

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE HOME HEALTH AGENCY  
PROVIDER COMPLIANCE AUDIT:  
VISITING NURSE ASSOCIATION OF  
MARYLAND**

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A-03-17-00009**

# ***Office of Inspector General***

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## Report in Brief

Date: April 2021

Report No. A-03-17-00009

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

Under the home health prospective payment system (PPS) during calendar years 2015 and 2016, the Centers for Medicare & Medicaid Services paid home health agencies (HHAs) a standardized payment for each 60-day episode of care that a beneficiary received. The PPS payment covers part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies.

Our prior audits of home health services identified significant overpayments to HHAs. These overpayments were largely the result of HHAs improperly billing for services to beneficiaries who were not confined to the home (homebound) or were not in need of skilled services.

Our objective was to determine whether Visiting Nurse Association of Maryland (VNA) complied with Medicare requirements for billing home health services on selected types of claims.

### How OIG Did This Audit

We selected a stratified random sample of 100 home health claims and submitted these claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

## Medicare Home Health Agency Provider Compliance Audit: Visiting Nurse Association of Maryland

### What OIG Found

VNA did not comply with Medicare billing requirements for 19 of the 100 home health claims that we audited. For these claims, VNA received overpayments of \$25,295 for services provided in calendar years 2015 and 2016. Specifically, VNA incorrectly billed Medicare for: (1) services provided to beneficiaries who were not homebound, (2) services provided to beneficiaries who did not require skilled services, (3) services that were not delivered in accordance with the beneficiary's plan of care, and (4) claims that were assigned with incorrect Health Insurance Prospective Payment System (HIPPS) payment codes. On the basis of our sample results, we estimated that VNA received overpayments of at least \$2.1 million for the audit period. All 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

### What OIG Recommends and VNA Comments

We recommend that VNA exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any returned overpayments as having been made in accordance with this recommendation. We also recommend that VNA ensure that: (1) the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented, (2) beneficiaries are receiving only reasonable and necessary skilled services, (3) services are provided in accordance with beneficiaries' plans of care, and (4) the correct HIPPS payment codes are billed.

In written comments on our draft report, VNA stated that it disagreed with the majority of our findings. VNA concurred with our finding regarding the homebound determination for one claim and also concurred that an incorrect HIPPS payment code was assigned to two sampled claims identified in our draft report. VNA stated that it would promptly make a repayment for those three claims but also stated that it did not have any repayment obligation with respect to the other claims that we found were paid in error. VNA retained a health care consultant to review the claims we questioned and challenged our independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were billed correctly. To address these concerns, we had our independent medical review contractor review VNA's written comments on our draft report as well as the spreadsheet prepared by VNA's consultant. Based on the results of that review, we reduced the sampled claims incorrectly billed from 36 to 19 and revised the related finding and recommendations. We maintain that our remaining findings and recommendations, as revised, are valid.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

For calendar year (CY) 2016, Medicare paid home health agencies (HHAs) about \$18 billion for home health services. The Centers for Medicare & Medicaid Services (CMS) determined through its Comprehensive Error Rate Testing program that the 2016 improper payment error rate for home health claims was 42 percent, or about \$7.7 billion. Although Medicare spending for home health care accounts only for about 5 percent of fee-for-service spending, improper payments to HHAs account for more than 18 percent of the total 2016 fee-for-service improper payments (\$41 billion).

This audit is part of a series of audits of HHAs. Using computer matching, data mining, and data analysis techniques, we identified HHAs at risk for noncompliance with Medicare billing requirements. Visiting Nurse Association of Maryland (VNA) was one of those HHAs.

### OBJECTIVE

Our objective was to determine whether VNA complied with Medicare requirements for billing home health services on selected types of claims.

### BACKGROUND

#### The Medicare Program and Payments for Home Health Services

Medicare Parts A and B cover eligible home health services under a prospective payment system (PPS). The PPS covers part-time or intermittent skilled nursing care and home health aide visits, therapy (physical, occupational, and speech-language pathology), medical social services, and medical supplies. Under the home health PPS, CMS pays HHAs for each 60-day episode of care that a beneficiary receives.<sup>1</sup>

CMS adjusts the 60-day episode payments using a case-mix methodology based on data elements from the Outcome and Assessment Information Set (OASIS). The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical severity, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups, to monitor the effects of treatment on patient care and outcomes, and to determine whether adjustments to the case-mix groups are warranted. The OASIS classifies HHA beneficiaries into 153 case-mix groups that are used as the basis for the Health Insurance Prospective Payment System (HIPPS)

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<sup>1</sup> Effective January 1, 2020, CMS changed the length of an episode of care from 60 days to 30 days.

payment codes<sup>2</sup> and represent specific sets of patient characteristics.<sup>3</sup> CMS requires HHAs to submit OASIS data as a condition of payment.<sup>4</sup>

CMS administers the Medicare program and contracts with four of its Medicare administrative contractors to process and pay claims submitted by HHAs.

### **Home Health Agency Claims at Risk for Incorrect Billing**

In prior years, our audits at other HHAs identified findings in the following areas:

- beneficiaries did not always meet the definition of “confined to the home,”
- beneficiaries were not always in need of skilled services,
- HHAs did not always submit the OASIS in a timely fashion, and
- services were not always adequately documented.

For the purposes of this report, we refer to these areas of incorrect billing as “risk areas.”

### **Medicare Requirements for Home Health Agency Claims and Payments**

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (Social Security Act (the Act) § 1862(a)(1)(A)). Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act and regulations at 42 CFR section 409.42 require, as a condition of payment for home health services, that a physician certify and recertify that the Medicare beneficiary is:

- confined to the home (homebound);
- in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or has a continuing need for occupational therapy;
- under the care of a physician; and

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<sup>2</sup> HIPPS payment codes represent specific sets of patient characteristics (or case-mix groups) on which payment determinations are made under several Medicare prospective payment systems, including those for skilled nursing facilities, inpatient rehabilitation facilities, and HHAs.

<sup>3</sup> The final payment is determined at the conclusion of the episode of care using the OASIS information but also factoring in the number and type of home health services provided during the episode of care.

<sup>4</sup> 42 CFR §§ 484.20, 484.55, 484.210(e), and 484.250(a)(1), 74 Fed. Reg. 58077, 58110-58111 (Nov. 10, 2009), and CMS’s *Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1.

- receiving services under a plan of care that has been established and periodically reviewed by a physician.

Furthermore, as a condition for payment, a physician must certify that a face-to-face encounter occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of care (42 CFR § 424.22(a)(1)(v)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

The determination of “whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS as required by 42 CFR 484.55 or a medical record of the individual patient” (*Medicare Benefit Policy Manual* (the Manual), chapter 7, § 20.1.2). Coverage determination is not made solely on the basis of general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care (42 CFR § 409.44(a)).

Appendix B contains the details of selected Medicare coverage and payment requirements for HHAs.

### **Medicare Requirements for Providers To Identify and Return Overpayments**

The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of: (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>5</sup>

The 6-year lookback period is not limited by OIG’s audit period or restrictions on the Government’s ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>6</sup>

### **Visiting Nurse Association of Maryland**

VNA is a home health care provider with its main office in Baltimore, Maryland. CGS Administrators, LLC, its Medicare administrative contractor, paid VNA approximately

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<sup>5</sup> The Act § 1128J(d); 42 CFR §§ 401.301-401.305; and 81 Fed. Reg. 7654 (Feb. 12, 2016).

<sup>6</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, *Provider Reimbursement Manual*, Pub. No. 15-1, part 1, § 2931.2; 81 Fed. Reg at 7670.

\$49.1 million for 15,472 claims for services provided in CYs 2015 and 2016 (audit period) on the basis of CMS's National Claims History (NCH) data.

## **HOW WE CONDUCTED THIS AUDIT**

Our audit covered approximately \$45.6 million in Medicare payments to VNA for 14,703 claims.<sup>7</sup> These claims were for home health services provided in CYs 2015 and 2016.<sup>8</sup> We selected a stratified random sample of 100 claims with payments totaling \$344,525 for review. We evaluated these claims for compliance with selected billing requirements and submitted these claims to independent medical review to determine whether the services met coverage, medical necessity, and coding requirements.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit 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 scope and methodology, Appendix C contains our statistical sampling methodology, Appendix D contains our sample results and estimates, and Appendix E contains the types of errors by sample item.<sup>9</sup>

## **FINDINGS**

VNA did not comply with Medicare billing requirements for 19 of the 100 home health claims that we audited. For these claims, VNA received overpayments of \$25,295 for services provided in CYs 2015 and 2016. Specifically, VNA incorrectly billed Medicare for:

- services provided to beneficiaries who were not homebound,
- services provided to beneficiaries who did not require skilled services,
- services that were not delivered in accordance with the beneficiary's plan of care, and
- claims that were assigned incorrect HIPPS payment codes.

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<sup>7</sup> In developing this sampling frame, we excluded from our review home health claim payments for low utilization payment adjustments, claims less than \$1,000, partial episode payments associated with HHA transfers, claims that were excluded by another entity, and requests for anticipated payments.

<sup>8</sup> CYs were determined by the HHA claims' "through" dates of service. The through date is the last day on the billing statement covering services provided to the beneficiary.

<sup>9</sup> Sample items may have more than one type of error.

These errors occurred primarily because VNA did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas.

On the basis of our sample results, we estimated that VNA received overpayments of at least \$2.1 million for the audit period.<sup>10</sup> As of the publication of this report, all 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

## **VISITING NURSE ASSOCIATION BILLING ERRORS**

VNA incorrectly billed Medicare for 19 of the 100 sampled claims, which resulted in overpayments of \$25,295.

### **Beneficiaries Were Not Homebound**

#### *Federal Requirements for Home Health Services*

For the reimbursement of home health services, the beneficiary must be “confined to his home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42)). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1). Revision 172 of section 30.1.1 (effective November 19, 2013) and Revision 208 of section 30.1.1 (effective January 1, 2015) covered our audit period.

Revisions 172 and 208 state that for a patient to be eligible to receive covered home health services under both Part A and B, the law requires that a physician certify in all cases that the

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<sup>10</sup> VNA received overpayments of at least \$2,138,299. To be conservative, we estimated overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

patient is confined to his or her home and an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

#### *Criterion One*

The patient must either:

- because of illness or injury, need the aid of supportive devices, such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave his or her place of residence or
- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criterion One conditions, then the patient must also meet two additional requirements defined in Criterion Two below.

#### *Criterion Two*

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

#### *VNA Did Not Always Meet Federal Requirements for Home Health Services*

For 16 of the sampled claims, VNA incorrectly billed Medicare for home health episodes for beneficiaries who did not meet the above requirement for being homebound for the full episode (6 claims) or for a portion thereof (10 claims).<sup>11</sup>

#### **Example 1: Beneficiary Not Homebound – Entire Episode**

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The physical therapy evaluation documentation for one beneficiary showed that, from the start of the episode, the patient was able to transfer and ambulate with a one-handed assistive device on both even and uneven surfaces and on stairs, and he had caregiver assistance available. For the entire episode, leaving the home did not require a considerable or taxing effort.

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#### **Example 2: Beneficiary Not Homebound – Partial Episode**

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For another beneficiary, records showed that the patient was initially homebound and was being treated for myocardial infarction. The patient had shortness of breath when walking more than 20 feet or when climbing stairs. At the start of care, leaving the home would have required a considerable and taxing effort for this patient. By a later date in the episode, the patient was able

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<sup>11</sup> Of these 16 claims with homebound errors, 2 claims were also billed with skilled services that were not medically necessary and 1 claim was also billed with an incorrect HIPPS code. Appendix E provides detail on the extent of errors, if any, per claim reviewed.

to ambulate 165 feet and had progressed to higher-level gait activities and ambulation outdoors. The patient was able to ambulate on unlevel surfaces without hands-on assistance. Leaving the home would no longer require a considerable and taxing effort.

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These errors occurred primarily because VNA did not have adequate controls to prevent the incorrect billing of Medicare claims within selected risk areas. VNA did not provide a reason why these errors occurred because VNA officials contended that these claims met Medicare requirements.

### **Beneficiaries Did Not Require Skilled Services**

#### *Federal Requirements for Skilled Services*

A Medicare beneficiary must be in need of either skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or have a continuing need for occupational therapy (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42(c)). In addition, skilled nursing services must require the skills of a registered nurse or a licensed practical nurse under the supervision of a registered nurse, must be reasonable and necessary to the treatment of the patient's illness or injury, and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).<sup>12</sup> Skilled therapy services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition (42 CFR § 409.44(c) and the Manual, chapter 7, § 40.2.1). Coverage of skilled nursing care or therapy does not turn on the presence or absence of a patient's potential for improvement but rather on the patient's need for skilled care. Skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition (the Manual, chapter 7, § 20.1.2).

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<sup>12</sup> Skilled nursing services can include observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things (the Manual, chapter 7, § 40.1.2).

## *VNA Did Not Always Meet Federal Requirements for Skilled Services*

For four of the sampled claims, VNA incorrectly billed Medicare for an entire home health episode (1 claim) or a portion of an episode (3 claims) for beneficiaries who did not meet the Medicare requirements for coverage of skilled nursing or therapy services.<sup>13, 14</sup>

### **Example 3: Beneficiary Did Not Require Skilled Services**

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The medical information for a beneficiary supported that the beneficiary was homebound at the start of care and remained homebound throughout the home health episode. Home health services were ordered for monitoring, medication oversight, and education. Home health services were to assess the beneficiary's activities for daily living and adaptive device use as well as the beneficiary's training in wheelchair transfers. A physical therapy evaluation was indicated to assess the beneficiary's mobility and need for an assistive device or home exercise program. However, the beneficiary had been non-ambulatory for a long period of time and was receiving occupational therapy treatments addressing his mobility impairment and remaining activities of daily living. Ongoing physical therapy services were excessive after the initial evaluation.

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These errors occurred primarily because VNA did not have adequate controls to prevent the incorrect billing of Medicare claims within selected risk areas. VNA did not provide a reason why these errors occurred because VNA officials contended that these claims met Medicare requirements.

### **Services Were Not Delivered in Accordance With the Plan of Care**

As a condition of coverage and payment, 42 CFR sections 409.42(d) and 424.22(a)(1)(iii) require that a plan of care be established and periodically reviewed by a physician. The plan of care must include those items listed in 42 CFR section 484.18(a). Federal regulations at 42 CFR section 484.18(a) state, "Orders for therapy services include the specific procedures and modalities to be used and the amount, frequency, and duration." In addition, 42 CFR section 409.43(b) states, "The physician's orders for services in the plan of care must specify the medical treatments to be furnished as well as the type of home health discipline that will furnish the ordered services and at what frequency the services will be furnished."

For one sampled claim, VNA did not deliver services in accordance with the plan of care. For the claim, a physical therapy visit was made that was not covered by a physician's order.

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<sup>13</sup> Of these four claims with skilled need services that were not medically necessary, two claims were also billed for beneficiaries with homebound errors and one claim included services that were not delivered in accordance with the plan of care. Appendix E provides details on the extent of errors, if any, per claim reviewed.

<sup>14</sup> For all four claims that did not always meet Federal requirements for skilled services, skilled nursing services were necessary for either the entire home health episode or a portion of the episode. However, at least one of the billed skilled therapy services was not.

Physical therapy had discharged the patient on an earlier date; a new physical therapy order was not received until after the physical therapy visit.

VNA did not provide a reason why this error occurred because VNA officials contended that the claim met Medicare requirements.

### **Incorrect Health Insurance Prospective Payment System Codes Were Assigned to Claims**

#### *Federal Requirements for Billing Health Insurance Prospective Payment System Codes*

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, states, “In order to be processed correctly and promptly, a bill must be completed accurately” (*Medicare Claims Processing Manual*, Pub No. 100-04, chapter 1, § 80.3.2.2).

#### *VNA Did Not Always Meet Federal Requirements for Billing Health Insurance Prospective Payment System Codes*

For two sampled claims, VNA assigned incorrect HIPPS payment codes to the claims.<sup>15</sup> The OASIS and other supporting medical records did not support the HIPPS billing code that VNA used. The incorrect HIPPS billing codes resulted in higher HHA payment for the two claims. Using the correct HIPPS billing code, we computed the payment amount in error by subtracting the correct payment amount from the original payment.<sup>16</sup>

VNA did not provide a reason why these errors occurred because VNA officials contended that these claims met Medicare requirements.

### **OVERALL ESTIMATE OF OVERPAYMENTS**

On the basis of our sample results, we estimated that VNA received overpayments totaling at least \$2.1 million for the audit period. As of the publication of this report, all 100 claims in our sample are outside of the Medicare 4-year claim-reopening period.

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<sup>15</sup> One of the two claims was billed for a beneficiary also associated with a homebound error. Appendix E provides details on the extent of errors, if any, per claim reviewed.

<sup>16</sup> We also made adjustments to the claim due to a homebound error.

## RECOMMENDATIONS

We recommend that Visiting Nurse Association of Maryland:<sup>17</sup>

- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule and identify any returned overpayments as having been made in accordance with this recommendation and
- ensure that:
  - the homebound statuses of Medicare beneficiaries are verified and continually monitored and the specific factors qualifying beneficiaries as homebound are documented,
  - beneficiaries are receiving only reasonable and necessary skilled services,
  - services are provided in accordance with beneficiaries' plans of care, and
  - the correct HIPPS payment codes are billed.

### VISITING NURSE ASSOCIATION COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, VNA stated that it disagreed with the majority of our findings. VNA concurred with our finding regarding the homebound determination for one claim and also concurred that an incorrect HIPPS payment code was assigned to two sampled claims identified in our draft report. VNA stated that it would promptly make a repayment for those three claims but also stated that it did not have any repayment obligation with respect to the other claims that we found were paid in error. Moreover, VNA stated that it was not possible to implement any corrective actions because VNA was no longer a provider after being sold. VNA acknowledged that it will remain responsible for dealing with this audit.

VNA retained a health care consultant to review the claims we questioned and submitted to us a spreadsheet with comments for each claim questioned. VNA challenged our independent medical review contractor's decisions, maintaining that nearly all of the sampled claims were

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<sup>17</sup> Our draft report contained a recommendation that VNA refund to the Medicare program the portion of the estimated overpayment for claims incorrectly billed that were within the reopening period. As of the date of issuance of this final report, all estimated overpayments are beyond the reopening period. Therefore, we have removed the recommendation to refund them. We have also consolidated our two 60-day rule recommendations that appeared in our draft report into one that appears in this final report.

billed correctly. VNA's comments, excluding the spreadsheet with claim-by-claim comments, appear as Appendix F.<sup>18</sup> We are providing VNA's comments in their entirety to CMS.

To address VNA's concerns related to the medical review decisions, we had our independent medical review contractor review VNA's written comments on our draft report as well as the spreadsheet prepared by VNA's consultant. Based on the results of that review, we revised our determinations, reducing the total number of sampled claims incorrectly billed from 36 to 19, and revised our related findings and recommendations accordingly. We also adjusted the finding for 5 of these 19 claims. The overpayment amount decreased for two claims, increased for one claim, and did not change for two claims. With these actions taken, we maintain that our remaining findings and recommendations are valid, although we acknowledge VNA's right to appeal the findings. Below is a summary of the reasons that VNA did not concur with our recommendations and disputed our findings, as well as our responses.

## **BENEFICIARY HOMEBOUND STATUS**

### **Visiting Nurse Association Comments**

VNA disagreed with the medical reviewer's determinations that the beneficiary was not homebound under Medicare standards: (1) for the entire episode of care for 5 sampled claims and (2) for part of the episode of care for 23 sampled claims. VNA objected to the use of any specific ambulation distance, degree of motion, accessibility of the home in which the beneficiary resides, or any other "rule of thumb" for deciding whether a beneficiary is homebound in accordance with the Medicare rules and CMS's interpretive guidance. VNA stated that the rationale given for denying certain claims did not provide the required detailed analysis or an explanation why leaving the home would no longer have required a considerable and taxing effort.

### **Office of Inspector General Response**

Based on the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to homebound status (and the associated recommended disallowance) to specify that 16, rather than 28, sampled claims were associated with beneficiaries who did not meet the criteria for being homebound (6 claims for the full episode of care and 10 claims for part of the episode of care). Specifically, we revised our finding to indicate that 12 claims we had identified as an error in our draft report were not an

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<sup>18</sup> VNA included a comprehensive spreadsheet with comments as part of its comments on our draft report. This spreadsheet, prepared by VNA's health care consultant, contained a claim-by-claim rebuttal of the findings in our draft report. We provided this spreadsheet to our independent medical review contractor as part of our request for an additional review of claims identified as having errors. However, because this spreadsheet was long and contained a considerable amount of personally identifiable information, we excluded it from this report.

error and identified 1 claim as an error for the entire episode of care and not as an error for part of the episode of care.<sup>19</sup>

We disagree with VNA's assertion that our medical review contractor allowed individual clinical factors to determine homebound status and, therefore, failed to consider the entire medical record. Our medical review contractor prepared detailed medical review determination reports that documented relevant facts and the results of the reviewer's analysis. We provided these reports to VNA after issuing our draft report. Each determination report included a detailed set of facts based on a thorough review of the entire medical record for the beneficiary associated with the sampled claim. For all sampled claims, our medical reviewer considered the entire medical record and relied on the relevant and salient facts necessary to determine whether the beneficiary met the criteria for being homebound in accordance with CMS's definition of homebound status.

Ambulation distance is one factor among others that our medical reviewer considered in determining beneficiaries' homebound status. In each medical review determination report, our medical reviewer reviewed and documented in detail the beneficiary's relevant medical history, including diagnoses, skilled nursing or therapy assessments, cognitive function, and mobility. The determination of homebound status and whether claims meet Medicare requirements must be based on each beneficiary's individual characteristics as reflected in the available medical record. Our medical reviewer carefully considered ability to ambulate in conjunction with the individual characteristics noted in each beneficiary's medical record. Ambulation distance is not noted in all of the decisions, and when it is, it is simply one factor the reviewer considered in making the homebound status determination. This is evident from the relevant facts and discussion included in the individual decisions.

Our independent medical review contractor took VNA's comments into consideration when performing its additional medical review and revised the determinations accordingly.

Accordingly, having revised our findings and the associated recommendation for the 28 claims identified as homebound errors in our draft report to indicate that 12 claims were not homebound errors and 1 claim was a homebound error for the entire episode of care and not for part of the episode of care, we maintain that our homebound error findings for the remaining 16 claims, and the revised recommendation, are valid.

## **SKILLED SERVICES**

### **Visiting Nurse Association Comments**

VNA disagreed with all 12 medical review determinations for beneficiaries who did not meet Medicare requirements for coverage of skilled services. VNA stated that, based on the

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<sup>19</sup> In our draft report, one claim was identified as not meeting the requirements for part of the episode of care. Our independent medical review contractor's additional medical review determined that the claim did not meet the requirement for being homebound for the full episode of care, which increased the error amount for this claim.

rationale applied by the medical reviewer, it did not appear that coverage for “observation and assessment,” “management and evaluation of a patient plan of care,” or “teaching and training” was considered. VNA also stated that the medical reviewer’s conclusions reflected a lack of understanding of the differences between physical and occupational therapy and a lack of ability to determine the need for each type of therapy to treat the beneficiary’s medical conditions and functional losses. VNA said that the conclusions highlighted the errors that occur when the review is not provided by a professional of the same discipline who understands the scope of practice. VNA stated that if a professional of the same discipline were to review a claim shown as an example, that professional would reach the decision that the beneficiary needed both physical and occupational therapy.

### **Office of Inspector General Response**

Based on the conclusions of our independent medical review contractor’s additional medical review, we revised our findings related to skilled services to specify that 4, rather than 12, sampled claims were associated with beneficiaries who did not meet Medicare requirements for coverage of skilled nursing or therapy services.

Our medical review contractor’s determinations of the medical necessity of skilled therapy services were made in accordance with the Manual, chapter 7, section 40.2. In accordance with these CMS guidelines, it is necessary to determine whether individual therapy services are skilled and whether, in view of the beneficiary’s overall condition, skilled management of the services provided is needed. The guidelines also state that although a beneficiary’s particular medical condition is a valid factor in deciding whether skilled therapy services are needed, a beneficiary’s diagnosis or prognosis should never be the sole factor in deciding whether a service is or is not skilled. The key issue is whether the skills of a therapist are needed to treat the illness or injury or whether the services can be carried out by nonskilled personnel. The skilled therapy services must be reasonable and necessary for the treatment of the beneficiary’s illness or injury within the context of the beneficiary’s unique medical condition.

Skilled nursing services may include observation and assessment of a beneficiary’s condition (the Manual, chapter 7, § 40.1.2). To determine the medical necessity of skilled nursing for observation and assessment, our medical review contractor considered the reasonable potential of a change in condition, a complication, or a further acute episode (e.g., a high risk of complications) under the provisions of the Manual, chapter 7, section 40.1.2.1.

Rather than disregarding the Manual’s guidance related to the medical necessity of home health skilled nursing, the medical review contractor examined all of the material in the records and documentation submitted by VNA and carefully considered this information to determine whether VNA billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that VNA provided after we issued our draft report. For all medical review, the independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements.

Accordingly, having revised our findings and the associated recommendation with respect to eight of the sampled claims identified in our draft report, we maintain that our findings for the remaining four claims, and the revised recommendation, are valid.

## **QUALIFICATIONS OF THE MEDICAL REVIEW CONTRACTOR**

### **Visiting Nurse Association Comments**

VNA expressed concerns about the medical reviewer's qualifications and stated that "for each claim reviewed, the OIG reviewer/s were a physician or additionally a certified coding specialist/registered health information technician, not clinicians with specialized expertise in nursing, physical therapy, occupational therapy, or speech language pathology, as required by the Medicare Program Integrity Manual ("MPIM"), CMS Pub. 100-08." VNA also stated that the reviewer's "biography" does not show that the reviewer is "board certified in physical medicine and rehabilitation or neurology, such that the physician would have received training in assessing rehabilitation needs, or in a specialty that would render the physician qualified to assess homebound status." VNA also stated that each of the reviewer's medical determinations contains the same narrative statement that the reviewer is a "physician who is duly licensed to practice medicine," "knowledgeable in the treatment of the enrollee's medical condition," and "familiar with the guidelines and protocols in the area of treatment under review." In addition, VNA said that "there is no indication of the physician reviewer's specialty here, which is particularly important given that the services under review involved making decisions regarding homebound status and/or the medical reasonableness and necessity of skilled physical therapy, occupational therapy, and speech language pathology services."

### **Office of Inspector General Response**

With respect to the qualifications of OIG's medical reviewers, the contract with our independent medical review contractor requires that all claims with a medical necessity determination be reviewed by two clinicians before being provided to OIG. The second-level reviews are to be conducted by the medical director or a physician with the same qualifications who had experience in the appropriate specialty under review. Specifically, all medical necessity determinations were made by licensed physicians who were board certified in an area appropriate to the treatment under review. All reviewers were also required to be free of any conflict of interest.

## **ESTIMATION OF OVERPAYMENTS**

### **Visiting Nurse Association Comments**

VNA stated that the claims it concurred with accounted for less than one percent of the total payment for the 100 audited claims and that that error rate is too low to allow extrapolation. VNA further stated that if the error rate were to be recalculated, any remaining isolated payment errors for a particular claim would not rise to the "sustained or high level of payment error" required by the statute to support extrapolation.

VNA also stated that it had concerns with our statistical sampling and extrapolation methodology. VNA stated that we did not disclose how the sample size was calculated and how the strata were identified, and we did not provide VNA with the universe of claims, which it needed to determine whether the strata were properly selected and confirm whether the extrapolation calculation was correct. VNA said that it was unable to replicate the sample selection because it did not have access to these documents.

Finally, VNA stated that the sampling frame was flawed because of the presence of a duplicate claim. The claim line items had the same beneficiary Health Insurance Claim number, beneficiary date of birth, claim from date, and paid amount.

### **Office of Inspector General Response**

We carefully considered VNA's comments on our sampling and estimation methods, and we maintain that our statistical approach resulted in a legally valid and reasonably conservative estimate of the amount overpaid by Medicare to VNA. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>20</sup>

VNA's statement that extrapolation would be inappropriate if we were to remove all but the three claims with VNA concurrences because our error rate would not support a "sustained or high level of payment error" according to guidelines prescribed for CMS and its contractors is not applicable because OIG is not a Medicare contractor.<sup>21</sup> The Medicare Program Integrity Manual (PIM) and the statutory provisions upon which the PIM guidelines are based do not prohibit CMS from accepting and acting upon any monetary recommendation we may make.

The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>22</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. These formulas properly accounted for the allocation of sample items across strata.

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<sup>20</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (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).

<sup>21</sup> The Act § 1839(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4 (effective Jan. 2, 2019).

<sup>22</sup> 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); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

To account for our choice of sample size and stratification, we estimated the overpayment amount using the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment in the sampling frame 95 percent of the time. The use of the lower limit accounts for the sample design, including the choice of strata bounds and the manner that the sample was allocated across strata, in a manner that favors the auditee.<sup>23</sup>

We provided VNA with all the information necessary to replicate the sample from the sampling frame and recalculate the overpayment estimate amount included in the report. VNA has direct access to the claim information necessary to validate the sampling frame.<sup>24</sup> We informed VNA of the process for requesting information outside the scope of our estimate.

With respect to VNA's statement that the sampling frame contained a duplicate claim, we reviewed the relevant claims and found that they represent separate claims billed by VNA. The appearance that there were duplicate items arose from VNA canceling one claim and then creating a new claim for the same service but with different values in the "Statement Covers Period Through Date" field. If the original claim was selected in the sample, we would have properly coded the claim as having no overpayment because it was canceled. If the rebilled claim was selected, we would have reviewed that claim in the same manner as any other claims. The treatment of the original or rebilled claim would be no different from what it would have been had we reviewed all the items in the sampling frame. Therefore, the presence of these claims in the frame did not bias our estimate.

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<sup>23</sup> See e.g., *Puerto Rico Dep't of Health*, DAB No. 2385, at 10 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

<sup>24</sup> There appears to be some confusion about the term "universe." The term most commonly refers to either the set of items that the sample was selected from or the set of items that the estimate applies to. The sampling frame that we provided to VNA meets both of these definitions. We understand VNA to be requesting claims that extend beyond our sample and estimate. Such claims were not used to determine the stratification or to calculate our estimate.

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered \$45,592,754 in Medicare payments to VNA for 14,703 home health claims with episode-of-care through dates in CYs 2015 and 2016. From this sampling frame, we selected for review a stratified random sample of 100 home health claims with payments totaling \$344,525.

We evaluated compliance with selected billing requirements and submitted the sampled claims to an independent medical review contractor to determine whether the services met coverage, medical necessity, and coding requirements.

We limited our review of VNA's internal controls to those applicable to specific Medicare billing procedures because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established reasonable assurance of the authenticity and accuracy of the data obtained from CMS's NCH file, but we did not assess the completeness of the file.

We conducted our audit from September 2017 through October 2020. Our audit work included: (1) fieldwork performed at VNA's offices in Baltimore, Maryland; (2) medical review performed by our independent medical review contractor, the results of which were included in our draft report; and (3) additional medical review performed by our independent medical review contractor after we received VNA's written comments on our draft report. We incorporated the results of the additional medical review into our final report.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted VNA's paid claims data from CMS's NCH file for the audit period;
- removed from our sampling frame payments that were: (1) for services provided in CY 2017, (2) less than \$1,000, (3) low-utilization payment adjustments, (4) partial episode payments, (5) requests for anticipated payments, and (6) identified in the Recovery Audit Contractor data warehouse as having been previously excluded by other entities;
- selected for detailed review a stratified random sample of 100 home health claims totaling \$344,525 (Appendix C);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been canceled or adjusted;

- obtained and reviewed billing and medical record documentation provided by VNA to support the claims sampled;
- reviewed the sampled claims for compliance with known risk areas;
- used an independent medical review contractor to determine whether the 100 claims contained in the sample were reasonable and necessary and met Medicare coverage and coding requirements;
- reviewed VNA's procedures for billing and submitting Medicare claims;
- verified State licensure information for selected medical personnel providing services to the beneficiaries in our sample;
- calculated the correct payments for those claims requiring adjustments;
- used the results of our sample to estimate the total Medicare overpayments to VNA for our audit period (Appendix D);
- discussed the results of our audit with VNA officials; and
- after receiving VNA's written comments on our draft report, had our independent medical review contractor perform an additional medical review of all claims questioned in our draft report and incorporated the results of that additional medical review into our own analysis and determination of the allowability of the claims in light of VNA's comments.

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

## **APPENDIX B: MEDICARE REQUIREMENTS FOR COVERAGE AND PAYMENT OF CLAIMS FOR HOME HEALTH SERVICES**

### **GENERAL MEDICARE REQUIREMENTS**

Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)).

CMS’s *Medicare Claims Processing Manual*, Pub. No. 100-04, states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

### **OUTCOME AND ASSESSMENT INFORMATION SET DATA**

The OASIS is a standard set of data elements that HHA clinicians use to assess the clinical needs, functional status, and service utilization of a beneficiary receiving home health services. CMS uses OASIS data to assign beneficiaries to the appropriate categories, called case-mix groups; to monitor the effects of treatment on patient care and outcome; and to determine whether adjustments to the case-mix groups are warranted. HHA beneficiaries can be classified into 153 case-mix groups that are used as the basis for the HIPPS rate codes Medicare uses in its prospective payment systems. Case-mix groups represent specific sets of patient characteristics and are designed to classify patients who are similar clinically in terms of resources used.

CMS requires the submission of OASIS data as a condition of payment as of January 1, 2010 (42 CFR § 484.210(e); 74 Fed. Reg. 58078, 58110 (Nov. 10, 2009); and CMS’s *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 3, § 3.2.3.1).

### **COVERAGE AND PAYMENT REQUIREMENTS**

To qualify for home health services, Medicare beneficiaries must: (1) be homebound; (2) need intermittent skilled nursing care (other than solely for venipuncture for the purpose of obtaining a blood sample) or physical therapy, speech-language pathology, or occupational therapy;<sup>25</sup> (3) be under the care of a physician; and (4) be under a plan of care that has been established and periodically reviewed by a physician (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A), 42 CFR § 409.42, and the Manual, chapter 7, § 30).

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<sup>25</sup> Effective January 1, 2012, CMS clarified the status of occupational therapy to reflect when it becomes a qualifying service rather than a dependent service. Specifically, the first occupational therapy service, which is a dependent service, is covered only when followed by an intermittent skilled nursing care service, a physical therapy service, or a speech language pathology service as required by law. Once that requirement for covered occupational therapy has been met, however, all subsequent occupational therapy services that continue to meet the reasonable and necessary statutory requirements are considered qualifying services in both the current and subsequent certification periods (subsequent adjacent episodes) (76 Fed. Reg. 68526, 68590 (Nov. 4, 2011)).

Per the Manual, chapter 7, § 20.1.2, whether care is reasonable and necessary is based on information reflected in the home health plan of care, the OASIS, or a medical record of the individual patient.

The Act and Federal regulations state that Medicare pays for home health services only if a physician certifies that the beneficiary meets the above coverage requirements (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and 42 CFR § 424.22(a)).

Section 6407(a) of the Affordable Care Act<sup>26</sup> added a requirement to sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act that the physician have a face-to-face encounter with the beneficiary. In addition, the physician responsible for performing the initial certification must document that the face-to-face patient encounter, which is related to the primary reason the patient requires home health services, has occurred no more than 90 days prior to the home health start-of-care date or within 30 days of the start of the home health care by including the date of the encounter.<sup>27</sup>

### **Confined to the Home**

For reimbursement of home health services, the beneficiary must be “confined to his home” (the Act §§ 1814(a)(2)(C) and 1835(a)(2)(A) and Federal regulations (42 CFR § 409.42)). According to section 1814(a) of the Act:

[A]n individual shall be considered to be “confined to his home” if the individual has a condition, due to illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home,” the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual.

CMS provided further guidance and specific examples in the Manual (chapter 7, § 30.1.1).<sup>28</sup>

The Manual states that for a patient to be eligible to receive covered home health services under Medicare Part A or B, the law requires that a physician certify in all cases that the patient

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<sup>26</sup> The Patient Protection and Affordable Care Act, P.L. No.111-148 (Mar. 23, 2010), as amended by the Health Care and Education Reconciliation Act of 2010, P.L. No. 111-152 (Mar. 30, 2010), collectively known as the Affordable Care Act.

<sup>27</sup> See 42 CFR § 424.22(a)(1)(v) and the Manual, chapter 7, § 30.5. The initial effective date for the face-to-face requirement was January 1, 2011. However, on December 23, 2010, CMS granted HHAs additional time to establish protocols for newly required face-to-face encounters. Therefore, documentation regarding these encounters must be present on certifications for patients with starts of care on or after April 1, 2011.

<sup>28</sup> Revision 208 of § 30.1.1 (effective January 1, 2015) covered all of our audit period.

is confined to his or her home. For purposes of the statute, an individual will be considered “confined to the home” (homebound) if the following two criteria are met:

#### *Criterion One*

The patient must either:

- because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person in order to leave their place of residence or
- have a condition such that leaving his or her home is medically contraindicated.

If the patient meets one of the Criterion One conditions, then the patient must also meet two additional requirements defined in Criterion Two below.

#### *Criterion Two*

There must exist a normal inability to leave home, and leaving home must require a considerable and taxing effort.

#### **Need for Skilled Services**

##### *Intermittent Skilled Nursing Care*

To be covered as skilled nursing services, the services must require the skills of a registered nurse or a licensed practical (vocational) nurse under the supervision of a registered nurse; must be reasonable and necessary to the treatment of the patient’s illness or injury; and must be intermittent (42 CFR § 409.44(b) and the Manual, chapter 7, § 40.1).

The Act defines “part-time or intermittent services” as skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week (or, subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours each week) (the Act § 1861(m) and the Manual, chapter 7, § 50.7).

##### *Requiring Skills of a Licensed Nurse*

Federal regulations (42 CFR § 409.44(b)) state that in determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice. If the nature of a service is such that it can be safely and effectively performed by the average nonmedical person without direct supervision of a licensed nurse, the service may not be regarded as a skilled nursing service. The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary’s family or friends does not negate the skilled aspect of the service when performed by the nurse. If the service could be performed by the

average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

### *General Principles Governing Reasonable and Necessary Skilled Nursing Care*

Skilled nursing services are covered when an individualized assessment of the patient's clinical condition demonstrates that the specialized judgment, knowledge, and skills of a registered nurse or licensed practical (vocational) nurse are necessary to maintain the patient's current condition or prevent or slow further deterioration so long as the beneficiary requires skilled care for the services to be safely and effectively provided.

Some services may be classified as a skilled nursing service on the basis of complexity alone (e.g., intravenous and intramuscular injections or insertion of catheters) and, if reasonable and necessary to the patient's illness or injury, would be covered on that basis. If a service can be safely and effectively performed (or self-administered) by an unskilled person, without the direct supervision of a nurse, the service cannot be regarded as a skilled nursing service even though a nurse actually provides the service. However, in some cases, the condition of the patient may cause a service that would ordinarily be considered unskilled to be considered a skilled nursing service. This would occur when the patient's condition is such that the service can be safely and effectively provided only by a nurse. A service is not considered a skilled service merely because it is performed by or under the supervision of a nurse. The unavailability of a competent person to provide a nonskilled service does not make it a skilled service when a nurse provides the service.

A patient's overall medical condition, without regard to whether the illness or injury is acute, chronic, terminal, or expected to extend over a long period of time, should be considered in deciding whether skilled services are needed. A patient's diagnosis should never be the sole factor in deciding that a service the patient needs is either skilled or not skilled. Skilled care may, depending on the unique condition of the patient, continue to be necessary for patients whose condition is stable (the Manual, chapter 7, § 40.1.1).

### *Reasonable and Necessary Therapy Services*

Federal regulations (42 CFR § 409.44(c)) and the Manual (chapter 7, § 40.2.1) state that skilled services must be reasonable and necessary to the treatment of the patient's illness or injury or to the restoration or maintenance of function affected by the patient's illness or injury within the context of the patient's unique medical condition. To be considered reasonable and necessary for the treatment of the illness or injury, the therapy services must be:

- inherently complex, which means that they can be performed safely and effectively only by or under the general supervision of a skilled therapist;
- consistent with the nature and severity of the illness or injury and the patient's particular medical needs, which include services that are reasonable in amount, frequency, and duration; and

- considered specific, safe, and effective treatment for the patient’s condition under accepted standards of medical practice.

## **Documentation Requirements**

### *Face-to-Face Encounter*

Federal regulations (42 CFR § 424.22(a)(1)(v)) and the Manual (chapter 7, § 30.5.1) state that, prior to initially certifying the home health patient’s eligibility, the certifying physician must document that he or she, or an allowed nonphysician practitioner, had a face-to-face encounter with the patient that is related to the primary reason the patient requires home health services. In addition, the Manual (chapter 7, § 30.5.1) states that the certifying physician must document the encounter either on the certification, which the physician signs and dates, or a signed addendum to the certification.

### *Plan of Care*

The orders on the plan of care must indicate the type of services to be provided to the patient, both with respect to the professional who will provide them and the nature of the individual services, as well as the frequency of the services (the Manual, chapter 7, § 30.2.2). The plan of care must be reviewed and signed by the physician who established the plan of care, in consultation with HHA professional personnel, at least every 60 days. Each review of a patient’s plan of care must contain the signature of the physician and the date of review (42 CFR § 409.43(e) and the Manual, chapter 7, § 30.2.6).

## APPENDIX C: SAMPLE DESIGN AND METHODOLOGY

### SAMPLING FRAME

The sampling frame consisted of a database of 14,703 home health claims, valued at \$45,592,754, from CMS's NCH file.<sup>29</sup>

### SAMPLE UNIT

The sample unit was a home health claim.

### SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample.

**Table 1: Claims by Stratum**

Stratum	Frame Information			Sample Size
	Payment Range of Claims	Number of Claims	Total Value of Frame	
1	\$1,287.69 to \$2,737.46	6,886	\$15,412,002.58	34
2	\$2,739.78 to \$3,838.55	4,834	\$15,500,533.50	33
3	\$3,838.80 to \$8,296.59	2,983	\$14,680,218.28	33
<b>Total</b>		<b>14,703</b>	<b>\$45,592,754.36</b>	<b>100</b>

### SOURCE OF RANDOM NUMBERS

We generated the random numbers using the Office of Inspector General, Office of Audit Services (OAS), statistical software.

### METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in each stratum, and after generating the random numbers, we selected the corresponding frame items for review.

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<sup>29</sup> We excluded home health payments for low utilization adjustments, partial episode payments, and requests for anticipated payments. We also excluded paid claims less than \$1,000 and claims that had previously been reviewed by a Recovery Audit Contractor.

## **ESTIMATION METHODOLOGY**

We used the OAS statistical software to estimate the total amount of overpayments in the sampling frame that were paid to VNA during the audit period. To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total in the sampling frame 95 percent of the time.

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Table 2: Sample Results**

<b>Stratum</b>	<b>Frame Size</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Incorrectly Billed Sample Items</b>	<b>Value of Overpayments for Incorrectly Billed Sample Items</b>
1	6886	\$15,412,002.58	34	\$75,419	7	\$10,932
2	4834	15,500,533.50	33	108,188	6	4,692
3	2983	14,680,218.28	33	160,918	6	9,671
<b>Total</b>	<b>14,703</b>	<b>\$45,592,754.36</b>	<b>100</b>	<b>\$344,525</b>	<b>19</b>	<b>\$25,295</b>

**ESTIMATES**

**Table 3: Estimated Overpayments in the Sampling Frame  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$3,775,603
Lower limit	\$2,138,299
Upper limit	\$5,412,906

**APPENDIX E: TYPES OF ERRORS BY SAMPLE ITEM**

**STRATUM 1 (Samples 1–34)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Not in Accordance with Plan of Care</b>	<b>Incorrect HIPPS Code</b>	<b>Overpayment</b>
1	X	-	-	-	\$1,586
2	-	-	-	-	-
3	-	-	-	-	-
4	-	-	-	-	-
5	X	-	-	-	1,844
6	-	-	-	-	-
7	-	-	-	-	-
8	X	-	-	-	1,856
9	X	-	-	-	1,856
10	-	-	-	-	-
11	-	-	-	-	-
12	-	-	-	-	-
13	-	-	-	-	-
14	-	-	-	-	-
15	-	-	-	-	-
16	-	-	-	-	-
17	-	-	-	-	-
18	-	-	-	X	387
19	-	-	-	-	-
20	-	-	-	-	-
21	-	-	-	-	-
22	-	-	-	-	-
23	-	-	-	-	-
24	-	-	-	-	-
25	-	-	-	-	-
26	-	-	-	-	-
27	-	-	-	-	-
28	-	-	-	-	-
29	-	-	-	-	-
30	-	-	-	-	-
31	X	-	-	-	801
32	X	-	-	-	2,603
33	-	-	-	-	-
34	-	-	-	-	-

**STRATUM 2 (Samples 35–67)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Not Delivered in Accordance with Plan of Care</b>	<b>Incorrect HIPPS Code</b>	<b>Overpayment</b>
35	-	-	-	-	-
36	X	-	-	-	622
37	-	-	-	-	-
38	-	-	-	-	-
39	-	-	-	-	-
40	-	-	-	-	-
41	-	-	-	-	-
42	-	-	-	-	-
43	-	-	-	-	-
44	-	-	-	-	-
45	X	X	-	-	985
46	-	-	-	-	-
47	-	-	-	-	-
48	X	-	-	-	806
49	-	-	-	-	-
50	-	-	-	-	-
51	-	-	-	-	-
52	-	-	-	-	-
53	-	-	X	-	426
54	-	-	-	-	-
55	-	-	-	-	-
56	-	-	-	-	-
57	-	-	-	-	-
58	-	-	-	-	-
59	-	-	-	-	-
60	X	-	-	-	728
61	-	-	-	-	-
62	-	-	-	-	-
63	-	-	-	-	-
64	-	-	-	-	-
65	-	-	-	-	-
66	-	-	-	-	-
67	X	-	-	-	1,124

**STRATUM 3 (Samples 68–100)**

<b>Sample</b>	<b>Not Homebound</b>	<b>Did Not Require Skilled Services</b>	<b>Not Delivered in Accordance with Plan of Care</b>	<b>Incorrect HIPPS Code</b>	<b>Overpayment</b>
68	-	-	-	-	-
69	-	-	-	-	-
70	-	-	-	-	-
71	-	-	-	-	-
72	-	-	-	-	-
73	X	-	-	-	763
74	-	-	-	-	-
75	-	-	-	-	-
76	-	-	-	-	-
77	-	-	-	-	-
78	X	-	-	-	4,321
79	-	-	-	-	-
80	-	-	-	-	-
81	-	-	-	-	-
82	-	-	-	-	-
83	-	-	-	-	-
84	-	-	-	-	-
85	-	-	-	-	-
86	-	-	-	-	-
87	-	-	-	-	-
88	-	-	-	-	-
89	-	-	-	-	-
90	-	-	-	-	-
91	-	-	-	-	-
92	-	-	-	-	-
93	X	X	-	-	1,169
94	-	-	-	-	-
95	-	-	-	-	-
96	-	X	-	-	2,605
97	-	-	-	-	-
98	X	-	-	-	89
99	-	-	-	-	-
100	X	-	-	X	725
<b>Total</b>	<b>16</b>	<b>3</b>	<b>1</b>	<b>2</b>	<b>\$25,295*</b>

\* Amounts may not add up exactly due to rounding.

APPENDIX F: VISITING NURSE ASSOCIATION COMMENTS<sup>30</sup>

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November 12, 2019

VIA FEDERAL EXPRESS

[REDACTED]  
[REDACTED]  
DHHS, Office of Inspector General  
Office of Audit Services, Region III  
801 Market Street, Suite 8500  
Philadelphia, PA 19107

Re: Visiting Nurse Association of Maryland's Response to  
DHHS, OIG Draft Audit Report No. A-03-17-00009

[REDACTED]:

The enclosed correspondence is being submitted on behalf of the Visiting Nurse Association of Maryland ("VNA") in response to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") draft report "Medicare Home Health Agency Provider Compliance Review: Visiting Nurses Association of Maryland" (the "Draft Report"). Our firm was engaged to assist the VNA in its response to the Draft Report. In accordance with our prior written communication with you, this response is timely submitted by the November 13, 2019 submission deadline. We appreciate your careful consideration of the enclosed response.

By way of background, the VNA was a Medicare-certified home health agency operating in Maryland. The OIG's review consisted of a stratified random sample of 100 claims from a universe of 14,703 claims for home health services with episodes of care that ended in calendar years 2015 and 2016. The stratification consisted of three strata including: (i) 34 claims from a random sample for which payment was between \$1,287.69 and \$2,737.46, (ii) 33 claims from a random sample for which payment was between \$2,739.78 and \$3,838.55, and (iii) 33 claims from a random sample for which payment was between \$3,838.80 to \$8,296.59. The review identified 36 claims that allegedly did not comply with the Medicare payment requirements; however, the calculated payment error rate was only 14.44%. The amount that the OIG reviewers identified to be denied or downcoded on the 36 claims was \$49,740, compared to the

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ALABAMA \* FLORIDA \* GEORGIA \* LOUISIANA \* MARYLAND \* MISSISSIPPI \* SOUTH CAROLINA \* TENNESSEE \* TEXAS \* VIRGINIA \* WASHINGTON, D.C.

<sup>30</sup> **OIG Note:** We redacted text in several places in this appendix because it is personally identifiable information.

original payment amount of \$344,423.20 for all 100 claims. The OIG then calculated an extrapolated<sup>1</sup> overpayment amount to be \$4,489,615. The OIG made specific findings regarding why these 36 claims did not comply with the Medicare payment requirements; however, as discussed below the VNA disagrees, in the majority of the claims, with the OIG reviewers' decisions.

Upon receipt of the Draft Report, the VNA, with the assistance of our firm and an outside consulting company with professional staff who have home health expertise, undertook a review of each of the 36 claims, where the OIG reviewer determined that payment should be denied or downcoded, for compliance with the applicable Medicare payment rules. This included a review of all of the associated VNA beneficiary records, which were prepared in the normal course and provided to the OIG to review. The spreadsheet provided by the OIG following its review and prior to the issuance of the Draft Report was revised to only show pertinent information for the 36 claims that were allegedly paid in error and to add columns to record the OIG Review Decisions and to include the "VNA Response Comments" for these 36 claims. [Exhibit 1.] In addition to providing an overview of the facts in the patient records that evidence compliance with the Medicare payment rules and highlight the specific reasons for disputing the OIG findings, the VNA Response Comments include references to the legal analyses provided below.<sup>2</sup> The VNA has not enclosed a copy of the applicable patient records for each claim decision being disputed, since those records were provided to the OIG to conduct its review.<sup>3</sup> These patient records, viewed in the context of the legal arguments raised below, confirm the VNA's adherence to the Medicare payment rules for all but a few isolated claims. Accordingly, the vast majority of the 100 claims that were included in the OIG audit complied with the Medicare payment rules.

For the few isolated claims in which the VNA concurs with the OIG reviewers' decisions, the VNA is not including any statement describing corrective action taken. During the two-year period that this audit was ongoing, after the VNA was sold. Accordingly, since the VNA is no longer a provider, it is not possible to implement any

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<sup>1</sup> As discussed more fully below, the VNA was not provided the source document necessary to confirm that the extrapolation calculation was correct or not.

<sup>2</sup> To the extent that the OIG is willing to publish the spreadsheet in the final report, the VNA will provide a redacted version of the claims spreadsheet that does not include any beneficiary or claim information other than the dates of service.

<sup>3</sup> Should the OIG need a duplicate copy of any previously provided set of patient records to review the VNA's response to the Draft Report, a copy is available upon request.

corrective action. The OIG was made aware of the sale and understands that the VNA will remain responsible for dealing with this audit.

#### MEDICARE HOMEBOUND CRITERIA SATISFIED

In the Draft Report, the most significant finding of the OIG reviewers related to the beneficiary's homebound status, with a decision that for 28 of the 36 claims the beneficiary was not "homebound" for all or part of the dates of service included in the claim. The VNA disagrees with the OIG findings in all but one (1) claim denied or downcoded on the basis that the beneficiary was not "homebound" as required for Medicare home health services coverage. The VNA agrees that the OIG cited to applicable Medicare statutes and regulations and interpretive guidance from CMS in the Medicare Benefit Policy Manual ("MBPM") on pages 5 and 6 of the Draft Report. The Draft Report did not, however, cite to all of the pertinent CMS guidance, including guidance that prevents the adoption of any arbitrary "rule of thumb," such as when an OIG reviewer inappropriately used ambulation distance or the number of degrees of range of motion in a particular joint as the controlling factor in determining whether a beneficiary was or was not homebound. Further, the OIG reviewers based certain decisions regarding homebound status on the fact that the individual resided in an assisted living facility ("ALF") or assumed to be accessible apartment building, without any legal support for arriving at those decisions. For the reasons set forth below, the VNA strongly objects to the use of any specific ambulation distance, degree of motion, accessibility of the "home" in which the beneficiary resides, or any other "rule of thumb" when deciding whether a beneficiary is or is not homebound in accordance with the Medicare rules and CMS's interpretive guidance.

The Draft Report appropriately cites to the provisions in Section 1814(a) of the Social Security Act ("Act") in effect during the audited dates of service, provisions that set forth the requirements for determining if a beneficiary is "confined to his home." And, the Draft Report includes the provisions in Section 30.1.1 of Chapter 7 of the MBPM that contain the corollary CMS interpretive policy guidance. In addition to these specific rules, CMS has issued interpretive guidance prohibiting the use of any "rule of thumb" benchmark or standard, like those utilized by the OIG reviewers. In particular, CMS instructs:

Medicare recognizes that determinations of whether home health services are reasonable and necessary must be based on an assessment of each beneficiary's individual care needs. Therefore, denial of services based on numerical utilization screens, diagnostic screens, diagnosis or specific treatment norms is not appropriate.

MBPM, CMS Pub. 100-02, Ch. 7, § 20.3 (appearing under the heading, “Use of Utilization Screens and “Rules of Thumb”). [Exhibit 2.]

Medicare’s prohibition on the use of “rules of thumb” when performing medical reviews was front and center in the *Jimmo v. Sebelius* case, where the plaintiffs argued coverage for skilled services was inappropriately being denied based on the use of a “rule of thumb” improvement standard. CMS agreed that its rules prohibited the use of any “rule of thumb” standard in review decisions. In fact, CMS guidance published many years earlier included the following:

“Rules of thumb” in the MR process are prohibited. Intermediaries must not make denial decisions solely on the reviewer’s general inferences about beneficiaries with similar diagnoses or on general data related to utilization. Any “rules of thumb” that would declare a claim not covered solely on the basis of elements such as lack of restoration potential, ability to walk a certain number of feet, or degree of stability is unacceptable without individual review of all pertinent facts to determine if coverage may be justified. Medical denial decisions must be based on a detailed and thorough analysis of the beneficiary’s total condition and individual need for care.

CMS Pub. 100-08, Transmittal 3 (Nov. 22, 2000) (emphasis added) (making significant changes to chapters 1-9). [Exhibit 3 (containing excerpts from Transmittal 3.)]

For at least 19 of the 28 claims denied in whole or in part on the basis of homebound status, the OIG reviewer denied or downcoded a claim based on the beneficiary’s “ability to walk a certain number of feet,” a specific example of a “rule of thumb” that may not be used. *See, e.g.* OIG Stratum 1, Sample 27. Accordingly, nowhere in the regulatory or policy guidance specific to homebound status is there any instruction that ambulation distance is a factor to be considered, such that being able to ambulate a particular number of feet would not make an individual confined to the home. Such arbitrary limitation simply would not take into consideration the size of a patient’s home, the distance from the kitchen at one end of the first floor to the only bathroom at the other end of the second floor, etc., the type of “detailed and thorough analysis” required by the reviewer in deciding if a beneficiary is or is not “confined to the home.” Even assuming *arguendo* that ambulation distance was just one factor considered by the OIG reviewers in determining homebound status, there is nothing in the “Rationale” sections of the individual review decisions<sup>4</sup> that would lead to a

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<sup>4</sup> The review decisions were given to the VNA in a preliminary report provided in advance of the VNA’s receipt of the Draft Report. All the discussions of the OIG reviewers’ Rationale will be identified by the

conclusion that the reviewer provided the “detailed and thorough analysis” of the distance in the context of the beneficiary’s home (size, layout, interior and exterior steps with or without railings, etc.) or the beneficiary’s physical condition (physical effort required to leave the home, stability when outside of the home, etc.). To illustrate, the following are excerpts from the “Rationale” for the partial denial of services because the beneficiary was no longer “homebound” after a particular date:

However, as of 9/30/2015, she had been progressed to ambulating on a ramp and was able to ambulate over 150 feet without hands-on assistance. OIG Stratum 3, Sample 31.

Although at the start of care she was able to ambulate over 350 feet, she had sternal precautions and was not using an assistive device . . . On 6/23/2016, her ambulation had improved and was now at nearly 500 feet.” OIG Stratum 2, Sample 33.

The medical information supports that the patient was homebound at the start of care . . . He was able to walk 80 feet but had loss of balance . . . However, as of 10/21/2016, he had been progressed to ambulating on stairs and was able to ambulate 200 feet. OIG Stratum 3, Sample 30.

These examples further illustrate the arbitrary nature of noting ambulation distance without the required detailed analysis. In one case, the reviewer acknowledged ambulating 350 feet did not prevent a patient from being considered homebound and in another case ambulating 200 feet led to the conclusion the beneficiary was no longer homebound. In fact, in all the claims denied or downcoded based on an arbitrary ambulation distance “rule of thumb,” the above examples reflect the vast differences in the distances ranging from 150 feet to 500 feet.

Even assuming *arguendo* that ambulation distance inside the home should be considered at all for purposes of a homebound determination; and, putting aside the demonstrable difference between being able to ambulate 150 feet versus 500 feet, ambulation distance outside the home is significantly more involved. This requires navigating uneven sidewalks or perhaps only non-paved surfaces, curbs without railings, inclines and declines, the lack of furniture or walls to hold onto when needed to regain balance, conditions outside that change due to weather, multiple distractions

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particular Stratum and Sample numbers assigned in that report and noted on the enclosed spreadsheet.

(noise, movement of vehicles and other pedestrians), the level of exertion that is required, balance coordination required, awareness of the environment, and general safety concerns. Thus, even if an individual could ambulate inside the home a particular distance does not mean that leaving home and ambulating outside the home could be done without considerable and taxing effort by the individual. There is no evidence in the Draft Report that the OIG reviewers considered these factors and performed the required detailed analysis when determining that these particular beneficiaries were no longer homebound.

Similarly, whether a beneficiary resides in an assisted living facility (“ALF”) or apartment and/or has caregiver assistance available is not dispositive of whether a beneficiary is “confined to the home” or not. The following is Rationale illustrative of these “rule of thumb” decisions:

However, he had access to a power wheelchair and used a scooter outside his apartment which would be expected to be ADA compliant in terms of accessibility . . . He was able to perform transfers at a modified independent level and would have been able to access the community with use of his power wheelchair and scooter.

OIG Stratum 3, Sample 21 (emphasis added). *See also*, OIG Stratum 3, Sample 31 (deciding homebound status in part simply because the beneficiary was “residing in an accessible assisted living facility and had caregiver assistance available”).

There are any number of apartment buildings without an elevator and/or with stairs leading to the building entrance. Further, the rationale for denial does not provide the required detailed analysis or even an explanation of why leaving the home “no longer” would have required a considerable and taxing effort. Determining homebound status on the basis that a beneficiary resides in an apartment building or an ALF is simply another arbitrary “rule of thumb.” Even in an accessible building there can be hallways/corridors without secure handrails, ramps, areas of carpeting or area rugs, multiple distractions, liquids or debris on the floor, other safety hazards *inside* the facility or apartment building. The homebound criteria require an analysis of a beneficiary’s ability to leave the home. Whether a beneficiary is able to ambulate inside the home or even outside the home during a physical therapy session does not equate to a detailed analysis that the beneficiary does not need assistance to leave the home or does not have a medical condition such that leaving the home is contraindicated or requires considerable and taxing effort.

Another illustration of the arbitrary “rules of thumb” applied in the OIG’s review is the use of a specific range of motion to decide that a beneficiary is no longer homebound:

At the start of care, he was able to ambulate 150 feet and negotiate stairs at a modified independent level. However, he had decreased right knee range of motion of only 90 degrees, which would be expected to interfere with his ability to perform transfers in a seated position . . . However, as of 12/18/2015, his knee range of motion had improved and was more than 100 degrees . . . Leaving the home no longer would have required a considerable and taxing effort.  
OIG Stratum 1, Sample 32.

There is no similar analysis or even a conclusory statement regarding the additional functional mobility this beneficiary gained with 10 more degrees of knee motion. Such a small increase would, for example, equate to less of a functional improvement if the beneficiary additionally had limited ankle motion or spine flexibility or weakness in the lower extremity muscles required to go from sitting to standing.

Nowhere in the statutory, regulatory, or policy guidance, setting forth the “confined to the home” criteria, does Medicare suggest that the accessible nature of an individual’s home, the individual’s ambulation distance inside the home, or the individual’s range of motion in one joint, are factors to be utilized in determining if the criteria was met. Rather, it is clear that a reviewer is prohibited from using any arbitrary “rule of thumb” to make such a determination. The enclosed spreadsheet contains the VNA’s specific reasons, based on a detailed analysis by licensed professionals making decisions within their scope of practice, why the beneficiaries<sup>5</sup> remained “homebound” during the dates of service under review.

#### PHYSICAL AND OCCUPATIONAL THERAPY ARE NOT INTERCHANGEABLE

In twelve (12) claims, the OIG reviewer found that the home health services did not satisfy Medicare coverage and payment criteria because the beneficiary did not require skilled services. In seven (7) of the claims, the OIG reviewer concluded that physical or occupational therapy was not medically reasonable and necessary for a beneficiary because that beneficiary’s rehabilitation needs were already being addressed through one therapy service; and, therefore, the beneficiary did not require

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<sup>5</sup> As noted above, the VNA concurs with the OIG decision on homebound status for one claim. See OIG Stratum 1, Sample 8 in the enclosed spreadsheet.

the other therapy service. This conclusion reflects a lack of understanding of the differences -- the core educational curriculum, the clinical treatments utilized, the treatment objectives, etc. -- between these two professions and being able to determine the clinical need for each distinct therapy to treat the beneficiary's medical conditions and functional losses. Not only are these decisions unsupported by the Medicare statute, regulations and CMS guidance that considers physical therapy and occupational therapy to be distinct benefits, but the conclusions highlight the errors that occur when the review is not provided by a professional of the same discipline who understands the scope of practice.

The rationale of the OIG reviewers in the following examples, reflects the reviewers' incorrect assumption that physical therapy and occupational therapy services are interchangeable:

Physical therapy was needed to progress the patient's mobility and to establish a maintenance home exercise program. Occupational therapy was needed for treatment of the patient's upper extremity impairments and to develop a home exercise program as well as for treating the patient's pain through nonpharmacological methods . . . A third visit was reasonable to reassess her condition and make any further recommendations if needed . . . The patient's primary rehabilitation needs were being addressed through the physical therapy being provided. Ongoing occupational therapy visits after 11/9/2016 were excessive.  
OIG Stratum 2, Sample 31.

There was no new impairing upper extremity condition . . . The patient's rehabilitation needs were being addressed through the physical therapy being provided. The occupational therapy services provided were duplicative.  
OIG Stratum 3, Sample 28.

Not only do these comments reflect the lack of understanding regarding the distinct professional services provided by physical therapy versus occupational therapy personnel, but the OIG reviewers appear to believe there must be some type of new upper extremity impairment for occupational therapy services to be justified. This comment raises even further questions, since it appears to signal a common misconception that physical therapists address lower extremity function and occupational therapists address upper extremity function. That simply is an untrue myth that seems to have influenced the OIG reviewers' decision.

These findings and those involving the other five (5) claims for which the OIG reviewer reached the same or similar conclusion are inconsistent with the Medicare statute, regulations, and policy guidance. The statutory Section 1814(a)(2)(C) of the Act provides:

in the case of home health services, such services are or were required because the individual is or was confined to his home . . . and needs or needed skilled nursing care . . . on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy.

Section 1814(a)(2)(C) of the Act; 42 C.F.R. § 409.44(c).

Different therapy services may be covered when the individualized assessment of a patient's clinical condition "demonstrates that the specialized judgment, knowledge, and skills" of a physical therapist and/or an occupational therapist are necessary. *See* MBPM, Ch. 7, §§ 40.2.2, 40.2.4. A physical therapist cannot provide occupational therapy services, nor can an occupational therapist render physical therapy services. Accordingly, any claim in which one of the services was denied as duplicative or excessive (because the other therapy was continuing) must be reviewed. The VNA urges that a professional of the same discipline reviewing the claim will reach the decision that the beneficiary needed both services in these cases.

Additionally, the conditions of participation for home health agencies ("HHAs") confirm that the professional services provided by an HHA "include skilled nursing services, physical therapy, speech-language pathology services, and occupational therapy, as specified in §409.44." 42 C.F.R. § 484.75 (emphasis added). These same regulations require the HHA to ensure "professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115." *Id.* The regulations at 42 C.F.R. § 484.115, setting forth "the appropriate qualifications," contain great detail regarding the qualifications for occupational therapy as opposed to physical therapy personnel. There would be no reason for separate educational programs with distinct professional association approvals, separate national examinations, and separate state licensure if these licensed professionals were able to provide the same clinical services. Furthermore, due to the level of detail in these qualification standards for HHA therapy personnel, the HHA regulations are cited as the qualification standards for other Medicare providers and suppliers that render physical and/or occupational therapy.

**COVERAGE IS NOT LIMITED TO PARTICULAR SKILLED NURSING AND/OR  
SKILLED THERAPY SERVICES**

Observation and assessment of a beneficiary's condition, management and evaluation of a patient plan of care, and teaching and training activities are three types of Medicare covered services in the home health setting, in addition to when a beneficiary needs a particular skilled nursing and/or skilled therapy service. Based on the Rationale applied by the OIG reviewers it does not appear that coverage for "observation and assessment" or "management and evaluation of a patient plan of care" or "teaching and training" was considered. In the Background section of Draft Report (where the OIG provides an overview of the Medicare statutes, regulations, and CMS manual interpretive guidance relied upon to determine whether the Medicare rules allowed coverage for the audited claims), there is a footnote that mentions that covered services can include "observation and assessment of a patient's condition, management and evaluation of a patient plan of care, teaching and training activities, and administration of medications, among other things." Draft Report at 7, fn. 11 (citing "the Manual, chapter 7, § 40.1.2"). However, aside from a brief reference to "observation and assessment" or "management and evaluation of a patient plan of care" or "teaching and training activities" in the aforementioned footnote, there is no explanation or analysis of when a patient's changing condition or the complexity of the patient's condition or the patient's need for a home exercise program would require such covered services.

The Medicare regulations set forth the basic criteria, and include examples, for when coverage beyond discrete skilled nursing or therapy services<sup>6</sup> exists.

The development, management, and evaluation of a patient care plan based on the physician's orders constitute skilled services when, because of the patient's physical or mental condition, those activities require the involvement of technical or professional personnel in order to meet the patient's needs, promote recovery, and ensure medical safety.  
42 C.F.R. § 409.33(a)(1).

Observation and assessment constitute skilled services when the skills of a technical or professional person are required to identify and evaluate the

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<sup>6</sup> Refer to the Medicare regulations at 42 C.F.R. § 409.33(b) for examples of discrete skilled nursing services and 42 C.F.R. § 409.33(c) for examples of discrete skilled therapy services. These are separately covered services.

patient's need for modification of treatment or for additional medical procedures until his or her condition is stabilized.  
42 C.F.R. § 409.33(a)(2).

Patient education services are skilled services if the use of technical or professional personnel is necessary to teach a patient self-maintenance.  
42 C.F.R. § 409.33(a)(3).

Additional examples of patient conditions that warrant coverage under these three areas are found in Section 30.2.3 of Chapter 8 of the MBPM.

The Draft Report provides the following example, which highlights the lack of focus on these additional bases upon which Medicare coverage is available:

A beneficiary with a medical history including cerebral infarction without residual deficits; generalized muscle weakness, type 2 diabetes mellitus with long term use of insulin, hypertensive chronic kidney disease . . . . The medical information supports that the patient was homebound at the start of care and remained homebound throughout the episode. Home health services were ordered for monitoring, medication oversight and education and also to assess the patient's activities of daily living and for adaptive device use, as well as for training in wheelchairs transfers. A physical therapy evaluation was indicated to assess the patient's mobility and need for an assistive device or home exercise program. However, the patient had been non-ambulatory for a long period of time and was receiving occupational therapy treatments addressing his mobility impairment and remaining activities of daily living. Ongoing physical therapy services were excessive after the initial evaluation.  
Draft Report at 7-8.

The words "monitoring," "oversight," "education," and "training" should have signaled to the OIG reviewers that this particular beneficiary was receiving coverage under "observation and assessment" and/or the "teaching and training activities" coverage criteria. Rather, the OIG reviewers determined that the "patient had been non-ambulatory for a long period of time and was receiving occupational therapy treatments addressing his mobility impairment and remaining activities of daily living [and] [o]n going physical therapy services were excessive after the initial evaluation on 12/26/2015." Draft Report at 8 (referring to OIG Stratum 3, Sample 16). Further, the OIG reviewer concluded that "VNA did not provide a reason why these errors occurred because VNA officials contended that these claims met Medicare requirements." Draft

Report at 8. The VNA stands firm that it was providing covered services. The OIG reviewers appear to equate a physical therapy plan to assess the patient's mobility with gait training rather than the intended and provided wheelchair mobility training. The excerpt in the Draft Report fails to acknowledge the physical therapist identified the need for the patient to obtain a new wheelchair, which occurred during the dates of service audited, and that training in the use of the new wheelchair was needed.

The Medicare regulations require an application of all coverage criteria and a reviewer cannot deny a claim if there is a need for and provision of "observation and assessment," "teaching and training activities," and/or "management and evaluation of a patient plan of care." The VNA contends that further review focused on these additional reasons for which there is Medicare coverage will lead to a reversal of the decision to deny or downcode claims based on the beneficiary not receiving a discrete skilled nursing or skilled therapy service.

#### DECISIONS LACK EVIDENCE REVIEWER QUALIFICATIONS WERE MET

For each claim reviewed, the OIG reviewer/s were a physician or additionally a certified coding specialist/registered health information technician, not clinicians with specialized expertise in nursing, physical therapy, occupational therapy, or speech language pathology, as required by the Medicare Program Integrity Manual ("MPIM"), CMS Pub. 100-08. In particular, under section 3.3.1(C) in Chapter 3 of the MPIM, with respect to credentials of reviewers, CMS instructs:

The MACs, MRAC, and CERT shall ensure that medical record reviews for the purpose of making coverage determinations are performed by licensed nurses (RNs), therapists or physicians. Current LPNs may be grandfathered in and can continue to perform medical record review. The MACs, MRAC, and CERT shall not hire any new LPNs to perform medical record review. ZPICS/UPICS, RACs and the SMRC shall ensure that the credentials of their reviewers are consistent with the requirements in their respective SOWs. During a medical record review, nurse and physician reviewers may call upon other health care professionals (e.g., dietitians or physician specialists) for advice. The MACs, MRAC, and CERT, shall ensure that services reviewed by other licensed health care professionals are within their scope of practice and that their MR strategy supports the need for their specialized expertise in the adjudication of particular claim type (i.e., speech therapy claim, physical therapy). RACs and the SMRC shall follow guidance related to calling upon other healthcare professionals as outlined in their respective SOWs. RACs shall ensure that a licensed medical professional will perform medical record

reviews for the purpose of determining medical necessity, using their clinical review judgment to evaluate medical record documentation. Certified coders will perform coding determinations. CERT and MACs are encouraged to make coding determinations by using certified coders. ZPIC/UPICs/UPICs have the discretion to make coding determinations using certified coders.

MPIM, Ch. 3, § 3.3.1(C) (emphasis added).

CMS requires that services reviewed by health care professionals are within those professionals' scope of practice, specifically using physical and speech therapy as examples. This illustrates CMS's understanding that there are certain services for which a certain expertise is required. In contrast, there is nothing in the "Biography" for the physician reviewer that demonstrates that the physician is board certified in physical medicine and rehabilitation or neurology, such that the physician would have received training in assessing rehabilitation needs, or in a specialty that would render the physician qualified to assess homebound status. And, a certified coding specialist/registered health information technician is not a "licensed nurses (RNs), therapists or physicians" required to make coverage determinations based on a medical record review.

Each of the individual review determinations included the following narrative for the physician reviewer; and, many of the individual review determinations also included the following narrative when the certified coding specialist/registered health information technician was involved in the review:

I am a physician who is duly licensed to practice medicine. I am knowledgeable in the treatment of the enrollee's medical condition, and I am familiar with guidelines and protocols in the area of treatment under review. In addition, I hold a current certification by a recognized American medical specialty board in an area appropriate to the treatment under review. I have no history of disciplinary action or sanctions against my license.

I am a certified coding specialist and a registered health information technician. I am skilled in classifying clinical data from medical records and assigning numeric codes for each diagnosis and procedure. I have expertise in the ICD-9, ICD-10, and CPT coding systems and I am knowledgeable in medical terminology, disease processes, and pharmacology.

*See, e.g.* OIG Stratum 3, Sample 16.

There is no indication of the physician reviewer's specialty here, which is particularly important given that the services under review involved making decisions regarding homebound status and/or the medical reasonableness and necessity of skilled physical therapy, occupational therapy, and speech language pathology services. A physician who specializes in internal medicine or geriatrics would not necessarily have the expertise required to evaluate the medical necessity for therapy services. Irrespective of the physician reviewer's credentials, the utilization of arbitrary "rules of thumb" calls into question the physician reviewer's basis understanding of the applicable Medicare statute, regulations, and implementing policy guidance regarding home health services. The VNA requests that professionals with proper credentials and a thorough understanding of the applicable rule review each disputed claim using their specialized professional expertise.

#### FAILURE TO PROVIDE THE CLAIMS UNIVERSE IS ERROR AND UNFAIR

The OIG reported that it utilized a stratified random sample in lieu of conducting a claim-by-claim review of all claims for the audited dates of service. Specific dollar amounts, detailed above, were used to determine the three strata. The OIG Draft Report included a calculated overpayment amount that consisted of extrapolating the error rate to the universe of claims. However, the VNA is unable to provide an analysis to determine if: (i) appropriate strata were selected, and (ii) the calculated extrapolated amount is accurate because the OIG would not provide the claims universe to perform the analysis.

By not having access to the OIG's sampling documents, the VNA is unable to replicate the sample selection. For example:

- Although the OIG's Sampling Plan states, no "claims that (a) had a claim type of [Low Utilization Payment Adjustment] LUPA, (b) were less than \$1,000, and (c) corresponded to a [Partial Episode Payment] PEP" were included in the universe, without having the universe that the OIG utilized it is impossible for the VNA to determine if this is an accurate statement.
- There is no documentation regarding how the sampling frame was sorted prior to sample number assignment and then sample selection.
- Since the universe cannot be verified to be accurate the sampling frame as a subset of the universe cannot be verified for accuracy.

Further, since the Sampling Plan did not disclose how sample size was calculated or how the three strata were identified, the VNA has the following concerns.

- The OIG statistician identified three strata, which appear to be based on ubiquitous dollar ranges (\$1,287.69 to \$2,737.466, \$2,739.78 to \$3,838.554, and \$3,838.80 to \$8,296.59) without justification why these ranges were selected or why the cut-off points were used. The strata appear to arbitrary, since when the paid amounts are graphed there is no distinct jump or break that would indicate the need to use stratification.
- The distribution was not proportional to the size of the strata (number of claims) and total sample size. The proportion of the highest paid strata is excessively sampled. This creates a greater density of higher paid claims in the sample, which then inflates the calculated overpayment. Similarly, the lower paid claims, which account for nearly half of the universe, are underrepresented.

In addition to the significant issues noted above, the VNA notes there was a duplicate sampling unit in the Strata 1 frame. The duplicates are claims numbers ending in "47807MDR" and "54207MDR." These claim line items have the same beneficiary HIC number, beneficiary date of birth, claim from date and paid amount. Although, it is common to have duplicates in a universe, due to claims adjustments and resubmissions, any duplicate in the universe should have been removed before selecting a sample. If the selected sample of 100 claims had at least one duplicate claim, without the universe there is no way for the VNA to confirm how many other similar errors are in the stated universe of 15,472 claims. By analogy, the error rate for the 100 sampled claims would extrapolate to 155 errors in the universe. Duplicate claims could result in the sampling frame not being comprised of unique sampling units; and, could lead to an exaggerated extrapolation for a particular stratum by having more sampling units represented than what is accurate.

On October 14, 2019, counsel for VNA requested a copy via email to the OIG of the actual statistical sampling documents, complete with a file that contains the universe of claims. [Exhibit 4.] On October 18, 2019, ██████████ responded to this request, stating:

Here is the information requested to recreate the sample. Everything requested is provided except for the universe file. We do not provide any claims outside of the sampling frame without a formal FOIA request. Our estimate applies only to the sampling frame. If there are claims outside of the sampling frame that are in error, they are not covered by our audit

and are not included in our overpayment estimate. Moreover, VNA can verify the validity of the claims within the sampling frame with its own claims data. To submit a formal FOIA request, go to <https://oig.hhs.gov/foia/>. [Exhibit 5.] (emphasis added).

The VNA takes issue with respect to the OIG's failure to provide the universe of claims. The provision of the universe is necessary to determine if the strata were properly selected, to ensure that the sampling could be recreated, and to confirm the extrapolation accuracy. Moreover, a claims universe is replete with Protected Health Information and is not the type of electronic file that would be released under a Freedom of Information Act ("FOIA") request. It simply does not fall within the definition of an agency record. 5 U.S.C. § 552(f)(2) (The term "record" includes any information that would be an agency record when maintained by an agency in any format, including an electronic format and maintained for an agency by an entity under Government contractor for the purposes of record management.). The description of records that an agency must make public subject to FOIA include:

- (A) Final opinions, including concurring and dissenting opinions, as well as orders, made in the adjudication of cases;
- (B) Those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register;
- (C) Administrative staff manuals and instructions to staff that affect a member of the public;
- (D) Copies of all records, regardless of form or format -
  - i. That have been released to any person under [5 U.S.C. § 552(a)(3)]; and
  - ii. (I) That because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records; or  
(II) That have been requested 3 or more times and
- (E) A general index of the records referred to under subparagraph (D).  
5 U.S.C. § 226(a)(2).

Making a determination that the audited overpayment amount of \$49,740 justifies a recommendation to assess a \$4,489,615 overpayment requires that the OIG provide the documentation that supports such a determination. To deny this documentation to the VNA at this crucial stage in the OIG audit is akin to a denial of due process, since the VNA cannot appropriately challenge the selection of strata, nor the extrapolation, without the universe.

Not only is the OIG's refusal to provide the claims universe inconsistent with past audits, but it is inconsistent with CMS's statistical sampling guidance that requires the maintenance of "all documentation pertinent to the calculation of an estimated overpayment including but not limited to the statistician-approved sampling methodology, universe, sample frame and formal worksheets." MPIM, Ch. 8, § 8.4.4.5. And, it is inconsistent with the general requirement in administrative proceedings that an agency include "findings and conclusions, and the reasons or basis therefore, on all the material issues of fact, law, or discretion presented on the record." 5 U.S.C. § 557(b)(3) (emphasis added). The OIG audit is no different. The agency (the Department of Health and Human Services ("HHS")), through the OIG, has made a determination that its sampling methodology was appropriate and that it correctly calculated the extrapolated overpayment amount, yet the agency has not provided the core document that sets forth the basis for selecting strata and calculating an overpayment.

Further, this type of "agency action" is subject to the rules of the Administrative Procedure Act ("APA") and the OIG cannot disregard the rules and procedures that govern federal agencies. 5 U.S.C. § 551(13) ("'[A]gency action' includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act . . ."). In this particular instance, the only mechanism to confirm that the OIG's statistician properly: (i) chose the appropriate number of strata and the dollar amounts to be included in each stratum; and, (ii) correctly calculated the extrapolated overpayment is if the claims universe that the OIG utilized is made available to the VNA. By failing to provide this critical electronic file, the OIG has deprived the VNA of its ability to challenge the OIG's findings and conclusions. The OIG should not be allowed to utilize extrapolation in this case, where the VNA is without any due process.

Even though the VNA believes that the sampling methodology and extrapolation should be disallowed on procedural due process grounds, the VNA urges that further review of disputed claims, considering the legal arguments and factual responses contained in this response, will result in a diminishment of the error rate such that extrapolation will no longer be permissible.

#### ERROR RATE DOES NOT SUPPORT EXTRAPOLATION

The VNA respectfully urges that when the applicable payment rules are applied to the 33 of the 36 claims which the VNA disputes, the remaining error rate for the three (3) claims<sup>7</sup> in which the VNA concurs will not support extrapolation. The claims in

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<sup>7</sup> In addition to concurring with the homebound determination in the one claim discussed above, the

which the VNA concurs accounts for less than one percent (<1%) of the total payment that was made for the 100 audited claims, -- an error rate that is simply too low to allow extrapolation.

In 2003, Congress passed the Medicare Modernization Act (“MMA”) specifying in Section 935 that, with respect to Medicare claims, extrapolation of an error rate to the universe of claims to determine an overpayment may only be used when there is a “sustained or high level of payment error” or “documented educational intervention has failed to correct the payment error.” 42 U.S.C. § 1395ddd(f)(3). [Exhibit 6.] These two reasons were not provided as examples -- rather the legislation specified that only these two reasons would support extrapolation to determine an overpayment amount. CMS incorporated this MMA provision into its guidance in the Medicare Program Integrity Manual (“MPIM”), instructing that “before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset or otherwise, there must be a determination of sustained or high level of payment error or documentation that educational intervention has failed to correct the payment error.” MPIM, Ch. 8 § 8.4.1.2 (emphasis added). [Exhibit 7.] Nowhere in the Draft Report has the OIG alleged that the identified payment errors are the result of a failed educational intervention. Therefore, extrapolation would only be lawful in this case if a careful and appropriate review of the 33 disputed claims demonstrates a “sustained or high level of payment error.”

VNA asserts that the MMA provisions expressly note that “a Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise” unless the Secretary determines one of the above two stated reasons applies. To the extent that the OIG disagrees with VNA’s response with regard to the claim determinations it is disputing, the OIG will direct the applicable Medicare Administrative Contractor (“MAC”) to issue an overpayment demand to recoup the amount the OIG determines was paid in error. Should that occur, this statute prohibits the MAC from using any extrapolated overpayment calculation which did not comply with the MMA Section 935 restrictions. Therefore, the OIG is indirectly bound by these provisions.

VNA respectfully submits that when the error rate is re-calculated to reflect appropriate claims payment determinations based on the evidence in its response to the Draft Report, any remaining isolated payment errors for a particular claim will fail to

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VNA concurs with the OIG regarding the two claims identified as having an “Incorrect HIPPS Code.” The payment amount for these three claims was \$2,967.28, compared to the total \$344,423.20 paid amount for the 100 audited claims.

██████████, Assistant Regional IG for Audit Services  
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rise to the “sustained or high level of payment error” required by the statute to support extrapolation.

#### REPAYMENT OBLIGATION

With respect to the very limited number of claims to which the VNA agrees with the findings in the Draft Report, the VNA will promptly make repayment. With regard to the remaining claims for which the VNA has provided a detailed legal and factual response disagreeing with the OIG reviewer’s findings, the VNA does not believe it has any repayment obligation, since the claims complied with the conditions for payment and coverage for home health services. Accordingly, VNA does not believe that those claims are subject to the 60-day repayment rule.

In closing, VNA wishes to thank the OIG for carefully considering its responses to the OIG’s findings in its Draft Report. VNA took care to comply with the Medicare conditions for coverage and payment rules and believes that the resulting low error rate, after consideration of the legal and factual issues raised in its response, reflects its efforts to do so. Should you have any questions or wish to further discuss this response, please do not hesitate to contact us.

Respectfully Submitted,

Donna J. Senft

Deborah S. Samenow

Enclosures

cc: Barry Ray, CEO

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