coding guidance published in the Medicare statute, regulations, LCDs, Policy Articles, and informal guidance from the DME MACs were used to develop a comprehensive audit tool that encompassed all of the relevant coverage criteria for PMDs. To understand the alleged deficiencies in the claim and issues that could require special

Office of Inspector General Note—The deleted text has been redacted because it is proprietary and sensitive business information.

attention, the reviewers performed a careful analysis of the OIG's Initial Review Contractor's findings. An experienced PMD claim reviewer then conducted an initial review of the documentation, including (i) the face-to-face examination, (ii) medical records of prior visits, (iii) the seven element order, (iv) the detailed product description, (v) the home assessment, and (vi) proof of delivery, with preliminary findings recorded in the audit tool. All initial findings were evaluated by a separate quality control team (including medical doctors specializing in physical medicine and rehabilitation) to ensure that findings were clearly stated, facts were properly cited and supported, and no additional issues needed to be addressed. Upon passing quality control, the findings were documented using a standard reporting template that included the Initial Review Contractor's findings, the clinical background of the beneficiary, and the Independent Consultants' analysis. In a final quality control phase, these reports were reviewed by the Independent Consultants to ensure the relevant standards and analysis were applied appropriately and consistently.

The independent third-party review found Hoveround's claims complied with Medicare's medical necessity and documentation standards for PMDs in 93 percent (93%) of the claims identified as problematic by the Initial Review Contractor, resulting in an overall compliance rate of 94 percent (94%) for the 200-claim sample. The divergence of results between the OIG contractor and this independent third-party review is hardly a "battle of the experts." Instead, the divergence represents a fundamental difference in legal standards and substantive analysis that revealed fatal errors in the First Draft Audit Report:

- Incorrect review standards were used by the OIG contractor to evaluate the claims, such as requiring a trial of alternative mobility assistive equipment prior to providing a power wheelchair or denying claims because documentation from physician visits other than the face-to-face examination did not include a mobility assessment.

- The OIG contractor made inappropriate or otherwise incorrect clinical interpretations that did not consider the entire medical record and the full scope of the beneficiaries' medical conditions that necessitated the use of PMDs.

- The Independent Consultants reviewed supplemental medical record documentation, obtained by Hoveround generally within a matter of days upon the Independent Consultants' request, that corroborated or reinforced the clinical documentation supporting the necessity of the PMD.

IV. OIG'S CONCLUSIONS ARE UNSUPPORTED BY SUFFICIENT OR APPROPRIATE EVIDENCE.

Beyond procedural violations, there are material shortcomings in the OIG medical necessity evaluation process and conclusions. These inadequacies stem, most significantly, from a failure to apply the appropriate Medicare standards in evaluating the claims. The apparent

failure to obtain the complete medical records of all patients in the sample prior to conducting the medical review of the claims further contributed to the preparation of materially flawed medical reviews by OIG's Initial Review Contractor, which were carried over to the second review when those flawed results were shared with the DME MACs (unless expressly identified otherwise, the initial contractor and the DME MACs are referred to collectively as the "OIG Contractors.")

The Yellow Book requires OIG staff members conducting audits to possess the technical knowledge, skills, and experience necessary to perform the audit competently, including but not limited to (i) knowledge of the environment in which the audited entity operates and the subject matter; and (ii) specialized knowledge in relevant subject matters, such as medical or regulatory subjects if the work calls for such expertise.[15] The Yellow Book also requires that auditors have an understanding of the program being audited—in this case, Medicare.[16] Thus, the Yellow Book requires that OIG auditors have a clear understanding of the laws and regulations governing the Medicare program, and states that this knowledge and understanding is a necessary and required step in the audit process.[17] In addition, the audit planning process requires auditors to identify the criteria against which the audited entity's performance will be compared or evaluated, including relevant laws, regulations, and standards.[18] Audit management is also required to assign sufficient staff and specialists with adequate collective competence.[19]

Hoveround's review of the OIG Contractor's reports found consistent misapplication of the Medicare coverage criteria for PMDs, from imposing entirely new requirements that conflict with existing written guidance, to citing restrictive documentation requirements not found in any regulation, coverage policy, or written guidance applicable to 2010 claims. Moreover, even if a claim was held to the correct coverage standard, the OIG Contractors often reached clinical conclusions that conflicted with the clinical judgment of the physician that performed the face-to-face examination—inexplicably rejecting documented first-hand observations made by treating physicians who often served as long-time primary care physicians to the beneficiaries and were intimately familiar with their patients' medical conditions and functional limitations. Many times, where the clinical judgment of the prescribing physician was supported in the record, the OIG Contractor instead identified an irrelevant measure that was otherwise omitted from the examination (*e.g.*, range of motion), but that would make no difference to the particular beneficiary's mobility deficits caused by his or her existing conditions (*e.g.*, dyspnea and deconditioning caused by chronic obstructive pulmonary disease and morbid obesity). Similarly,

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15 Yellow Book § 3.72.

16 *Id.* §§ 6.15, 6.17.

17 *Id.* § 6.15.

18 *Id.* § 6.37.

19 *Id.* § 6.45.

the OIG Contractor failed to take a holistic view of the beneficiary's condition and multiple co-morbidities that caused the mobility deficit, instead choosing to emphasize discrete portions of the record or specific measurements to justify a denial, even when that measurement or observation otherwise played no role in the beneficiary's mobility deficit.

By consistently misapplying the relevant medical review standards, overlooking facts supportive of medical necessity while emphasizing irrelevant observations purported to weigh against medical necessity, and neglecting to obtain the complete medical record in many cases, the OIG Contractors failed to abide by required GAGAS criteria, and thus failed to provide OIG with supportable or accurate conclusions on the validity of Hoveround's claims. Since the findings of the Second Draft Audit Report are based almost entirely on these flawed decisions by the OIG Contractors, the recommendations lack factual basis and support.

A. OIG Contractors Failed To Review And Consider All Parts Of The Patient Record.

In addition, the OIG Contractors performed inadequately by consistently failing to consider the full patient record; instead, they focused on isolated pieces of information within a particular beneficiary's file that may or may not have accurately reflected the beneficiary's condition. The OIG Contractors' repeated failures to consider the full record generally fell into one of the following three groups.

First, in numerous instances, the OIG Contractors ignored or overlooked documentation related to a particular component of the NCD algorithm to evaluate coverage for mobility assistive equipment, including a PMD. This algorithm provides a flowchart of nine inquiries that must be addressed prior to finding that a PMD is the appropriate mobility assistive equipment to be prescribed.[20] For example, the documentation should support the beneficiary's capability to operate the equipment safely. In a number of instances, the OIG's Initial Review Contractor based the denial of a claim on a finding that "[t]he patient's ability to safely operate a PMD was not assessed" when, in fact, the medical record documentation did provide evidence that the beneficiary was alert and oriented and/or had a normal neurological exam. The OIG Contractors provided this basis for denial in instances where there was nothing in the record to suggest that the beneficiary *was not* mentally capable of safely operating the PMD. Similarly, in patient sample 95, the Initial Review Contractor based its denial on the conclusion that the beneficiary was "apparently . . . ambulatory, as her gait is described as 'antalgic' but there is no description." But the use of the term "antalgic" itself refers to a particular gait abnormality, so contrary to the Initial Review Contractor's claim, the very use of this term is, in and of itself, a description of the beneficiary's gait.

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[20] CMS, *Medicare National Coverage Determinations Manual* (100-03), Chapt. 1, Part 4, § 280.3.B (eff. May 5, 2005).

Second, the OIG Contractors failed to review and consider all parts of the record by placing greater weight on one part of the record, to the detriment of other parts of the record. This practice occurred in instances where the OIG Contractors placed excess focus to parts of the record that may have reflected the beneficiary's well-being, effectively ignoring parts of the record that demonstrated a mobility limitation. For example, in patient sample 106, the Initial Review Contractor based its denial on the documentation of a prior physician encounter, *not* the face-to-face examination, that "states that strength was 5/5 throughout and that the patient was ambulatory with a rolling walker." Focusing on this information apparently caused the OIG Contractors to ignore other documentation showing that the beneficiary suffered from ataxia (a neurological condition that causes poor balance and coordination) and had suffered multiple falls. Because the beneficiary suffered from ataxia—at such severity that he experienced falls—his strength measurements were irrelevant to addressing his mobility limitations, as the 5/5 strength measurement would not compensate for sufficient balance to ambulate. The DME MAC that continued to identify this claim for denial included as a denial reason that the examination "does not provide objective information about how diagnosis of ataxia affects gait," when that objective information is clear from the record—the ataxia impacts the gait enough to result in repeated falls—and is not required by any coverage criteria in the NCD, LCD, or other guidance.

Since the audit conducted by OIG's Initial Review Contractor, a federal court expressly rejected the review posture of denying claims for one element that weighs against coverage, while ignoring the mountain of evidence in support of coverage. Specifically, the court in *Heart 4 Heart, Inc. v. Sebelius* reversed the medical necessity denials of PMD claims reviewed by the Medicare Appeals Council because the denials were "not supported by substantial evidence" when reviewers placed too great an emphasis on evidence justifying denial while disregarding evidence in support of coverage.[21] For instance, the court rejected an adjudicator's decision to deny a PMD claim upon concluding that a beneficiary could propel a manual wheelchair because her strength was described as "within functional limits" and "4-/5" in one record, when the physician concluded that the patient could not do so and the adjudicator did not actually examine the beneficiary. Importantly, the treating physician's statements were included in post-delivery addenda to the face-to-face examination, which the court prohibited the ALJ and Medicare Appeals Council from disregarding. Similar to the findings of the Independent Consultants when they reviewed the claim denials written by OIG's Initial Review Contractor, the court in *Heart 4 Heart* found the PMD case to be an instance when "the facts in the record support only one conclusion: that the documentation submitted by Plaintiff . . . proves that Beneficiary's motorized wheelchair was reasonable and necessary."

Third, the OIG Contractors imposed a requirement that a beneficiary's medical record contain "documentation of a trial of a walker or other assistive device, or [the] ability to use a manual wheelchair" in instances where there was clear documentation of a beneficiary's inability

[21] Nos. 13-cv-03156, 1-756545121, M-11-2558, 2014 WL 3028684 (C.D. Ill. July 1, 2014).

to use these forms of assistance. This denial justification is directly inconsistent with explicit language in the applicable NCD stating that "[i]n individual cases where the beneficiary's condition clearly and unambiguously precludes the reasonable use of a device, it is not necessary to undertake a trial of that device for that beneficiary."[22] Examples of this error were found in Initial Review Contractor denials of patient samples 74, 78, 84, 115, 130, 133 (some of which were recognized as improper and overturned by the DME MACs), among others. In the context of the Second Review, this category of errant denials is particularly important since the number of claims denied for this reason increased from 9 in the Initial Audit to 45 in the Second Review. This stark disparity in denial reasons appears to correlate directly to the decrease in denials in the first category of medical necessity (records did not establish a significant impairment to participate in MRADLs), which were reduced from 141 to 71. When conducting the review underlying the Second Draft Audit Report, OIG's Contractors effectively "moved the goalposts" when Hoveround successfully rebutted the original denial reason.

Recognizing the inherent unfairness of moving the target once the initial denial reason is rebutted, CMS recently published instructions to its review contractors that prohibit them from engaging in this behavior when reviewing appeals of claim denials.[23] If a claim is denied for one reason, and that reason is remedied or rebutted, contractors are now prohibited from finding another reason to deny the claim. In the same way, OIG should not allow its Contractors to move the target, particularly after Hoveround expended significant resources and time to correct OIG's initial claim determinations and denials. If Hoveround's initial response in February 2014 rebutted the initial denial reason to the point that the claim was not denied for the same reason in the Second Draft Audit Report, that claim hardly qualifies as erroneous.

B. The OIG Contractors Applied Incorrect Medical Necessity and Documentation Review Standards.

Beyond ignoring specific portions of the record, the OIG's Contractors also consistently ignored or misinterpreted established Medicare policies that govern the medical necessity of PMD claims. The medical review reports from the Initial Review Contractor and the DME MACs contain numerous instances where the reviewer based the denial of a claim on a requirement that is not found in governing statutes, implementing regulations, or assorted forms of sub-regulatory authority such as the applicable National Coverage Determination ("NCD"), LCDs, or various articles and published guidance in effect at the time of the date of service.

1. The DME MACs retroactively applied heightened documentation and medical necessity standards adopted after the claims' dates of service.

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[22] CMS, *Medicare National Coverage Determinations Manual* (100-03), Chapt. 1, Part 4, § 280.3.B (eff. May 5, 2005).

[23] *See* CMS, *MLN Matters: Limiting the Scope of Review on Redeterminations and Reconsiderations of Certain Claims*, SE1521 (eff. Aug. 1, 2015).

While there are a number of reasons that OIG's use of the DME MACs to confirm the Initial Review Contractor's denials was improper, perhaps the most fundamental issue relates to the DME MAC reviewers' unavoidable familiarity with the PMD coverage criteria in place in 2015, as opposed to the criteria in place in 2009 and 2010. Since the dates of service of OIG's sample claims, the DME MACs have published innumerable LCD revisions, Policy Article updates, FAQs, guidance documents, and checklists that have altered these reviewers' interpretations of the PMD coverage criteria. This iterative process imposed heightened documentation and medical necessity requirements on PMD suppliers through the years, with significant alterations in late 2010, June 2011, throughout 2012, and beyond. Critically, since the launch and expansion of the Prior Authorization of PMDs Demonstration Program in 2012 and 2014, the DME MACs have applied the post-2012 PMD review standards to over 100,000 prior authorization requests,[24] cementing these more stringent requirements in the processes and minds of reviewers responsible for this benefit.

a. *The DME MACs improperly excluded medical record documentation from their medical necessity considerations.*

Most egregiously, denial explanations from more than 12 claim reviews included a near copy-and-paste of new language imposing a more stringent documentation standard that was not added to the LCD until April 2013—more than three years after the date of service for a number of claims. In 2009 and 2010, physicians' use of follow-up attestations, letters of medical necessity, and record-keeping templates such as those developed by the Florida Academy of Family Physicians ("FAFP") was authorized by applicable Medicare guidance at that time and routinely accepted by the DME MACs during that time period. In an October 2008 publication to physicians, the DME MACs specifically stated that "there is no specific prohibition against the use of a form to facilitate record-keeping," while noting that templates developed by the Texas or Florida Academy of Family Physicians were not sufficient on their own to meet statutory coverage requirements.[25] Similarly, the Program Integrity Manual provision addressing physician attestation requires only that there be "information in the patient's medical record" that "substantiates" the information on a physician attestation or supplier-prepared statement.[26] Guidance in place at the time this medical review was conducted specifically requires medical reviewers to "review any information necessary to make a . . . claim determination, unless

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[24] CMS, *Medicare Prior Authorization of Power Mobility Devices Demonstration Status Update*, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/PMDDemoOctoberStatusUpdate10142015.pdf (Oct. 14, 2015).

[25] Cigna Government Services, Inc., *Power Wheelchairs and Power Operated Vehicles – Documentation Requirements (MOB)* (Oct. 30, 2008) (the "2008 Dear Physician Letter"); *see also* NGS, Power Mobility Devices – Physician Documentation Requirements – October 2008, A48234 (eff. Oct. 30, 2008).

[26] *See* CMS, Transmittal 242, Change Request 5909 (Feb. 22, 2008) (updating PIM Chapt. 5, § 5.7) (eff. Mar. 1, 2008).

otherwise directed in [the Program Integrity Manual]."[27]

Later publications adopted a stricter standard of excluding physician attestations from the medical record for purposes of medical review. First, in September 2010, the DME MACs published an update to the 2008 "Dear Physician" Letter that deleted the language stating there was no specific prohibition against the use of a form. Instead, the DME MACs replaced that language with a statement that physicians are ***required*** to provide "a thorough narrative description of your patient's current condition, past history, and pertinent physical examination.[28] Later, in the April 2013 update to the PMD LCD, the DME MACs adopted even more specific language related to the use of physician attestations. The "Documentation" section of the LCD was revised to state "[s]upplier-produced records, even if signed by the ordering physician, and attestation letters (e.g., letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.[29] Prior to this update to the LCD, this language did not exist in any of the NCD, applicable LCDs, or Medicare Program Integrity Manual sections to which it is attributed (Sections 5.7 and 5.9). Despite the standard not being adopted in the LCD until 2013, the denial explanations developed by the DME MACs for claims 45, 52, and 150 all include ***this exact language***. Additional claim denials at 96, 134, and 135 apply this standard to exclude consideration of a document that should have been considered under the correct template and attestation standards in place at the time.

In full awareness of the standards in place in 2009 and 2010, Hoveround consistently confirmed that when physicians chose to submit a completed FAFP form or provided a signed attestation, the information included in those materials was corroborated by the patient's medical records. Hoveround did not accept templates or physician attestations as the sole source of medical information to establish medical necessity. In fact, during the DME MACs' prepayment review of Hoveround's claims in 2010, the DME MACs routinely approved the medical necessity of claims that included FAFP forms and physician attestations in the medical record. The Company has attached these examples at Appendix 3, demonstrating the true standard applied by DME MACs when reviewing 2010 claims in 2010.

Yet, in approximately 50 reviews conducted by the DME MACs resulting in denials, the denial reason for the claim refers to the physician's use of a FAFP template or attestation, often discounting or entirely disregarding the information contained on those documents without addressing whether or not the information was corroborated elsewhere. Hoveround engaged FTI to perform a second review of these claims, and in all cases, FTI was able to identify prior

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27 PIM Ch. 3, § 3.3.2.1 (eff. June 28, 2011).

28 *See* CIGNA Government Services, *Power Wheelchairs and Power Operated Vehicles – Documentation Requirements* at 3 (Sept. 2010) (the "2010 Dear Physician Letter").

29 *See, e.g.,* NHIC, Corp., *LCD for Power Mobility Devices L21271)* (eff. June 1, 2011) (updated on Apr. 12, 2013).

records produced to OIG that corroborated the information on the disputed document. Those reviews are enclosed at Appendix 2.A, along with the detailed claim summaries prepared by the Independent Consultants in response to the Initial Review Contractor's denial of the claim.

The retroactive application of this 2013 review standard to deny 2009 and 2010 claims represents clear error and is indicative of the overly stringent review conducted by the DME MACs. Claims denied by the DME MACs due to the application of this standard must be overturned.

b. *The Initial Review Contractor and DME MACs Imposed Post-2010 Medical Necessity Documentation Standards to Deny Claims.*

The Initial Review Contractor and DME MACs also improperly required the face-to-face documentation to contain certain types of information or metrics that were inapplicable to the particular beneficiary's condition, unnecessary for a medical necessity determination, and not required in 2009 and 2010. Most frequently, the OIG Contractors applied a restrictive and unreasonable requirement that documentation may only be considered if there are objective measurements, which was developed significantly in the years after 2010 as DME MACs and CMS published guidance in 2011 and 2012 requesting more objective documentation. Prior to September 2010, the DME MACs most recent communication to physicians to describe the documentation requirements for PMDs included no requirement to include certain elements of objective data or measurements. Instead, the 2008 Dear Physician Letter noted that the evaluation "should paint a picture of your patient's functional abilities and limitations" and "contain as much objective data as possible," focusing on "the body systems that are responsible for the patient's ambulatory difficulty."[30] The Letter also included elements that are "typically" included in a face-to-face examination, but did not include specific documentation requirements. Similarly, the Letter and the LCD in place at the time of these examinations noted that each category of information identified in the LCD "would not have to be addressed in every evaluation," and certain information identified in the LCD—for example, "symptoms that limit ambulation"—will necessarily be subjective because it requires input from the beneficiary on how his or her condition affects Mobility Related Activities of Daily Living ("MRADLs").[31]

The September 2010 update to the Dear Physician letter highlights the change in the DME MACs' approach. This letter specifically addressed "vague or subjective descriptions" of the patient's mobility limitations, including examples of "upper extremity weakness, difficulty walking, SOB on exertion, gait instability, and weakness."[32] The DME MACs instructed that as of the date of this publication, "[t]hese types of statements are insufficient and do not objectively

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30 2008 Dear Physician Letter at 2.

31 *Id.*

32 2010 Dear Physician Letter at 2.

address the mobility limitation or provide a clear picture of the patient's mobility deficits." This new statement clearly expresses a heightened standard that would be used after September 2010 to review PMD claims. Later publications and efforts by CMS and the DME MACs highlighted the focus on objective data, such as the development of a draft "electronic clinical template" by CMS and the DME MACs to guide record-keeping procedures for physicians prescribing PMDs.[33] Far from the LCD's half-page summary of elements "typically" included in a face-to-face examination, this template spans 7 pages of specific, objective measurements and criteria that are "suggested" to be included in the face-to-face report, such as the number of hours per day the patient spent in various positions (in bed, sitting in a chair, sitting in a wheelchair, walking, etc.), the specific delivery system and flow rate of the patients home oxygen system, and whether there is jugular venous distention present when the patient is declined at 30 degrees.[34]

The most recent draft of this template was published in November 2, 2012, and while it has not yet been finalized, this guidance had been published for more than two years after most sample claim dates of service—but also more than two years before the DME MACs conducted this review. CMS and the DME MACs spent many months developing the template, accepting public comments, and revising the "suggested" documentation criteria, as evidenced by the fact that the most recent update to the template was labeled version 9.8. Similar to the September 2010 update to the Dear Physician letter, this stringent documentation standard has been in the public sphere long enough to permanently influence the perspectives of the DME MACs when reviewing claims for medical necessity documentation. Unfortunately, if the reviewers ever were familiar with the actual 2010 standards (a fact Hoveround does not know), those five-year-old standards have been long replaced by the later, more stringent standards, resulting in unjustified denials. For example, in claim 143, the denial reason provided by the DME MAC states that "documentation does not provide quantifying or objective documentation such as strengths, range of motion, transfer abilities, or distance the beneficiary is able to walk with a walker." The patient was an 86-year-old man with congestive heart failure and hypoxia (low oxygen saturation) to the point that he reached a dangerously low oxygen saturation of 82% when he presented for the face-to-face examination (physician noted he becomes "severely short of breath with any activity"). He also had a history of falls, was on medication to treat pain caused by degenerative joint disease of the knees, back, and shoulders, and "had a very difficult time elevating his arms." Despite these observations, the DME MAC concluded that the physician did not sufficiently rule out the patient's ability to resolve his mobility deficit by using a walker

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[33] *See* CMS, *Suggested Electronic Clinical Template Elements of a Progress Note Documenting a Face-to-Face PMD Examination v9.8* (Nov. 2, 2012), https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/Downloads/Suggested-PMD-Electronic-Clinical-Template-v98-508posted-11-02-12-.pdf.

[34] *Id.*

or propelling a manual wheelchair—a conclusion clearly at odds with the significant documentation of this patient's limitations due to sever hypoxia, weakness, and severe pain,

c. *The DME MAC Reviewers Imposed Unauthorized Medical Necessity Requirements to Deny Claims.*

Beyond the heightened review standard, the DME MAC reviewers also denied claims by improperly imposing documentation "requirements" based on mere suggestions in applicable coverage criteria. The complexity of post-payment reviews conducted years after the fact is obvious and has resulted in auditors applying coverage *recommendations* as coverage *requirements*. Unfortunately, OIG and its contractors made just such a misstep in its review of Hoveround's claims. A brief review of *Albert v. Burwell*, a July, 2015 case from the U.S. District Court for the Eastern District of New York, highlights the incorrect behavior.

In *Albert*, a Medicare contractor performed a post-payment review of Medicare claims for chiropractic services rendered between April 6, 2007 and August 8, 2009.[35] When the review denied 100% of the reviewed claims, the practitioner unsuccessfully appealed the decision to an Administrative Law Judge ("ALJ") and the Medicare Appeals Council (the "Council"). Upon receiving claim denials at the Council, the practitioner appealed the claims to the district court. Despite utilizing a deferential standard of review, the court concluded that the Council misinterpreted the coverage requirements of a CMS policy manual published ten years prior to the Council's review.[36]

Specifically, the court found that the Medicare contractor, ALJ and Council misinterpreted language in the Medicare Carriers Manual (the "Manual") that stated that medical history files documenting covered chiropractic services "should" include 8 specific elements or factors. Instead of accepting the plain meaning of "should," the various review entities applied these eight factors as a *requirement,* reading "should" as "must." The court pointed out to the review entities that the Manual required compliance with other standards by using "must," so there obviously is a difference between these two standards. Unsurprisingly, the court reasoned that standards identified with "must" possesses a mandatory character, while standard identified with "should" merely suggest compliance would be preferred. Concluding that the eight-factor medical history provision described by "should" prescribes an "ideal rather than establishes a baseline," the court held that the practitioner's claims "consistently incorporate[d] several of the eight-factor history requirements," and therefore were improperly denied coverage by the contractor, ALJ and Council.

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35 *See Albert,* 2015 WL 240684 at *3.

36 *Id. at *7-8.*

The same interpretive flaw brought to light in *Albert* is fatal to many claims in the DME MAC denials. As summarized above, the applicable guidance in 2010 instructed that physicians "should" include as much objective data "as possible."[37] The PMD LCD effective in 2010 stated that the report "should" provide pertinent information about a list of history and physical examination elements. The 2008 Dear Physician Letter similarly provided guidance that physicians "should" record the visit and mobility evaluation in the usual record-keeping format. These suggestions are contrasted with the "must" statements, such as that a date stamp or equivalent "must" be used to document the supplier's receipt of the written order, and that the "basic coverage criteria" must be met for a PMD device to be covered.

Like the eight-element list in *Albert,* the list of history and physical elements included in the LCD and 2008 Dear Physician Letter, as well as later lists of objective criteria suggested by CMS to be included in the face-to-face examination, are characterized by the word "should." These lists prescribe an ideal, rather than establish a baseline of minimum elements that must be included in the record of the face-to-face examination. The DME MACs erroneously denied many Hoveround claims that met the actual requirements for coverage and "consistently incorporated" answers to "several" of these inquiries, but which did not include objective answers to these inquiries *in the face-to-face examination.* For example, the sole denial reason for claim 3 states that the face-to-face examination and supporting medical documentation "does not include objective measurements of [upper extremity] strength and function to [rule out] MWC [manual wheelchair]."

The court's mandates to the Council on remand are particularly instructive to OIG and the DME MACs. The court prohibited the Council from denying the practitioner's claims solely for failure to submit a medical history containing exactly the elements listed in the LCD. Instead, the court required the Council to consider whether the history he did submit, taken in totality with his other treatment notes, demonstrates that the patient met the coverage criteria for the therapy provided. In the same manner, the DME MACs are prohibited from denying claims based on the imposition of "requirements" for objective data that are merely "suggestions" in the applicable CMS guidance, and they must consider the totality of the documentation and treatment notes to determine whether the beneficiaries met the broad coverage criteria for PMDs in place in 2010.

C. The Alleged Deficiencies Noted in the Second Draft Audit Report Are Unsubstantiated.

The Second Draft Audit Report identifies six different categories of reasons for medical necessity denials, all of which contain numerous claims that have appropriate documentation and support for the medical necessity of the PMDs. The detailed claim evaluations conducted by the

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[37] 2008 Dear Physician Letter.

Independent Consultants, attached at Appendix 2, clearly demonstrate that the vast majority of the sampled claims met the medical necessity review standard in place in 2010. These individual claim analyses rebut the conclusions reached by OIG for the most voluminous categories of claim denials, including that (1) the records of the face-to-face examinations did not specify mobility limitations that would establishment significant impairment to participate in MRADLs within beneficiaries' homes; (2) the records of the face-to-face examinations did not indicate whether the mobility limitation could have been resolved by different equipment; and (3) that the records of the face-to-face examinations had insufficient detail or incomplete or conflicting narratives. As described above, these denials by the DME MACs resulted from clear misapplications of the correct coverage and documentation standards in place in 2010, as well as misinterpreted clinical documentation.

For the remaining 9 categories of claim denials that contained 5 or fewer claims, Hoveround has provided individual responses below and in Appendix 1.

1. The Medical Record Established That a Mobility Evaluation Was One of the Major Reasons for the Face-to-Face Examination.

Patient Sample #181: The DME MAC denied this claim because it asserted the initial face-to-face did not state the primary reason for the visit was a mobility examination. Within the denial explanation, however, the contractor acknowledged that an addendum validated by the treating physician and provided to Hoveround stated that the visit addressed mobility issues. This claim also includes information that was apparently excluded by the DME MAC because it was provided within a signed Florida Academy of Family Physicians (FAFP) form. Critically, the information contained within the addendum and the FAFP is corroborated by information in the medical record, as described in detail in Appendix 2.A. These documents, therefore, must be considered in the evaluation of medical necessity. Accordingly, while the physician may not have explicitly stated the examination was primarily for mobility issues in the original chart note, the validated addendum, the substance of the visit, the nature of the patient's evaluation, and the additional information on the FAFP clearly corroborated and manifested this intent.

2. The Medical Records Supported the Conclusion That the Beneficiary Had the Physical and Mental Capability to Safely Operate the PMD.

Patient Sample #174: The DME MAC denied this claim based on the assertion that the beneficiary's psychological assessment stated the beneficiary had poor insight and judgment, demonstrating the lack of mental capability to safely operate the PMD. The denial explanation continued, however, to acknowledge that the treating physician explicitly concluded that the beneficiary had the mental capability to operate a PMD. The DME MAC concluded these comments were contradictory and denied the claim. As discussed in the *Heart 4 Heart* case described above, it is simply not possible for the DME MAC reviewer to gain more insight into

the beneficiary's ability to operate a PMD than the insight the treating physician obtained when actually examining the patient and concluding the beneficiary could safely operate a PMD. There are obviously numerous circumstances and varying degrees of mental states that could lead a clinician to conclude a person demonstrates poor insight and judgment while allowing that same clinician to conclude a person can operate a PMD. These clinical notes do not create the sort of irresolvable conflict suggested by the DME MAC reviewer that denied the claim on this basis. Instead, the DME MAC reviewer must accept the signed statement from the treating physician that he or she had examined the patient and utilized professional judgment to conclude that the patient had the mental capability to operate a PMD.

3. Hoveround Provided Complete Documentation To Support the Fifteen Claims Identified by OIG as Incomplete.

While OIG's First Draft Audit Report only identified 3 out of 200 claims in which Hoveround's files contained a minor alleged documentation deficiency (all related to date stamps), OIG and its reviewers applied a new standard in the second review to deny 12 additional claims for incomplete documentation. Once again, these determinations consistently apply the wrong documentation standards to reach the wrong conclusions, often denying claims for reasons that are easily explained and addressed on the face of the documentation. Hoveround has provided detailed responses to each of these 15 denials in Appendix 1, fully rebutting the conclusions of the OIG auditors and their review contractors. When reviewing and interpreting those responses, OIG and its reviewers must adhere to the correct documentation standards in place during 2009 and 2010, as well as the review standards that applied to post-payment reviews conducted after 2010.

a. *Hoveround authenticated the identity of physician signatories for each claim denied due to missing physician signatures on critical medical records.*

At the time this review was conducted, CMS provided explicit instructions to medical review contractors on the procedure to follow if Medicare coverage criteria cannot be met but for a key piece of medical documentation that contains a missing or illegible signature.[38] In these circumstances, medical reviewers (including the DME MACs) are required to contact the provider or supplier that billed the claim and ask if the entity would like to submit an attestation statement or signature log. If a signature is missing or illegible, the reviewers are instructed to (1) accept a signature attestation from the author of the medical record entry as valid; and (2) consider evidence in a signature log, attestation, or other documentation submitted to determine the identity of the author of a medical record entry.[39] Reviewers must provide notice to the

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[38] *See* PIM Ch. 3 § 3.1.2.4.

[39] *Id.* § 3.1.2.4.A.

billing entity in the form of a telephone call or request letter and then provide 20 calendar days for the entity to acquire the signature attestation or signature log. Instead of contacting Hoveround and requesting validation of medical records with missing or illegible signatures, OIG and the DME MACs simply identified the claims for denial.

Upon receiving copies of the DME MAC denial reasons, Hoveround exercised its right to obtain signature logs and attestations for the 5 claims identified for denial due to missing signatures, as well as an additional 12 claims in which the DME MACs' denial reason excluded important medical record documentation due to a missing or allegedly illegible signature. Explanations of each claim, and the attendant attestation or signature log, are included at Appendix 1. This documentation clearly cures the denial reasons for the 5 claims identified for denial due to a missing signature and significantly impacts the claim determination for the additional 12 claims, which must be reconsidered in light of this evidence.

b. *Reviewers incorrectly applied 2011 documentation requirements to deny claims with complete written orders submitted in 2009 and 2010.*

The Medicare statute provides that payment will be made under Medicare Part B for a power wheelchair provided that a physician or other approved practitioner has conducted a face-to-face examination of the individual and written a prescription for the item.[40] The purpose of this examination is to evaluate and treat the beneficiary for his or her medical condition and to determine the medical necessity for the PMD as part of an overall treatment plan.[41] At the time Hoveround received the documentation and written orders related to OIG's sample claims (2009 and 2010), suppliers were required to keep on file the treating physician's report of the face-to-face examination, as well as a signed physician order. In neither the LCD nor the PIM, however, did CMS or the DME MACs require that the same person actually write and sign both the face-to-face and the seven-element order. That requirement was not imposed until June 2011 when the DME MACs revised the LCD to state "[t]he treating physician completing the face-to-face requirements must write the 7-element order."[42] Despite this statement not appearing in the NCD, LCD, or PIM in 2009 or 2010, the DME MACs explicitly denied three claims for this reason and referenced it as an alternative denial reason in three additional claims. These denials, summarized in greater detail in Hoveround's responses at Appendix 1, represent clear error and must be reversed.

c. *Reviewers ignored clear LCD guidance on documentation standards to justify denials for insignificant date stamp issues.*

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40 *See* 42 U.S.C. §1395m(a)(1)(E)(iv).

41 *See* 42 C.F.R. § 410.38(c)(2)(i).

42 *See, e.g.,* NHIC, Corp., *LCD for Power Mobility Devices L21271)* (eff. June 1, 2011) (updated on May 6, 2011).

While only four (4) claims were denied explicitly due to an allegedly missing date, the denial reasons provided by OIG and the DME MACs for ten (10) total claims reference a missing date stamp impacting the review in some way—all of which improperly reject Hoverround's reliable and verifiable process for documenting receipt of these documents. Hoverround provides detailed explanations for each of these claims in Appendix 1, many of which demonstrate the same fundamental error by the reviewer. To verify the supplier's receipt of the signed written order and detailed product description ("DPD"), the PMD LCD requires that a provider use "[a] date stamp *or equivalent*" to document the receipt date of documents such as the written order and detailed product description.[43] The LCD does not provide any additional guidance on what documentation would be considered "equivalent" to a date stamp. Guidance in place at the time these claims were processed contemplated that an automatic fax header line could provide the receipt date, but that it was often difficult to ascribe a particular date to the receipt due to multiple faxes.[44] Instead, suppliers were reminded that they must consistently "apply" a date stamp or equivalent—suggesting a more manual system of date stamping would be sufficient—if not preferred—over relying solely on automatically applied fax ribbons.[45]

In 2010, Hoverround utilized a fax system that automatically date-stamped materials upon receipt (stamping date and time separately from the automatic fax send/receive ribbon), and that system was largely effective. In each of these 10 cases, the fax system failed to record the receipt date on the document itself. Recognizing the potential for such mechanical failure, Hoverround requires that when a fax is manually received, the date and time of receipt of the particular document be recorded within the particular beneficiary's computer-maintained file.[46] For 10 of the cases that identify a claim as an error in part due to a "missing" date stamp, Hoverround representatives recorded the exact date and time of receipt in an electronic note within the patient's file. Hoverround provided these notes to OIG auditors when three (3) claims were initially denied for this reason,[47] and Hoverround has included copies of the notes for the additional claims denied by the DME MACs in the second review. These notes represent manual, contemporaneous entries by Hoverround personnel individually identified by unique user names, who entered the time and date on which the paperwork was received. This system provides even more accountability and certainty than a manual, physical date stamp that was clearly contemplated and accepted by the DME MACs at this time. OIG's apparent conclusion that

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43 *See, e.g.,* CIGNA Government Services, *LCD for Power Mobility Devices (L23613)* (eff. Oct. 1, 2009) (emphasis added).

44 *See* CGS Administrators, LLC, *Power Mobility Devices – Indicating Receipt Date of Documentation*, A49450 (eff. Oct. 8, 2009).

45 *Id.*

46 Hoverround has since upgraded from a mechanical fax system to a redundant, digital system.

47 *See* HOVEROUND_0004269 – HOVEROUND_0004274; HOVEROUND_0004430 – HOVEROUND_0004435; and HOVEROUND_0004449 – HOVEROUND_0004454.

Hoveround's system that recorded the exact date and time of receipt was not "equivalent" to a manual date stamp clearly misinterprets the applicable standard to wrongfully deny otherwise valid claims.

V. THE DRAFT REPORT SUFFERS FROM FATAL METHODOLOGICAL AND PROCEDURAL FLAWS

In addition to the substantive and methodological concerns, OIG's audit process also suffered from critical procedural flaws because the OIG auditors failed to provide Hoveround with notice that the audit would include a review of the medical records to evaluate the beneficiary's condition and failed to give Hoveround an opportunity to furnish documentation to support the medical necessity of its claims. Communicating notice of the scope of the audit and providing an opportunity for a meaningful response are required by the GAGAS, which are binding on the OIG auditors as well as their contract reviewers and are key components of due process.[48] Yet, Hoveround did not learn that OIG was conducting such a medical necessity review until the day the initial draft report was sent to the Company (November 15, 2013). This lack of process deprived Hoveround of the opportunity to provide the auditors with additional documentation that was critical to their findings and conclusions regarding medical necessity. Without critical evidence, the GAGAS requirement that audit findings and conclusions be supported by sufficient and appropriate evidence was not met, and those findings and recommendations must be withdrawn. By sharing the conclusions of the Initial Review Contractor with the DME MACs, OIG also tainted the Second Review, creating unacceptable conflicts of interest and preventing a truly independent review of the documentation from occurring. For these reasons, the results of the DME MACs' review should be disregarded.

A. OIG Auditors Were Required to Inform Hoveround That the Intended Scope of the Audit Would Include a Review of Medical Necessity.

Most relevantly, to ensure full transparency of audits, the Yellow Book requires OIG auditors to communicate "an overview of the objectives, scope, and methodology" of the audit, as well as the timing of the audit and planned reporting, to the "management of the audited entity."[49] The Yellow Book defines "scope" as "the boundary of the audit," including "the subject matter that the auditors will assess and report on."[50]

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48 5 U.S.C. App. § 4(b)(1)(C); *see also* Government Auditing Standards, United States Government Accountability Office, GAO-12-331G § A.102(a) (Dec. 2011) (recognizing that the Inspector General Act of 1978 includes these requirements).

49 Yellow Book § 6.47.

50 Yellow Book § 6.09.

No rationale for deviating from this standard has been provided, yet neither the full scope of the audit nor the methodology for the medical necessity review was communicated to Hoveround management or the Company's governing officers at any time during the audit process. Indeed, during the course of the audit process, when the Company specifically asked whether OIG was conducting a medical necessity review, the OIG auditors never advised the Company that they were doing so. Instead, during the initial meeting between OIG auditors, Hoveround personnel, and Hoveround's representatives, OIG expressly represented that the audit involved a review of documentation required for Medicare coverage—in Medicare terminology, a documentation compliance review[51]—rather than a complex medical review that included a clinical evaluation of medical necessity.[52]

Since Hoveround was not aware that the scope of the audit included medical necessity, it had no reason or opportunity to acquire and furnish to the auditor additional documentation to further support the medical necessity of the claims, as the Company does for every other medical necessity review. OIG personnel further represented that OIG would later determine whether the audit would include a medical necessity review and would affirmatively inform Hoveround of that decision. For several months following the on-site visit by OIG auditors in connection with the Initial Audit, Hoveround provided additional documentation to OIG auditors in response to requests for clarification or to supplement the file with certain documents related to the documentation compliance review. At no time from the commencement of the Initial Audit in May 2012 through the exit interview on June 28, 2012, did the OIG auditors inform Hoveround of the true scope of the audit.

When evaluating claims for compliance with Medicare coverage criteria, CMS has adopted a clear and real distinction between medical reviews involving only a non-clinical review of documentation related to the claim, and medical reviews that include a clinical evaluation of medical necessity. This complex medical review process "includes requests for, collection and evaluation of medical records or any other documentation."[53] Medicare regulations explicitly recognize that suppliers may have to obtain and provide additional

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[51] A "routine medical review" is a "document only review that is performed by specially trained non-clinical Medical Review staff. For example, non-clinical MR staff reviews a document for start and stop dates, dose ranges, attachment of [Certificate of Medical Necessity] as required, etc." PIM, Ch. 7, § 7.2.2.2. These reviews are alternatively referred to as "Documentation Compliance Reviews," described by CMS as "nonclinical, technical reviews to evaluate the presence or absence of particular pieces of documentation." *Id.* Ch. 3, § 3.3.1.2.D.

[52] A provider-specific "complex medical review" is defined as a review that "requires a licensed medical professional to use clinical review judgment to evaluate medical records." *Id.* Ch. 7, § 7.2.2.12. Clinical review judgment involves the "synthesis of all submitted medical record information . . . to create a longitudinal clinical picture of the patient" and "application of this clinical picture to the review criteria to make a reviewer determination of whether the clinical requirements of the relevant [coverage] policy have been met." *Id.* Ch. 3, § 3.3.1.3.

[53] *Id.* Ch. 7, § 7.2.2.12.

documentation to support the medical necessity of the PMD beyond the documentation provided by the prescribing physician. Importantly, the regulations specify that such documentation must be provided by the supplier ***upon request by CMS or its agents*** when necessary to support and/or substantiate the medical necessity for the PMD.[54] As a matter of standard and routine procedure and consistent with its rights under CMS guidance, Hoveround collects supplemental medical records to corroborate a beneficiary's medical condition each time a Medicare contractor or other insurer informs the Company of a complex medical review.

This lack of communication from OIG is not only a violation of the GAGAS, but it is also illustrative of an additional violation: "In performance audits that comply with the GAGAS, auditors obtain reasonable assurance that evidence is sufficient and appropriate to support the auditors' findings and conclusions in relation to the audit objectives."[55] Had OIG done what it was required to do, the Company would have acquired and provided supplemental medical records prior to the conclusion of the Initial Audit, which would have materially altered the results of the review. OIG's Initial Review Contractor also failed to collect the documentation required to conduct a complex medical review audit on its own. A number of individual medical review summaries of claims denied by OIG's Initial Review Contractor on the basis of medical necessity cited to the lack of corroborating documentation in the record available for review—documentation that Hoveround was able to obtain and provide to OIG once informed of the true scope of the audit. Due to this notice deficiency, the OIG auditors did not meet their obligation under GAGAS to obtain reasonable assurance that the evidence on which they based their findings and conclusions was sufficient or appropriate to support those findings or conclusions with regard to medical necessity.

B. OIG Tainted the Results of the Second Review by Sharing the Flawed Results of its First Review with the DME MACs.

In some recognition of the prejudice created by depriving Hoveround of the opportunity to collect additional records, OIG provided Hoveround with a short window to gather the relevant records. While this step appeared to be a good-faith effort by OIG to remedy the issues present in the first review created by the lack of notice, OIG's later actions directly undercut any remediation that might have been accomplished by allowing Hoveround to gather the necessary records and provide them to an independent reviewer. Specifically, according to OIG's communications, OIG provided the flawed claim determinations from the Initial Review Contractor to the DME MACs engaged to perform the second review. By providing the DME MACs with the Initial Review Contractor's claim denials and the reasoning behind those denials, OIG provided unnecessary information to the DME MACs that prejudiced Hoveround and

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[54] 42 C.F.R. § 410.38(c)(5)(ii).

[55] Yellow Book § 6.03.

carried the original deficiencies of the Initial Review Contractor into the second review. Instead of providing only the relevant claim documentation and requesting a new review, OIG essentially provided the DME MACs with the desired conclusion and had the DME MACs confirm the prior results. For the reasons listed below, there are a number of circumstances to suggest that the DME MACs may have felt pressured to confirm those findings. The apparent desire of the DME MACs to agree with the OIG's initial claim denials is evident throughout the DME MAC work papers, such as when the Jurisdiction B reviewers concluded a claim should be denied for certain new reasons but still felt the need to list "Additional Points of Agreement with OIG" to concur with the original summary from the Initial Review Contractor.

As a result of this second procedural misstep, OIG was not successful in curing the notice deficiency that undermined the Initial Review Contractor's conclusions.

C. OIG's Use of the DME MACs to Perform the Second Review Created Conflicts of Interest That Invalidate Those Contractors' Conclusions.

Although OIG initially suggested that it would engage an "independent" medical review contractor to perform the Second Audit, OIG informed Hoveround one month before providing it with the Second Draft Audit Report that the Second Review was undertaken by the DME MACs, who were assigned sample claims originating in their jurisdictions to perform medical review. As discussed above, these same DME MACs had already performed in-depth reviews of documentation related to more than 1,600 of Hoveround's PMD claims from 2010, which include complex medical reviews to evaluate the medical necessity of the claims. On initial review, these contractors approved more than 60 percent (60%) of Hoveround's claims from 2010—an initial claim approval rate that approaches *six times* the approval rate reached by the DME MACs during this audit, and a rate that increased even further through later claim development. OIG has not explained how the very same DME MACs, reviewing similar claims from the same year that were developed through the same uniform compliance processes, could reach such widely variable results.

There are two key differences between the reviews conducted by the DME MACs in 2010 and those conducted in 2015, and both impacted the accuracy of the reviews: (1) the 2015 reviews occurred five years later than the prior reviews, during which time coverage and documentation requirements for PMDs had heightened, and the DME MACs apparently could not ignore those later standards; and (2) the 2015 reviews were conducted at the request of OIG, with the OIG's prior conclusion communicated to the DME MACs. The first point is addressed in detail in Section IV.B, and the second point provides a basis for OIG to disregard these medical necessity reviews due to a conflict of interest.

OIG's use of the DME MACs creates conflict-of-interest concerns that introduce unacceptable audit risk and invalidate the contractors' review results. The standards enumerated

in Chapter 3 of the Yellow Book summarize potential threats to auditor independence, stating that "auditors should avoid situations that could lead reasonable and informed third parties to conclude that the auditors are not independent and thus are not capable of exercising objective and impartial judgment on all issues associated with conducting the audit and reporting on the work."[56] A threat to independence is not acceptable if it "could impact the auditor's ability to perform an audit without being affected by influences that compromise professional judgment or . . . expose the auditor or audit organization to circumstances that would cause a reasonable and informed third party to conclude that the integrity, objectivity, or professional skepticism of the audit organization, or a member of the audit team, had been compromised."[57] If a threat is identified as "significant," appropriate safeguards must be applied to eliminate or reduce the threat to an acceptable level before proceeding with the audit.[58] If safeguards cannot eliminate or reduce threats to an acceptable level, the audit should be terminated.[59]

The Yellow Book identifies a clear threat to auditor independence created by OIG's engagement of the DME MACs, which should have been sufficient for OIG to acknowledge the unacceptable risk created by the use of these contractors for the Second Review. A "self-interest" threat is present when there is the possibility that a financial interest will inappropriately influence an auditor's judgment or behavior.[60] Each of the DME MACs is part of an insurance company that maintains multi-million dollar contracts with the U.S. Department of Health and Human Services ("HHS"), OIG's parent entity, which are re-opened for competitive rebids on a regular basis. When OIG presented the DME MACs with the reviews of the Initial Review Contractor and OIG's acceptance of those conclusions in the First Draft Audit Report from November 2013, the DME MACs might have been uncomfortable disagreeing with the initial findings, and in the interest of maintaining positive relationships with OIG, among other reasons, did not fulfill their responsibilities as independent review entities to fully and fairly evaluate the claims under the standards in existence during the relevant time period. For all the reasons cited above in this document, a reasonable third party could readily conclude that this relationship compromised the objectivity of the DME MACs.

The OIG could have implemented a safeguard against the review contractor's threat to independence by engaging an independent entity, which was Hoveround's clear understanding of what the OIG was doing until the OIG announced shortly before the Second Draft Audit Report was issued that the DME MACs performed the second review. Additionally, the OIG, at

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56 Yellow Book § 3.04.

57 Yellow Book § 3.22.

58 *See* Yellow Book at Appendix II (Conceptual Framework for Independence). Examples of safeguards include "consulting an independent third party, such as . . . another auditor" or "involving another audit organization to perform or reperform part of the audit." *See* Yellow Book § 3.17.

59 Yellow Book § 3.25.

60 Yellow Book § A3.03(a)-(b).

minimum, could have withheld the results of the Initial Review Contractor from the DME MACs' review in order to ensure as independent a review as possible. Failing to adopt either of these safeguards, OIG has invalidated the review results of the DME MACs and must disregard the medical necessity review when establishing the Second Draft Audit Report's findings and recommendations.

VI. THE DEFICIENCIES AND DELAY IN OIG'S AUDIT PROCESS WEIGH STRONGLY AGAINST EXTRAPOLATION OF THE REVIEW RESULTS.

Even if OIG determines that the numerous deficiencies described above do not merit withdrawal of the Second Draft Audit Report, the extrapolation of those results to a larger claims universe would conflict with OIG's internal policies and procedures, as well as its precedent for audits of this type. First, the extrapolation of the review results for Stratum 1 (new PMD purchases) would be inconsistent with specific OIG policies and past behavior that call into question the minimal sample size that was extrapolated to a universe of more than 12,000 claims. Second, the significant delay since the dates of service and completion of OIG's audit work caused OIG in prior circumstances to limit its recommendations to the claims actually reviewed, not an extrapolated amount. Third, the rare and unique nature of many claim denial categories weighs against inclusion of those denials in any extrapolated overpayment estimate, since they are not present in sufficient numbers to suggest a representative trend for extrapolation. For all of these reasons, OIG must limit its findings and recommendations to the claims actually reviewed by the OIG and its contractors to the extent OIG decides to move forward with its issuance.

A. OIG's Sampling and Evaluation Processes Do Not Support Extrapolation of Review Results for Stratum 1.

First, Hoveround has serious concerns regarding the validity of a 100-claim review of new PMD purchases to recommend the repayment of approximately $26 million.[61] The conclusions reached on those 100 claims differ so greatly from the conclusions reached on the other 2,325 claims reviewed by the RACs and DME MACs and the results of an independent medical review of those same claims, as to put into grave question this entire audit process. The impropriety of reviewing only 100 out of 12,024 claims for new PMDs is highlighted by comparing this approach to OIG's past practices and other strata identified in the Draft Report.[62] For example, OIG's compliance audit of Marquis Mobility, Inc. ("Marquis Mobility"), another PMD supplier, included a review of 200 claims to evaluate a sample frame of 1,140 claims,

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61 While OIG reviewed 50 sample claims of used PMD purchases and 50 sample claims of rental PMDs, these strata account for $2 million of the total claim universe of $40.57 million. Given error rates of less than 100%, these 100 claims accounted for less than $2 million of the total estimated overpayment.

62 These concerns were communicated to OIG by written correspondence, dated November 25, 2013.

corresponding to a review of 17.5 percent (17.5%) of the total claim universe.[63] By comparison, OIG reviewed only 0.83 percent (0.83%) of Hoveround's 2010 claims for new PMDs and 1.5 percent (1.5%) of all claims in Hoveround's 2010 paid claims universe. OIG Office of Audit Services ("OAS") internal policies and procedures note that the sample size is "critical" for the efficient conduct of the audit, and that larger sample sizes should be considered when the estimate requires a minimum number of units with the characteristic of interest.[64] Given the enormous universe of claims subject to the review of the minimum 100 sampled claims—all subject to distinct and variable denial reasons—OIG should have increased the number of claims reviewed to establish sufficient evidence for an extrapolation of stratum 1. Having failed to do so, OIG should not extrapolate the results in this stratum.

Moreover, once OIG's aberrational error rate is reduced to a level that approximates the observations of the Independent Consultants and the other Medicare contractors (which, similar to OIG in the Marquis Mobility audit, reviewed approximately 17 percent of Hoveround's 2010 claim universe), the wide margin of error inherent to an extrapolation of a 100-claim sample with few errors would render the extrapolation of that stratum essentially meaningless. A statistical model developed from OIG's data and the Independent Consultants' claim evaluations concludes that an attempted extrapolation of the Independent Consultants' error rate in the 200-claim sample would result in an unacceptable relative precision level, exceeding 66 percent (66%) for a 90 percent (90%) confidence level. These calculations mean that, in order to establish a range of overpayment levels that would contain the true overpayment amount 90 percent (90%) of the time, the *range* of potential overpayments would be greater than the actual value of the estimated overpayment amount.[65] This precision level represents a dramatic departure from OIG's published recommendation that samples be designed to generate an estimate with a 90 percent (90%) level of confidence and a precision of 25 percent (25%) or less.[66] Moreover, the relative precision of specific strata are even higher, with stratum 1 yielding a relative precision greater than 72 percent (72%) for a 90 percent (90%) confidence level—nearly triple the OIG's recommended level of precision. In order to establish a meaningful statistical extrapolation to the 12,024 claims contained in stratum 1, we estimate that OIG would have had to review well over *six times* the number of claims they reviewed in that stratum.

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63 *See* OIG, *Review of Power Mobility Devices Supplied by Marquis Mobility, Inc.,* A-05-10-00042 (May 2012), *available at* http://oig.hhs.gov/oas/reports/region5/51000042.pdf.

64 *See* OIG Office of Audit Services, *OAS Audit Policies and Procedures Manual*, "Statistical Sampling and Mathematical Calculation Estimation Techniques in Auditing," § 20-02-50-05 (Mar. 16, 2015).

65 For example, if the extrapolation of the sample resulted in an estimated overpayment of $3 million, the confidence interval necessary to achieve a 90% confidence level would be $3 million +/- $2 million, resulting in an overpayment range of $1 million to $5 million (a $4 million spread).

66 OIG, *Publication of the OIG's Provider Self-Disclosure Protocol*, 63 Fed. Reg. 58399, 58402 (Oct. 30, 1998).

A review of the Marquis Mobility report also emphasizes the peculiar and improper stratification method employed by OIG in the Hoveround audit. For the Marquis Mobility audit, OIG stratified the sample frame into two strata based on geographic distinctions (beneficiaries inside and outside of Ohio), which accounted for geographic variations in medical practice and regional DME MAC interpretations of coverage criteria while also providing a fairly even split between the strata (59.5% and 40.5% of claims within each stratum). For Hoveround, OIG's stratification based on new, used, or rental purchases created an over-weighted stratum of new PMD purchases that failed to account for geographic distinctions and resulted in significantly disparate sample sizes when compared to the sample frame: (i) 100 out of 12,024 new PMD claims (0.83%); (ii) 50 out of 663 used PMD sales (7.5%); and (iii) 50 out of 338 rental claims (14.8%). Additional doubts are cast on the integrity of these data when one considers the extrapolation of a miniscule sample (0.83% of the stratum) to such a large heterogeneous sample frame, which includes documentation from dozens of physicians practicing in thirty-four different states, each making individualized medical decisions based on circumstances presented by 100 unique patients. A more appropriate stratification should have been undertaken by OIG prior to extrapolating the results of the review. As currently structured, the OIG's sampling and stratification methods raise concerns regarding whether the population of each stratum is appropriately homogeneous.

In addition, the audit methodology described in Appendix A of the Draft Report raises questions regarding the validity of the OIG auditor's findings and the legitimacy of the extrapolation. The Draft Report notes that fieldwork was performed "at prescribing physicians' offices in 34 states and the beneficiaries' residences in 33 states" and that OIG "interviewed (if available) the prescribing physicians and Medicare beneficiaries." The Draft Report is silent, however, on how the fieldwork and interviews impacted the reviews or conclusions of the OIG Contractor. If only some physicians or beneficiaries were available for interview and the information gained during the interview impacted the coverage decision, these informational discrepancies among the claims would invalidate the extrapolation. Further procedural discrepancies were introduced by the DME MACs' Second Review, since each contractor appears to have utilized unique forms and procedures to evaluate and report the results of their claim reviews. This disjointed system resulted in work papers summarizing the review decisions from the DME MACs varying from 11 pages from Jurisdiction C to report conclusions for 76 claims, to 112 pages from Jurisdiction B to report conclusions on 36 claims. The significant deviation among informational bases, review processes, review results, and reporting procedures undermines the legitimacy of any extrapolation of these results.

B. The Delay Between the Dates of Service, Audit Work, and Draft Report Requires OIG to Limit its Findings and Conclusions to the Claims Actually Reviewed.

When examining audit risk—the possibility that the auditors' findings, conclusions, or recommendations may be improper or incomplete—one factor to be considered is the time frame required to complete the audit work.[67] The longer the delay between the audit work, development of the draft report, acceptance of audited entity comments, and publication of the final report, the greater the risk that the original findings and recommendations are no longer proper or complete. The delay between the publication of OIG's First Draft Audit Report and the publication of its final report is likely to exceed 100 weeks, which appears to bethe longest delay for any audit of a Medicare provider or supplier since 2008.

The only audit reports that included a similar delay between the audited entity's comments and the publication of the final report were audits of four Medicare Advantage plans published in 2012 and 2013.[68] Those reports contained a number of parallels to Hoveround's situation, including the significant delay in final report publication, the multiple medical reviews performed by OIG in each of these audits, and the changing review standard applicable to the reviewed claims. In those audits, after publishing an initial draft report recommending that the audited entity refund the extrapolated overpayment amount, OIG accepted the comments of the audited entities and appropriately revised the report to recommend that the audited entity refund only the overpayments identified for the sampled beneficiaries. Given the similar concerns related to delays and altered claim review standards present in Hoveround's audit process, OIG must act consistently with its past audits and limit the refund recommendations of any published report to the sampled claims, not an estimated or extrapolated overpayment amount.

C. OIG's Policies Do Not Support Inclusion of the Unique Documentation and Medical Necessity Denials in Any Extrapolated Overpayment Estimate.

OIG's own internal policies and procedures also weigh against the extrapolation of Hoveround's claims denied for documentation and medical necessity issues when present in only

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67 Yellow Book § 6.05.

68 *See* Office Of Inspector Gen., Dep't Of Health & Human Servs., A-03-09-00003, *Bravo Health Pennsylvania, Inc. (Contract H3949), Submitted Many Diagnoses To The Centers For Medicare & Medicaid Services That Did Not Comply With Federal Requirements For Calendar Year 2007* (2013); Office Of Inspector Gen., Dep't Of Health & Human Servs., A-07-10-01082, *Cigna Healthcare Of Arizona, Inc. (Contract H0354), Submitted Many Diagnoses To The Centers For Medicare & Medicaid Services That Did Not Comply With Federal Requirements For Calendar Year 2007* (2013); Office Of Inspector Gen., Dep't Of Health & Human Servs., A-02-09-01014, *Risk Adjustment Data Validation Of Payments Made To Excellus Health Plan, Inc., For Calendar Year 2007* (Contract Number H3351) (2012); Office Of Inspector Gen., Dep't Of Health & Human Servs., A-05-09-00044, *Risk Adjustment Data Validation Of Payments Made To Paramount Care, Inc., For Calendar Year 2007* (Contract Number H3653) (2012) (the "Medicare Advantage Audit Reports").

rare instances. Sample sizes must be large enough to identify a minimum number of examples of the "character of interest" being measured and extrapolated.[69] The characteristic to be measured should relate to more than a simple determination of overpayment: For instance, the example provided by OAS in the relevant policy discusses the "characteristic to be measured" being a category of overpayments due to a specific reason (duplicate payments).[70] OIG's common practice of stratifying claim reviews by specific overpayment justification—and deciding whether or not to extrapolate based on the review results against those specific denial reasons—is demonstrated in the hundreds of hospital compliance reviews conducted over the last several years. In those audits, OIG did not calculate an overall review rate and extrapolate those percentages to the entirety of the hospitals' inpatient and outpatient claims; instead, OIG decided whether to extrapolate review results for specific claim denial reasons, such as the improper use of a modifier, and specifically declined to extrapolate where the denial reason was not present in a significant portion of the stratum, citing OAS policy.[71]

For the 156 allegedly deficient claims identified by OIG, OIG has categorized the claims into *twelve* separate denial categories, including nine categories with 5 or fewer denials and six categories with only 1 or 2 claim examples. As described above, these one-off denials are based on a hyper-technical interpretation of PMD documentation criteria—much of which was not even in place for these claims. Moreover, the claims in the largest category of documentation "denials" (consisting of only 5 out of 200 claims) were immediately remedied when Hoveround obtained the physician signature attestations attached at Appendix 1.

VII. HOVEROUND DISAGREES WITH BOTH RECOMMENDATIONS IN THE DRAFT REPORT.

The purpose of OIG's audits is to prevent and detect fraud, waste, abuse, and mismanagement, and promote economy, efficiency, and effectiveness in government programs and operations.[72] And in fulfilling these objectives, OIG—and its contractors—must act in an objective, transparent, and reasonable manner, remaining faithful to governing audit criteria and relevant standards. In issuing a Draft Report marred by serious substantive and procedural flaws, OIG failed to adhere to these governing principles:

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69 *Id.*

70 *Id.* at § 20-02-50-07 (Characteristics to Be Measured).

71 *See, e.g.,* Office Of Inspector Gen., Dep't Of Health & Human Servs., A-04-12-00083, *Baptist Medical Center South Complied With Most Medicare Requirements For Billing Inpatient And Outpatient Services For Calendar Years 2009 And 2010* at App. B, n.1 (June 2013) (noting for two sampled strata with identified errors in 5 out of 30 and 5 out of 50 claims, respectively, that "[i]n accordance with OAS policy, we did not use the results . . . in calculating the estimated [extrapolated] overpayments. Instead, we added the ***actual overpayments*** from strata 2 and 4 ($39,907) to the lower [extrapolated] limit ($1,745,075), which resulted in an adjusted lower limit of $1,784,982.").

72 *See, generally,* 5 U.S.C. App. § 2 *et seq.*

- Several different Medicare review contractors reviewing Hoveround claims for the same year evaluated by the OIG Contractors (2010) reached dramatically different results. All of these entities were examining medical necessity, and the larger sample sizes reviewed in connection with the ADR and RAC reviews indicate those audits have a greater measure of reliability. The ADR reviews resulted in an 87.7 percent (87.7%) affirmance rate and the RAC audits resulted in a 98.9 percent (98.9%) affirmance rate, while the Initial Review Contractor found an implausible 7.0 percent (7.0%) rate of claim affirmation and the DME MACs affirmed only 10.5% of claims reviewed.

- After the Draft Report was issued, nationally renowned consulting experts reviewed the very same claims as those audited by the OIG Contractors, applied the very same standards the OIG Contractors should have applied, and reached vastly different results. The work highlights a fundamental failure by the OIG Contractors to use the governing medical necessity standards applicable to the audited claims.

- OIG failed to provide Hoveround with adequate notice of the medical necessity review its Initial Review Contractor was purporting to conduct. Indeed, when explicitly questioned as to whether OIG was conducting a medical necessity review, its auditors expressly indicated that they were not conducting such a review. This failure and uninformed representation deprived Hoveround of the opportunity to collect, collate, and submit sufficient evidence necessary to inform any medical necessity evaluation, resulting in flawed review results from OIG's Initial Review Contractor.

- The medical necessity review conducted by the OIG's Initial Review Contractor and DME MACs was grossly inadequate, in large part due to the improper, retroactive application of documentation and medical necessity review standards adopted after the dates of service of these claims. The OIG's review contractors also misapplied the governing medical necessity standards, neglected to collect the entire medical record, and in those rare instances when it did have the entire medical record, failed to review and consider all parts of the medical record.

- By sharing the flawed results of the Initial Review Contractor, OIG tainted the results of the Second Review conducted by the DME MACs and amplified potential conflicts of interest that undermined the conclusions of the Second Review to such an extent that they must be disregarded.

- The statistical methods, stratification techniques, and extrapolation mechanics employed by OIG are inconsistent with government requirements and contradictory to the OIG's own internal policies and past practices.

For these reasons, Hoveround urges that the Second Draft Audit Report be withdrawn and the audit terminated. Additionally, Hoveround respectfully disagrees with both of the Draft Report's recommendations:

1) Hoveround disagrees that it should refund the recommended amount to the federal government, since 188 of 200 claims were documented and submitted in accordance with Medicare requirements. Moreover, Hoveround disagrees that OIG obtained sufficient or appropriate evidence to extrapolate the findings of this sample and urges OIG to limit its findings and recommendations to the sample claims reviewed to the extent OIG determines to issue the Draft Report.

2) Hoveround already maintains comprehensive internal controls and strives for full compliance with Medicare requirements regarding (a) the medical necessity criteria for PMDs, and (b) obtaining supporting documentation that meets Medicare requirements before providing PMDs to Medicare beneficiaries.

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The serious flaws in the process and methodology of the OIG's review invalidate the findings in the Second Draft Audit Report and undermine the proposed recommendations. Hoveround respectfully requests the immediate withdrawal of the Second Draft Audit Report and the audit terminated.